OZONE
TRANSPORT
COMMISSION

Connecticut
Delaware
District of Columbia
Maine
Maryland
Massachusetts
New Hampshire
New Jersey
New York
Pennsylvania
Rhode Island
Vermont
Virginia

Paul J. Miller
Executive Director

89 South St., Suite 602
Boston, MA 02111
(617) 259-2005
www.otcair.org

March 12, 2021

Michael Regan, Administrator
U.S. Environmental Protection Agency
Office of the Administrator, Mail Code 1101A
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Administrator Regan:

The members of the Ozone Transport Commission (OTC) write to welcome and congratulate you upon your arrival as Administrator of the U.S. Environmental Protection Agency (EPA). The OTC looks forward to working with you in pursuit of our common priorities to bring cleaner air and a healthier environment to all citizens, particularly those who live in communities that are disproportionally burdened by air pollution.

As an introduction to our organization, the OTC encompasses a multi-state "Ozone Transport Region" (OTR) created under sec. 184(a) of the 1990 Clean Air Act Amendments. Its members, as established by Congress, are Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Virginia. The EPA Administrator and the Regional Administrators of Regions 1, 2, and 3 are non-voting members. The state governors and mayor of the District typically appoint their lead environmental and air quality officials as representatives to the Commission. The OTC is responsible for advising EPA on ozone pollution transport issues and for developing and implementing regional solutions to the ground-level ozone problem in the Northeast and Mid-Atlantic regions. We work on a bipartisan basis.

While the OTC's mission is to help solve our regional ozone problem, the strategies to do this encompass actions that have cross-cutting benefits. For example, addressing non-EGU stationary sources, energy transformations on high electric demand days, and cleaner transportation options will help reduce regional ozone, but are also needed to address our changing climate and the pollution inequities placed upon disadvantaged communities.

With your own state background coming to EPA after leading the North Carolina Department of Environmental Quality, you bring a personal

understanding of the concerns that state environmental officials have in seeking to achieve public health, climate, and equity objectives through state and federal cooperation. Since its inception, the OTC has made enormous strides in reducing ground level ozone throughout the OTR, and much of the OTR has been brought into attainment with the National Ambient Air Quality Standards (NAAQS) for ozone. However, diminishing but persistent areas of ozone nonattainment remain (see attachment), and one of our major challenges is fully resolving the significant contributions to ozone problems in our region from upwind pollution sources located outside the OTR's borders.

To this end, our chief request upon the start of your tenure is for EPA to work with us in developing a complete remedy to the interstate transport of ozone pollution. The interstate nature of this problem requires a meaningful partnership between EPA and the states. Over many years and across multiple administrations, however, EPA has adopted pollution transport rules containing inadequate measures on extended timelines, and these rules have been repeatedly remanded or vacated by the courts for failure to fully address interstate pollution transport by the required statutory deadlines. In addition, several recent regulatory roll-backs imperil the progress that we have made and our ability to maintain attainment of clean air requirements where it has been achieved. This has left our citizens at continuing risk from elevated exposures to ozone. Furthermore, with the COVID-19 pandemic, this failure to timely resolve our longstanding regional ozone transport problem has brought into stark relief the inequities facing disadvantaged communities as they suffer greater mortality risk and other adverse health outcomes due to the impacts of COVID-19 compounded by their elevated air pollution burdens.[1] This could have been mitigated.

While we are frustrated, we see opportunities. There are a number of common priorities shared between the new administration and the OTC. We highlight just a few below that we believe align well with the agenda of the new administration.

- *California Motor Vehicle Standards*

  The OTC is on record strongly supporting California's right under the Clean Air Act to adopt and enforce clean vehicle emission standards, and by extension the right of other states to adopt California vehicle standards if they so choose.[2] Most of the OTC members have adopted California clean vehicle standards that have historically been more stringent than federal requirements. Some of our members have also adopted California's zero emissions vehicle requirement.

[1] A. Pozzer, F. Dominici, A. Haines, C. Witt, T. Münzel, and J. Lelieveld, Regional and global contributions of air pollution to risk of death from COVID-19, *Cardiovascular Research*, Vol. 116, pp. 2247–2253 (2020); doi:10.1093/cvr/cvaa288.

[2] Resolution of the Ozone Transport Commission Concerning States' Rights and Vehicle Emissions, June 7, 2018.

- *Zero Emission Medium- and Heavy-Duty Trucks*

The OTC recently issued a formal statement supporting cooperative efforts to accelerate the widespread introduction of zero emission medium- and heavy-duty trucks as a regional air quality strategy.[3] A number of the OTC states have also joined with states outside the region, including North Carolina, in a governor-level memorandum of understanding to further advance the introduction of zero-emission trucks through cooperative efforts.[4]

- *Aftermarket Catalysts and Anti-tampering Enforcement for Mobile Source Pollution Controls*

The OTC has a long history of seeking effective aftermarket catalytic converter performance requirements and anti-tampering enforcement of installed mobile source pollution controls.[5] We are heartened to see recent efforts by EPA in this area and look forward to working cooperatively with the Agency in this endeavor.

These collective measures will help reduce ozone within the OTC region, diminish upwind contributions, provide climate benefits, and ultimately eliminate air toxics from vehicle exhaust that disproportionately affect communities adjacent to busy highway corridors, distribution centers, ports, and industrial areas.

The OTC's strategies rely on sound science in decision making, and a robust accounting of benefits and costs arising from clean air measures. To that end, we urge you to restore EPA's use of the best available science and a fuller economic accounting of all co-benefits that underpin effective clean air programs. Unreasonably restricting the use of science and sound economic analysis only serves to continue the systemic failure to provide a complete picture of the air pollution burdens placed upon disadvantaged communities, while ignoring the full range of achievable benefits.

To reinvigorate our federal-state partnership, we request a meeting with you and your senior team in the Office of Air and Radiation to discuss the alignment of our interests in furthering progress in public health protection from the damages of air pollution, synergies with climate change policy, and an equitable framework that brings greater air quality benefits to our most burdened communities. Paul Miller, OTC's Executive Director, will contact your office to arrange an initial virtual meeting.

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[3] Statement of the Ozone Transport Commission Regarding the Need to Accelerate Electrification of Medium- and Heavy-duty Vehicles, June 2, 2020.

[4] Multi-State Medium- and Heavy-Duty Zero Emission Vehicle Memorandum of Understanding, July 14, 2020.

[5] Letter to U.S. EPA Administrator Wheeler, Re: EPA aftermarket catalytic converter enforcement policy (August 28, 2019); Letter to E. Belser and L. Cook, U.S. EPA, Re: Requesting EPA update aftermarket catalytic converter enforcement policy (December 31, 2018); Letter to U.S. EPA Administrator Pruitt, Re: 1986 Federal Aftermarket Catalytic Converter Enforcement Policy (August 21, 2017); Statement of the Ozone Transport Commission Requesting that the United States Environmental Protection Agency Update the Federal Aftermarket Catalytic Converter Policy (June 6, 2017); Letter to U.S. EPA Administrator McCarthy, Re: Updating the Federal Aftermarket Catalytic Converter Policy (June 14, 2014); Statement of the OTC Calling on the EPA to Update its Policy on Motor Vehicle Aftermarket Catalytic Converters (June 10, 2009).

Once again, congratulations and welcome as you take on leadership of the EPA. Your success will be our success, and we look forward to engaging in a renewed effort to fully and forthrightly address our most pressing air quality, climate, and equity issues.

Sincerely,

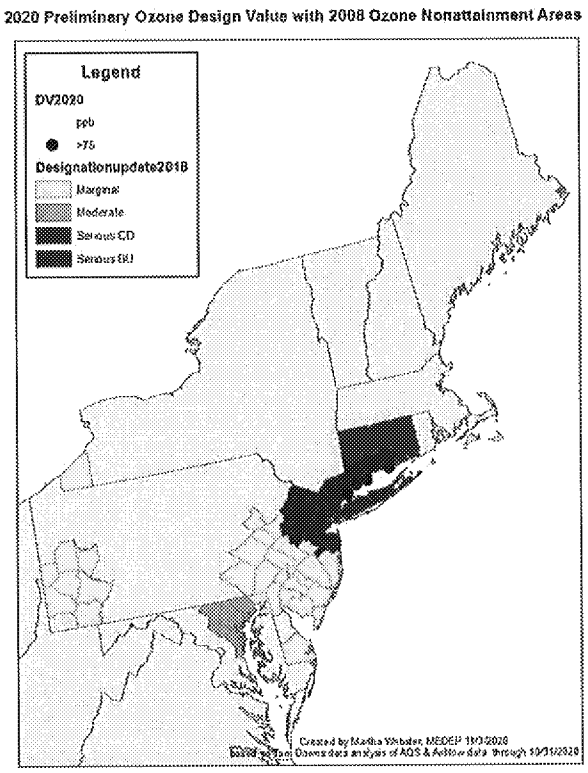
Terrence Gray, P.E.
Deputy Director for Environmental Protection
Rhode Island Department of Environmental Management
OTC Chair

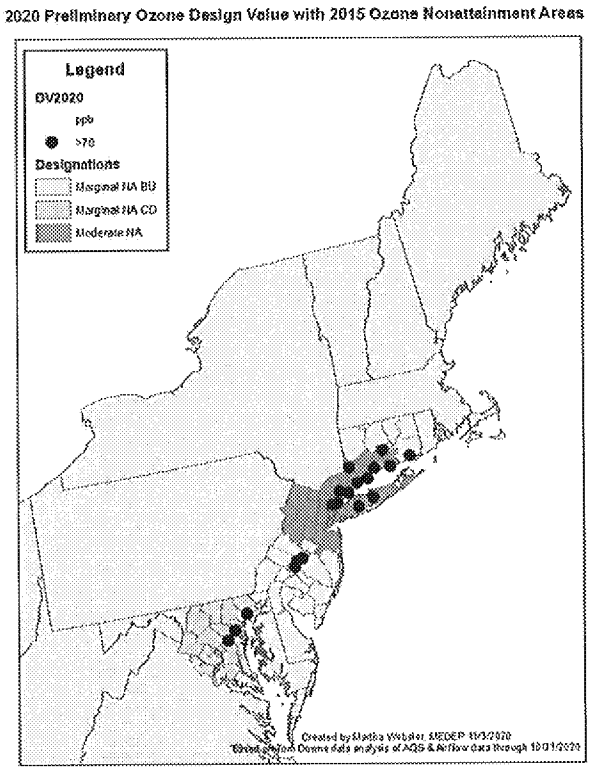
Attachment: Ozone NAAQS nonattainment map

cc: OTC Commissioners and Air Directors
U.S. EPA Acting Regional Administrators for Regions I, II, and III

## Attachment

Current Ozone Nonattainment Areas in the OTR - 2008 NAAQS (left), 2015 NAAQS (right)




Note: The OTR Marginal and Moderate areas for the 2008 NAAQS have achieved Clean Data as of 2020, meaning that the most recent final 8-hour ozone design values are below the NAAQS.

Appointment

**From**: Adhar, Radha [Adhar.Radha@epa.gov]
**Sent**: 1/25/2021 2:11:32 AM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Utech, Dan [Utech.Dan@epa.gov]; Deveny, Adrian (Schumer) [Adrian_Deveny@schumer.senate.gov]

**Subject**: To discuss CRA
**Location**: Microsoft Teams Meeting

**Start**: 1/25/2021 9:30:00 PM
**End**: 1/25/2021 10:00:00 PM
**Show Time As**: Tentative

**Required Attendees**: Goffman, Joseph; Utech, Dan; Deveny, Adrian (Schumer)

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# Microsoft Teams meeting

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Message

**From**: Mulholland, Denise [Mulholland.Denise@epa.gov]
**Sent**: 1/26/2021 4:31:35 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: RE: Message from Joe Goffman, Acting Assistant Administrator for OAR

Congratulations and welcome back, Joe!

I'm excited that you are back and am looking forward to working with you again - now under the Biden administration!

All the Best,
Denise

PS. I used to work on the State and Local Program in OAP's CPPD but moved to the Global Methane Initiative in OAP's CCD under the last administration.

**********
Denise M Mulholland | Team Lead | International Methane Reduction Programs
U.S. Environmental Protection Agency | mulholland.denise@epa.gov | Cell Phone +1-202-297-0624
1200 Pennsylvania Avenue, NW., Washington DC 20460

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Tuesday, January 26, 2021 10:35 AM
**To:** OAR-WIDE-EVERYONE <OARWIDEEVERYONE@epa.gov>
**Subject:** Message from Joe Goffman, Acting Assistant Administrator for OAR

Dear OAR Colleagues –

No one will enjoy a greater honor or privilege than the honor and privilege I now enjoy of returning to your side as your colleague. As some of you may recall, from 2009-2017, I served as OAR's Associate Assistant Administrator for Climate and Senior Counsel, which was the best experience of my career. Happy as I am to occupy a new role, now as OAR's Principal Deputy Assistant Administrator and current Acting Assistant Administrator, simply being back here with you all is what makes this return such a pleasure.

First, I would like to thank you all – and by "all" I mean every single person who works in OAR – for your service to the public and for your ongoing dedication and commitment to the mission of the Office of Air and Radiation and of the Environmental Protection Agency. No matter what your job here is, you have earned, and will continue to earn, the unending gratitude of our fellow Americans for the energy and care you devote to protecting the air we breathe, our health, and our quality of life. Of course, you are not here in quest of "thanks" and I'm pretty sure that when you look in the mirror you don't see a hero, but you're entitled both to the "thanks" and to seeing yourselves that way. You are certainly my heroes – every single one of you.

That's not an exaggeration. This has been a difficult year for our country and the world. Since March, the pandemic has brought hard times, fear, and illness to our communities, friends and families. Many of you may have been touched in some way by the hardships and tragedies this year has brought and we are here as colleagues to support you however we can; virtually everyone has had to cope with challenges none of us imagined having to face a year ago.

From everything I've seen and heard, OAR employees' resilience, ingenuity and perseverance has shone through, and that's a tremendous source of comfort. Maintaining your characteristic commitment to our mission with the utmost

professionalism while adapting to these tough times should give us all confidence that we can face the challenges, and harvest the opportunities, 2021 puts in our path and continue to deliver for the American people. After all, the OAR culture I knew when I was here last doubtless will propel us forward again: bringing out the best in each other and understanding that there is no success outside the success we all create and share in together.

In his note to all of us last week, EPA Chief of Staff Dan Utech introduced himself and members of the new leadership team who have arrived so far. He also called our attention to some of President Biden's executive orders. One in particular strikes to the core of our mission at OAR. The Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, says, "it is the policy of my Administration to listen to the science; to improve public health and protect our environment; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; to reduce greenhouse gas emissions; to bolster resilience to the impacts of climate change; ... and to prioritize ... environmental justice." It's as if President Biden were addressing EPA and OAR directly. Clearly, this is an amazing moment for us at OAR when our work will be even more vital and more highly valued in the coming months and years.

It is also my great pleasure to introduce Tomás Carbonell, who has joined the OAR leadership team as the Deputy Assistant Administrator for Stationary Sources. Tomás comes to EPA from the Environmental Defense Fund, where he was the Senior Counsel and Director of Regulatory Policy for that organization's clean air program. From 2008-2012, Tomás was an Associate at Van Ness Feldman, LLP, where he counseled diverse clients on federal legal and regulatory matters related to climate change, clean energy, and environmental and electricity regulation. He has a J.D. from Yale University, degrees in Environmental Change and Management and Development Economics from the University of Oxford, and bachelors' degrees in Chemical Engineering, Economics, and Multidisciplinary Studies from North Carolina State University. Please join me in welcoming Tomás, and please stay tuned for more introductions in the near future.

Very soon, via "Teams," we will have the chance to talk to and hear from each other directly as we get "all hands" meetings on the calendar with each of your offices. Please think about how you want to use that time to surface your concerns and share your suggestions for the best practices to continue or adopt in our work together going forward. A little later on we will also be engaging with the regions and states, the Office of General Counsel, the Office of Policy and other program offices as well as the public and our stakeholders.

Looking forward to connecting face-to-face

Thank you all very much for being here.

Stay safe and take care of yourselves and each other.

All best,
Joe

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From:** POLITICO Pro Energy [alert@email.politicopro.com]
**Sent:** 1/26/2021 11:06:58 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Climate "emergency" declaration would give Biden new tools — but limits unclear

## Climate "emergency" declaration would give Biden new tools — but limits unclear

By Anthony Adragna

01/26/2021 06:04 PM EST

Senate Majority Leader Chuck Schumer has called for President Joe Biden to declare a national emergency on climate, a move that would give the new administration a host of statutory authority. But the extent of those powers is untested, especially with statutes never envisioned to deal with a problem as broad as climate change.

Experts say Biden could invoke the 1976 National Emergencies Act to give himself the power to employ the Defense Production Act to manufacture clean energy technology, move Defense Department funds to deploy renewables on military bases, block exports of crude oil exports or even suspend offshore drilling — though that would require compensation to the owners. The law limits the emergency declarations to one year, but it could be renewed annually to keep the extraordinary power.

Doing so would, of course, trigger a political firestorm and rely on novel interpretations of the statutes around national emergencies. However, experts acknowledge an emergency declaration would generate powerful symbolism for the administration's goal of aggressively fighting climate change, and, as Schumer contends, empower Biden with new tools to confront the problem.

"He can do many, many things under the emergency powers of the president that wouldn't have to go through — that he could do without legislation," Schumer told "The Rachel Maddow Show" in an interview Monday night. "Now, Trump used this emergency for a stupid wall, which wasn't an emergency. But if there ever was an emergency, climate is one."

White House Press Secretary Jen Psaki did not directly respond — but notably didn't dismiss the idea — when asked about it at a Tuesday briefing.

"There will be more we have to share on our efforts on climate in the days ahead but I don't think Leader Schumer has any doubt about the president's commitment to this," she said.

The Brennan Center, a public policy institute at the NYU School of Law, has compiled a list of 123 statutory powers that become available to a president once a national emergency is declared. Former President Donald Trump declared a national emergency in February 2019, after which he reprogrammed Defense Department funds to construct parts of a border wall. Congress twice held bipartisan votes to override those national emergency declarations, but Trump vetoed them.

Even without testing the powers of the emergency declaration, it sends a signal about how the administration views climate change.

"I think the idea is mostly symbolic rather than practical because in practice what is freed up by a national emergency declaration is not nearly sufficient to address climate change," said Elizabeth Goitein, director of the Liberty and National Security Program at the Brennan Center. "In my mind, it doesn't get you very far and I

think it's vulnerable to the accusation that he's doing a version of what Trump did, which is using a national emergency declaration to get around Congress."

Dan Farber, director of UC Berkeley's Center for Law, Energy and Environment, noted that declaring a national emergency does not require Biden to take any specific actions, and inevitable political blowback might dissuade Biden from deploying it immediately, but it's a valuable option for him to hold onto.

"This doesn't mean that Biden can just declare an emergency and then implement the 'Green New Deal' or even implement the plan he proposed during the campaign," he said. "It is important symbolism and it also gives people in Congress and elsewhere a signal that if they try to stonewall too much, he has other options."

Republican Sen. John Barrasso, ranking member of the Energy Committee and whose state of Wyoming is the leading U.S. coal producer, warned that Schumer is "playing with fire" in urging a climate emergency declaration and urged Biden not pursue the idea.

"By calling on President Biden to declare a climate emergency, he is trying to muzzle Congress," Barrasso said in a statement. "President Biden should work with both parties in Congress, not listen to Chuck Schumer's dangerous ideas."

Sen. Kevin Cramer (R-N.D.), who represents the No. 2. oil producing state, called Schumer's idea "an early admission Democrats' climate proposals are too extreme to be passed by Congress" and warned it would "be a policy nightmare and a political disaster the Biden Administration would quickly regret."

During his interview Monday, Schumer said he intended to pursue other options for enacting bold climate legislation that would not require Republican support. He's exploring ways to advance measures through the budget reconciliation process, a maneuver that would allow a bill to pass the Senate with a simple majority.

"There may be things that are reconcilable," he told Maddow, suggesting Democrats would use the first of two opportunities this year to invoke budget reconciliation on a Covid-19 package, and the second for implementing Biden's "Build Back Better" agenda that would include climate provisions.

In particular, Schumer said he would push for a massive new electric vehicle subsidy program and that the eventual bill be consistent with the principles in a roadmap to address the pandemic and economic, racial, and climate crises he unveiled last year.

Climate advocates quickly welcomed Schumer's commitments out-of-the-gate and urged Biden to make the emergency declaration, even if the limits of the presidential powers are murky.

"It's very much a statute-by-statute, agency-by-agency analysis," said Brett Hartl, government affairs director at the Center for Biological Diversity. "[The limits are] somewhere in the middle between 'it's totally symbolic' and 'it totally gives the president full, undeterred power.'"

*To view online*:
https://subscriber.politicopro.com/energy/article/2021/01/climate-emergency-declaration-would-give-biden-new-tools-but-limits-unclear-2030901

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This email was sent to goffman.joseph@epa.gov by:
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Arlington, VA 22209
USA

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/25/2021 7:24:06 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: OAR Litigation Deadlines
**Attachments**: OAR Litigation Deadlines_Jan to April 2021.xlsx

Joe – at Tomas' request, I have pulled from OGC's materials the OAR litigation deadlines. Attached is a copy of those deadlines. I will send a different copy to Tomas removing the EDF deadlines.

Please let me know if you have any questions or would like time set with ARLO to go over anything.

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Message

**From**: Goffman, Joseph [jgoffman@law.harvard.edu]
**Sent**: 1/20/2021 2:38:23 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: Fwd: [ADMINLAW] [EXTERNAL] Re: [ADMINLAW] lots going on but

Sent from my iPhone

Begin forwarded message:

**From:** Todd Aagaard <aagaard@law.villanova.edu>
**Date:** January 20, 2021 at 9:08:16 AM EST
**To:** ADMINLAW@listserv.lsu.edu
**Subject: Re: [ADMINLAW] [EXTERNAL] Re: [ADMINLAW] lots going on but**
**Reply-To:** Todd Aagaard <aagaard@law.villanova.edu>

As to #2, Cass Sunstein has a recent paper making exactly that observation, fittingly entitled, There Are Two 'Major Question' Doctrines.

---

**From:** Owen, Dave <owendave@UCHASTINGS.EDU>
**Sent:** Tuesday, January 19, 2021 9:49 PM
**To:** ADMINLAW@LISTSERV.LSU.EDU
**Subject:** [EXTERNAL] Re: [ADMINLAW] lots going on but

A few thoughts in response to David Zaring's points/questions:

1. On reverse *Chevron*: this is one of those cases in which an agency says, "we cannot do X because the statute unambiguously forecloses us from doing so," and the court responds by saying, "you can do X (and we don't need to say whether you *have to* do X) because the statute does afford you that discretion."

2. Judge Walker's concurring and dissenting (mostly dissenting) opinion has a really striking treatment of major questions doctrine. It seems to me, and I wonder if others agree, that we now have two very different versions of major questions doctrine metastasizing through the courts. One version—the Justice-Roberts-*King-v-Burwell* version—requires de novo review when an ambiguous statute raises a major question but does not purport to place a pro-regulatory or anti-regulatory thumb on the scales. The other version—the Walker version—precludes major new regulatory efforts unless a statute clearly and unambiguously authorizes those efforts. There's nothing neutral about it.

   Though he relies heavily on major questions doctrine, Walker never once cites *King v. Burwell*. And if major questions doctrine works the way he says it does, that case clearly was wrongly decided. So he seems to be selecting a version of the doctrine at odds with key Supreme Court precedent.

3. The way Judge Walker decides the case presents a major question also is striking. To assess the costs of greenhouse gas regulation under section 111, he cites industry estimates, which are notoriously likely to be inflated (which he acknowledges but makes no adjustment for). Then, to

assess the scale of benefits, he mostly discusses the total benefits of addressing climate change and then only briefly refers to estimated benefits for this particular rule. It's also somewhat odd how much emphasis he gives to the scale of a regulatory program's benefits. The implication is that an agency could invoke an ambiguous statute as authorization for a rule that doesn't really benefit anyone all that much, but that if a rule with the same costs provides huge social benefits, the agency could not lawfully adopt it. That's perverse, to say the least.

It's a dissent, of course. But if this is a preview of major questions doctrine in a conservative judiciary, we'll all have a lot to write about.

Dave

---

**From:** Zaring, David <zaring@WHARTON.UPENN.EDU>
**Sent:** Tuesday, January 19, 2021 9:09 AM
**To:** ADMINLAW@LISTSERV.LSU.EDU
**Subject:** [ADMINLAW] lots going on but

I was trying to make a little sense out of the DC Circuit decision tossing the Trump EPA's version of the Clean Power Plan. I don't do environmental law except when required to, and this decision – per curiam, 185 pages, a standalone table of contents, and an introduction that didn't explain what the basis of the decision was – makes me kind of glad about that.

https://www.cadc.uscourts.gov/internet/opinions.nsf/6356486C5963F49185258662005677F6/$file/19-1140-1880546.pdf

But I gave it a skim. It appears that the majority thought that EPA's conclusion that the Clean Air Act did not permit the agency to regulate in the way it did in the Clean Power Plan was inconsistent with the act. The CPP I think permitted an aggregation of responses – a state/utility could meet national standards not only by reducing emissions at heavy CO2 emitting plants, but also by establishing that it was shifting to lower CO2 emitting sources. The Trump revision was justified on the basis that the CAA only permits regulation of stationary sources (power plants), and not inferential regulation beyond the smokestack.

A couple of inexpert thoughts:

- The majority is kind of a reverse Chevron? The idea is that the statute permits a wider range of actions than EPA thinks, and EPA is wrong to interpret the statute so narrowly. But it cites Chevron once.
- Classic Trump admin move of replacing a rule not by doing more science or cost-benefit analysis (though they might have done more in the part I skimmed too quickly), but by arguing that it just legally didn't have the right to do the thing the Obama admin did, as William Buzbee has argued IIRC. This also happened with DACA.
- New judge Walker, in concurrence, says that both the Obama and Trump rules would require congressional legislation, they are just too multi-billions big – a full-throated endorsement of the major questions doctrine that will be worth keeping an eye on. He cites Chevron a ton, but probably because it's a precondition to a major questions carveout. And that in turn raised an interesting question regarding what happens if Chevron gets tossed by the Supreme Court in these kinds of cases. Then courts would review agency rules to see if they decided questions that are too important to be decided without Congressional authorization – and that would mean that we'd have an actual reinvigoration of the nondelelgation doctrine, on some other basis than intelligible principle. Remarkable! And I say this as someone sympathetic to major questions constraints (I just don't think, say, the IRS should be able to toggle on or off the capital gains tax/OCC should give Apple and Amazon bank charters by rule).

Anyway, happy to hear what I'm getting wrong, &c.

David

David Zaring
Professor
Department of Legal Studies and Business Ethics
The Wharton School
3730 Walnut Street, #600
Philadelphia, PA 19104
215-573-7154 (o)
540-460-8398 (c)

Message

**From**: Cassady, Alison [Cassady.Alison@epa.gov]
**Sent**: 3/12/2021 2:10:23 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC**: Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: RE: Climate Principals -- OAR Milestones and Actions

Thank you!

Alison L. Cassady
Deputy Chief of Staff for Policy
U.S. Environmental Protection Agency
Cell: (202) 941-6036

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Thursday, March 11, 2021 9:32 PM
**To:** Cassady, Alison <Cassady.Alison@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** Climate Principals -- OAR Milestones and Actions

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/22/2021 10:21:56 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: OAR Actions Jan 20-June 2021
**Attachments**: OAR Action January 20 to June 1 2021_First Team 011321.xlsx

Joe, as requested, please find attached the spreadsheet initially provided to the ART but updated with the current status of actions and expanded to include non-public information.

Please let me know if you have any questions.

Thank you. Have a nice weekend.

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Message

**From**: McMichael, Nate [McMichael.Nate@epa.gov]
**Sent**: 1/26/2021 4:23:07 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: RE: Message from Joe Goffman, Acting Assistant Administrator for OAR

Welcome back, Joe!

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Tuesday, January 26, 2021 10:35 AM
**To:** OAR-WIDE-EVERYONE <OARWIDEEVERYONE@epa.gov>
**Subject:** Message from Joe Goffman, Acting Assistant Administrator for OAR

Dear OAR Colleagues –

No one will enjoy a greater honor or privilege than the honor and privilege I now enjoy of returning to your side as your colleague. As some of you may recall, from 2009-2017, I served as OAR's Associate Assistant Administrator for Climate and Senior Counsel, which was the best experience of my career. Happy as I am to occupy a new role, now as OAR's Principal Deputy Assistant Administrator and current Acting Assistant Administrator, simply being back here with you all is what makes this return such a pleasure.

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From everything I've seen and heard, OAR employees' resilience, ingenuity and perseverance has shone through, and that's a tremendous source of comfort. Maintaining your characteristic commitment to our mission with the utmost professionalism while adapting to these tough times should give us all confidence that we can face the challenges, and harvest the opportunities, 2021 puts in our path and continue to deliver for the American people. After all, the OAR culture I knew when I was here last doubtless will propel us forward again: bringing out the best in each other and understanding that there is no success outside the success we all create and share in together.

In his note to all of us last week, EPA Chief of Staff Dan Utech introduced himself and members of the new leadership team who have arrived so far. He also called our attention to some of President Biden's executive orders. One in particular strikes to the core of our mission at OAR. The Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, says, "it is the policy of my Administration to listen to the science; to improve public health and protect our environment; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; to reduce greenhouse gas emissions; to bolster resilience to the impacts of climate change; … and to prioritize … environmental justice." It's as if President Biden were addressing EPA and OAR directly. Clearly, this is an amazing moment for us at OAR when our work will be even more vital and more highly valued in the coming months and years.

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Looking forward to connecting face-to-face

Thank you all very much for being here.

Stay safe and take care of yourselves and each other.

All best,
Joe

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From**: Birnbaum, Rona [Birnbaum.Rona@epa.gov]
**Sent**: 1/26/2021 10:43:38 PM
**To**: OAR Briefings [OAR_Briefings@epa.gov]
**CC**: DeLuca, Isabel [DeLuca.Isabel@epa.gov]; Grundler, Christopher [grundler.christopher@epa.gov]; Gunning, Paul [Gunning.Paul@epa.gov]; Kocchi, Suzanne [Kocchi.Suzanne@epa.gov]
**Subject**: Material for Climate Change Website briefing (1/27 11:30)
**Attachments**: Climate Web Briefing_1-27-21.pptx

Message

**From**: Millett, John [Millett.John@epa.gov]
**Sent**: 1/27/2021 10:05:54 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**CC**: Campbell, Ann [Campbell.Ann@epa.gov]; Shaw, Betsy [Shaw.Betsy@epa.gov]; Monroe, Scott [Monroe.Scott@epa.gov]; DeLuca, Isabel [DeLuca.Isabel@epa.gov]
**Subject**: OAP All-Hands -- Talking points and employee questions
**Attachments**: Talking Points for Joe Tomas Live Event_OAP.docx

Hi Joe and Tomás – attached are the talking points from OAP – I haven't had a chance to edit them, except to add mention that EPA.gov will soon reflect the agency's climate work much more prominently – which I think will be a crowd-pleaser. The talkers do a good job of touching on each division of OAP and that employees in all roles are vital to fulfilling the EPA/OAR mission.

Just as important, Suzie passed along some questions in advance from OAP staff. They are below. I plugged in the key points from the EO as an answer to the priorities question. I think the others we can quickly discuss at RT tomorrow w/ Betsy's help. The q's will come in via chat.

From Suzie:

**Ex. 5 Deliberative Process (DP)**

Thanks – Suzie

Message

**From:** POLITICO Pro Energy [alert@email.politicopro.com]
**Sent:** 1/22/2021 9:44:17 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Biden executive order could pause on new oil and gas leases

**Biden executive order could pause on new oil and gas leases**

By Ben Lefebvre

01/22/2021 04:43 PM EST

The Biden administration is expected to order a pause on new oil, gas and coal leases on federal lands next week, two people familiar with the plan said on Friday.

**Details**: The administration is likely to include the move as part of a climate-related executive order planned for Wednesday, according to the people briefed on the plan who requested anonymity to discuss the unreleased order. It will include a moratorium on the Interior Department offering new oil and gas leases for onshore and offshore federal properties, they said.

The suspension would last one year for oil and gas and up to three years for coal, one of the people said. Bloomberg News first reported the possible temporary halts.

During that pause, the administration is expected to review the criteria under which leases and drilling permits are given and possibly invite public comment, the two people said. The administration may consider new requirements on how much methane companies may emit from the leases or other climate-related requirements, the people said.

Depending on which, if any, provisions are eventually added, it could be "death by several formidable cuts" for large scale oil and gas production on federal land, one of the people said.

An Interior Department spokesman declined to comment. A source with the White House said talk of "additional [executive orders] in the coming days that are circulating among the media are likely still drafts/pre-decisional."

**Context**: A pause on oil and gas leasing for review would be another step toward Biden's campaign promise to halt new oil and gas production on federal land, where about 20 percent of U.S. oil production — and methane emissions — occur. Interior earlier this week said only high-ranking officials would be able to authorize new permits to drill on public land for the next 60 days.

The administration would have a blueprint for placing a permanent moratorium on its offshore holdings if it decides to do so. The Obama administration in its final days removed the northern Bering Sea region from consideration for leasing, an action that the Trump administration challenged in court but was unable to overturn.

The case for a permanent ban on onshore oil and gas leases could be more complicated, analysts have said. The Mineral Leasing Act requires that eligible land be auctioned for leases, though one of the people familiar with the administration's plans said the administration could review what is considered "eligible."

Republicans have come out sharply against any curtailing of oil production on federal land. Sen. Steve Daines (R-Mon.) on Twitter called Biden's moves "an outright attack on American energy and union jobs."

But some industry analysts said curtailing some U.S. oil production, which has fallen dramatically in the past year, could help the industry overall.

Analysts at Morgan Stanley said that adding stricter provisions onto leases or drilling permits could drive companies to move to private land. But it could also benefit the overall industry by removing some of the supply that has kept oil prices too low for some companies to make a profit, the analysts noted.

The order this week "signals a more challenging regulatory backdrop ahead – one that likely includes restrictions on methane emissions, more stringent infrastructure permitting, and potentially, carbon regulations," Morgan Stanley analysts said in a report. "In effect, this policy backdrop is *constructive* for the oil & gas macro – constraining supply and putting upward pressure on the marginal cost of shale production without impacting short-term demand."

*To view online*:
https://subscriber.politicopro.com/energy/article/2021/01/biden-executive-order-could-pause-on-new-oil-and-gas-leases-2030089

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Message

**From**: Ling, Michael [Ling.Michael@epa.gov]
**Sent**: 1/26/2021 4:11:56 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: RE: Message from Joe Goffman, Acting Assistant Administrator for OAR

Hi Joe, I'll use my prior work with you (which I remember fondly) as an excuse to circumvent the normal channels of communication, so that I can directly welcome you back. It's always a pleasure to talk policy with you and I hope we will see opportunities to do that this time around as well. Look forward to working with you again, and wish you and the team all great success. Let me know if I can help in any way (though the normal channels, of course ☺).

Michael Ling
Air Quality Policy Division
U.S. EPA - OAQPS
(919) 541-4729

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Tuesday, January 26, 2021 10:35 AM
**To:** OAR-WIDE-EVERYONE <OARWIDEEVERYONE@epa.gov>
**Subject:** Message from Joe Goffman, Acting Assistant Administrator for OAR

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Looking forward to connecting face-to-face

Thank you all very much for being here.

Stay safe and take care of yourselves and each other.

All best,
Joe

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/26/2021 10:28:01 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: Goffman, Joseph Calendar
**Attachments**: Goffman Joseph Calendar.ics

Evening Joe. Below is your calendar for tomorrow. The morning is back to back. Please let Delaney and I know if you would like any revisions. If so, one option

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thank you for your patience and feedback.

**Goffman, Joseph Calendar**
Goffman.Joseph@epa.gov
On Wednesday, January 27, 2021
Time zone: (UTC-05:00) Eastern Time (US & Canada)
(Adjusted for Daylight Saving Time)

**January 2021**

| Su | Mo | Tu | We | Th | Fr | Sa |
|---|---|---|---|---|---|---|
| | | | | | 1 | 2 |
| 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| 24 | 25 | 26 | 27 | 28 | 29 | 30 |
| 31 | | | | | | |

Busy
Out of Office
Tentative
Working Elsewhere
Free
Outside of Working Hours

January 2021

**Wed, Jan 27**

| | | |
|---|---|---|
| | **Before 8:00 AM** | **Free** |
| | **8:00 AM – 8:30 AM** | **Free** |
| | 8:30 AM – 9:00 AM | Check-In |
| | 9:00 AM – 10:00 AM | Ex. 5 Deliberative Process (DP) |
| | 10:00 AM – 10:30 AM | |
| | 10:30 AM – 11:00 AM | |

| | | |
|---|---|---|
| ■ | 11:00 AM – 11:30 AM | Ex. 5 Deliberative Process (DP) |
| ■ | 11:30 AM – 12:00 PM | |
| ■ | 12:00 PM – 1:00 PM | |
| ■ | 1:00 PM – 1:45 PM | |
| □ | **1:45 PM – 2:00 PM** | |
| ■ | 2:00 PM – 2:30 PM | |
| □ | **2:30 PM – 2:45 PM** | |
| ■ | 2:45 PM – 4:15 PM | |
| □ | **4:15 PM – 4:30 PM** | |
| ■ | 4:30 PM – 5:00 PM | |
| ■ | 5:00 PM – 5:30 PM | Check-In |
| □ | **After 5:30 PM** | **Free** |

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/21/2021 8:51:42 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**CC**: Dunham, Sarah [Dunham.Sarah@epa.gov]; Shaw, Betsy [Shaw.Betsy@epa.gov]
**Subject**: 012121: CSAPR options selection prebrief materials
**Attachments**: Final_Administrator Briefing_Revised CSAPR Update_Options Selection_01.25.21.docx

Please find attached the briefing materials for tomorrow's pre-brief on the CSAPR Update rulemaking.

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Message

**From:** POLITICO Pro Energy [alert@email.politicopro.com]
**Sent:** 1/29/2021 5:22:24 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Another Cuomo energy aide likely heading to Biden administration

## Another Cuomo energy aide likely heading to Biden administration

By Marie J. French

01/29/2021 12:21 PM EST

Amanda Lefton, first assistant secretary for energy and environment under Gov. Andrew Cuomo, is widely expected to lead the Department of Interior's Bureau of Ocean Energy Management under President Joe Biden, according to multiple sources familiar with the move.

**Why it matters:** BOEM is a key agency for both Biden's and Cuomo's clean energy agenda. New York policymakers have a lengthy wishlist, starting with the opening of more lease areas and speedier permitting for offshore wind projects.

Lefton's familiarity with the issue and experience in New York could speed along offshore wind progress, which has stalled under the Trump administration.

Offshore wind will be crucial for reaching Biden's goal of 100 percent clean power by 2035, but the BOEM hasn't announced a lease auction since 2018, when demand for parcels south of New England set price records. BOEM has also slowed development of Vineyard Wind, an 800-MW project in waters off Massachusetts, requiring an additional environmental review that has delayed construction for years.

If appointed, Lefton will also oversee the agency responsible for offshore oil and gas drilling lease auctions, which Biden is expected to pause. And she will have an opportunity to reinstate safety rules put in place following the Deep Water Horizon disaster from 2010, many of which were weakened or rolled back by the Trump administration.

Biden is expected to press pause on offshore oil lease sales, which BOEM organizes.

**Who she is:** Lefton is a widely liked figure in Cuomo world, where she's worked for about two years, sticking it out amid lots of internal churn on the energy team — though Lefton has now departed the administration, according to the sources.

She did not respond to multiple requests for comment.

She came to the administration after working as a policy expert at The Nature Conservancy in New York, based in Albany, for seven years. She joined the administration after serving as the deputy policy director there.

Lefton is a graduate of the University at Albany and also previously worked at the Rochester Regional Joint Board of Workers United.

Lefton worked closely with Ali Zaidi, now Biden's deputy national climate adviser. Zaidi spent less than a year working as the deputy secretary for energy and the environment under Cuomo.

**What's next:** The director of BOEM does not need to be confirmed by the Senate.

*Eric Wolff contributed to this report.*

*To view online*:
https://subscriber.politicopro.com/energy/article/2021/01/another-cuomo-energy-aide-likely-heading-to-biden-administration-2031414

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Message

**From**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Sent**: 1/25/2021 6:44:27 PM
**To**: Dunham, Sarah [Dunham.Sarah@epa.gov]; Charmley, William [charmley.william@epa.gov]; Srinivasan, Gautam [Srinivasan.Gautam@epa.gov]; Simon, Karl [Simon.Karl@epa.gov]
**CC**: Campbell, Ann [Campbell.Ann@epa.gov]; Goffman, Joseph [Goffman.Joseph@epa.gov]; Hoffer, Melissa [Hoffer.Melissa@epa.gov]
**Subject**: FW: Material for today's Light-duty Vehicle meeting with OAR and OGC leadership
**Attachments**: SAFE 1 and 2 Briefing for the OAR and OGC leadership , Final.docx

Hi all – thank you for today's briefing and for the background materials circulated earlier today.

Having reviewed the agenda, I wanted to note that my former employer, Environmental Defense Fund, is a party to the SAFE 1 and SAFE 2 litigation. As I understand my ethics obligations, I am recused from any discussions bearing on the litigation itself. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

My apologies for the inconvenience, but I want to make sure I am honoring my ethics obligations. If I've misunderstood any aspect of the agenda please let me know. Thanks,

Tomás

**From:** Charmley, William <charmley.william@epa.gov>
**Sent:** Monday, January 25, 2021 10:54 AM
**To:** OAR Briefings <OAR_Briefings@epa.gov>
**Cc:** OTAQ Materials <OTAQMaterials@epa.gov>; Orlin, David <Orlin.David@epa.gov>; Srinivasan, Gautam <Srinivasan.Gautam@epa.gov>; Simon, Karl <Simon.Karl@epa.gov>
**Subject:** Material for today's Light-duty Vehicle meeting with OAR and OGC leadership

Please find attached material for today's 3:30 – 4:15pm meeting "Light-duty Vehicle SAFE 1 and 2" meeting.

Message

**From:** Grundler, Christopher [grundler.christopher@epa.gov]
**Sent:** 1/28/2021 5:24:55 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** RE: Heads Up--CRA

**Ex. 5 Deliberative Process (DP)**

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
202.343.9140 (o)
734.645.5221 (m)

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Thursday, January 28, 2021 12:22 PM
**To:** Grundler, Christopher <grundler.christopher@epa.gov>
**Cc:** Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>
**Subject:** RE: Heads Up--CRA

**Ex. 5 Deliberative Process (DP)** Dropping Tomas, who is recused

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Grundler, Christopher <grundler.christopher@epa.gov>
**Sent:** Thursday, January 28, 2021 12:05 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>; Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Subject:** Heads Up--CRA

Joe—
Via sources and methods, I understand that EDF will be reaching out to you to explain their decision supporting a methane CRA

I share this information with the hope that it is your practice not to shoot the messenger

C

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
202.343.9140 (o)
734.645.5221 (m)

Message

**From**: Millett, John [Millett.John@epa.gov]
**Sent**: 1/22/2021 9:39:27 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Shaw, Betsy [Shaw.Betsy@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: draft all-staff note
**Attachments**: note from joe.docx

Hi Joe, Betsy and Ann – below and attached is the draft note from to OAR staff. Thoughts and edits welcome!

~~~~~~~~~~~~~~~~~~

Dear OAR Colleagues –

**Ex. 5 Deliberative Process (DP)**
~~~~~~~~~~~~~~~~~~

# Ex. 5 Deliberative Process (DP)

~~~~~~~~~~~~~~~~~~

John Millett
Director, OAR Communications
Desk: 202-564-2903
Cell: 202-510-1822
~~~~~~~~~~~~~~~~~~

Message

**From**: Adamantiades, Mikhail [Adamantiades.Mikhail@epa.gov]
**Sent**: 1/26/2021 3:45:22 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: RE: Message from Joe Goffman, Acting Assistant Administrator for OAR

Welcome back Joe! Very nice message, can't wait to get back to work with you and the new team.

Misha

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Tuesday, January 26, 2021 10:35 AM
**To:** OAR-WIDE-EVERYONE <OARWIDEEVERYONE@epa.gov>
**Subject:** Message from Joe Goffman, Acting Assistant Administrator for OAR

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EPA and OAR directly. Clearly, this is an amazing moment for us at OAR when our work will be even more vital and more highly valued in the coming months and years.

It is also my great pleasure to introduce Tomás Carbonell, who has joined the OAR leadership team as the Deputy Assistant Administrator for Stationary Sources. Tomás comes to EPA from the Environmental Defense Fund, where he was the Senior Counsel and Director of Regulatory Policy for that organization's clean air program. From 2008-2012, Tomás was an Associate at Van Ness Feldman, LLP, where he counseled diverse clients on federal legal and regulatory matters related to climate change, clean energy, and environmental and electricity regulation. He has a J.D. from Yale University, degrees in Environmental Change and Management and Development Economics from the University of Oxford, and bachelors' degrees in Chemical Engineering, Economics, and Multidisciplinary Studies from North Carolina State University. Please join me in welcoming Tomás, and please stay tuned for more introductions in the near future.

Very soon, via "Teams," we will have the chance to talk to and hear from each other directly as we get "all hands" meetings on the calendar with each of your offices. Please think about how you want to use that time to surface your concerns and share your suggestions for the best practices to continue or adopt in our work together going forward. A little later on we will also be engaging with the regions and states, the Office of General Counsel, the Office of Policy and other program offices as well as the public and our stakeholders.

Looking forward to connecting face-to-face

Thank you all very much for being here.

Stay safe and take care of yourselves and each other.

All best,
Joe

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From**: Shaw, Betsy [Shaw.Betsy@epa.gov]
**Sent**: 1/29/2021 5:12:35 PM
**To**: Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Dunham, Sarah [Dunham.Sarah@epa.gov]; Grundler, Christopher [grundler.christopher@epa.gov]; Edwards, Jonathan [Edwards.Jonathan@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]; Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: FW: Older Grant Competitions from FY 2010

Hi again all,

After sending me the current grant list, Courtney was inspired to go back and look at previous grant programs we've run in an earlier era (circa 2010) that may, with some tweaks, have relevance today, so I'm sending that along too in the hopes that it may be helpful. I've noted two of the tribal grants that are ongoing, although under different names, that I wouldn't spend time worrying about too much for the current exercise.

Thanks,

Betsy

---

**From:** Hyde, Courtney <Hyde.Courtney@epa.gov>
**Sent:** Friday, January 29, 2021 11:58 AM
**To:** Shaw, Betsy <Shaw.Betsy@epa.gov>
**Subject:** Older Grant Competitions from FY 2010

Betsy,

I went back to the OAR Funding Page to look at some older grant competitions when we had a more robust grant programs that might be useful information to share with the ODs.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thanks
Courtney

Ex. 5 Deliberative Process (DP)

# Ex. 5 Deliberative Process (DP)

Message

**From:** Joseph Goffman [joegoffman Ex. 6 Personal Privacy (PP)
**Sent:** 1/25/2021 1:14:20 AM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Fwd: Some follow up thoughts

---------- Forwarded message ---------
From: **William Niebling** < Ex. 6 Personal Privacy (PP)
Date: Sat, Jan 16, 2021 at 10:29 PM
Subject: Some follow up thoughts
To: Joseph Goffman Ex. 6 Personal Privacy (PP) .com>

Joe -

Thanks again for the courtesy of giving me an update. Even if it wasn't good news, it's nice to know - and nice to be thought of highly enough to be worth telling.

Ex. 6 Personal Privacy (PP)

-Wm.

--

_ _ _ _ _ _ _ _ _

William Niebling
Arlington, Va.

Message

**From:** Kellie Ortega Ex. 6 Personal Privacy (PP)
**Sent:** 2/1/2021 2:46:41 AM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Position at the Environmental Protection Agency, Biden-Harris Administration
**Attachments:** Kellie Ortega CV.pdf

Joe –

Congratulations on your appointment as Principal Deputy Assistant Administrator of OAR! I spoke with Cynthia Giles this weekend, and she suggested that I reach out to you at your EPA address for advice and support. (I tried your former Harvard email address in November, and until last week, I had been trying to find contact information for Cynthia.)

Ex. 6 Personal Privacy (PP)

I hope all is well and that you and your family have stayed healthy during this difficult time.

Best regards,

Kellie Ortega

Message

**From**: Weinstock, Larry [Weinstock.Larry@epa.gov]
**Sent**: 1/26/2021 3:37:13 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: RE: Message from Joe Goffman, Acting Assistant Administrator for OAR

Congratulations Joe, welcome back!

Best wishes,
Larry Weinstock
Program Innovation Coordinator
202-564-9226

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Tuesday, January 26, 2021 10:35 AM
**To:** OAR-WIDE-EVERYONE <OARWIDEEVERYONE@epa.gov>
**Subject:** Message from Joe Goffman, Acting Assistant Administrator for OAR

Dear OAR Colleagues –

No one will enjoy a greater honor or privilege than the honor and privilege I now enjoy of returning to your side as your colleague. As some of you may recall, from 2009-2017, I served as OAR's Associate Assistant Administrator for Climate and Senior Counsel, which was the best experience of my career. Happy as I am to occupy a new role, now as OAR's Principal Deputy Assistant Administrator and current Acting Assistant Administrator, simply being back here with you all is what makes this return such a pleasure.

First, I would like to thank you all – and by "all" I mean every single person who works in OAR – for your service to the public and for your ongoing dedication and commitment to the mission of the Office of Air and Radiation and of the Environmental Protection Agency. No matter what your job here is, you have earned, and will continue to earn, the unending gratitude of our fellow Americans for the energy and care you devote to protecting the air we breathe, our health, and our quality of life. Of course, you are not here in quest of "thanks" and I'm pretty sure that when you look in the mirror you don't see a hero, but you're entitled both to the "thanks" and to seeing yourselves that way. You are certainly my heroes – every single one of you.

That's not an exaggeration. This has been a difficult year for our country and the world. Since March, the pandemic has brought hard times, fear, and illness to our communities, friends and families. Many of you may have been touched in some way by the hardships and tragedies this year has brought and we are here as colleagues to support you however we can; virtually everyone has had to cope with challenges none of us imagined having to face a year ago.

From everything I've seen and heard, OAR employees' resilience, ingenuity and perseverance has shone through, and that's a tremendous source of comfort. Maintaining your characteristic commitment to our mission with the utmost professionalism while adapting to these tough times should give us all confidence that we can face the challenges, and harvest the opportunities, 2021 puts in our path and continue to deliver for the American people. After all, the OAR culture I knew when I was here last doubtless will propel us forward again: bringing out the best in each other and understanding that there is no success outside the success we all create and share in together.

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exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; to reduce greenhouse gas emissions; to bolster resilience to the impacts of climate change; … and to prioritize … environmental justice." It's as if President Biden were addressing EPA and OAR directly. Clearly, this is an amazing moment for us at OAR when our work will be even more vital and more highly valued in the coming months and years.

It is also my great pleasure to introduce Tomás Carbonell, who has joined the OAR leadership team as the Deputy Assistant Administrator for Stationary Sources. Tomás comes to EPA from the Environmental Defense Fund, where he was the Senior Counsel and Director of Regulatory Policy for that organization's clean air program. From 2008-2012, Tomás was an Associate at Van Ness Feldman, LLP, where he counseled diverse clients on federal legal and regulatory matters related to climate change, clean energy, and environmental and electricity regulation. He has a J.D. from Yale University, degrees in Environmental Change and Management and Development Economics from the University of Oxford, and bachelors' degrees in Chemical Engineering, Economics, and Multidisciplinary Studies from North Carolina State University. Please join me in welcoming Tomás, and please stay tuned for more introductions in the near future.

Very soon, via "Teams," we will have the chance to talk to and hear from each other directly as we get "all hands" meetings on the calendar with each of your offices. Please think about how you want to use that time to surface your concerns and share your suggestions for the best practices to continue or adopt in our work together going forward. A little later on we will also be engaging with the regions and states, the Office of General Counsel, the Office of Policy and other program offices as well as the public and our stakeholders.

Looking forward to connecting face-to-face

Thank you all very much for being here.

Stay safe and take care of yourselves and each other.

All best,
Joe

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From:** POLITICO Pro [politicopro@info.politicopro.com]
**Sent:** 3/15/2021 5:01:18 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** You're Invited | Live Tutorial: Premium Analysis Overview

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Dear Joseph,

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Register

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**Note:** This call is open to all POLITICO Pro subscribers but will focus on Premium Analysis content that is exclusively available to POLITICO Pro Premium customers.

**Conference Call Details:**

- Thursday, March 18th, 2021
- 11:00 a.m. EST - 12:00 p.m. EST
- Exclusive to POLITICO Pro subscribers
- Q&A session at the end of the call

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Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/29/2021 4:56:04 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Shaw, Betsy [Shaw.Betsy@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: RE: docs

The challenge with the timing of this is you'll be in the PFAS briefing from 3-4 so there won't be an opportunity to put your eyes on it by 4p and after that you're with Sec'y Regan. As such, I'm going to ask them to send me whatever they have ready at 2:30 so you can get a feel for it, and they can continue to send information up until 3:30. We'll attempt to do this in stages.

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Friday, January 29, 2021 11:01 AM
**To:** Edwards, Jonathan <Edwards.Jonathan@epa.gov>; Dunham, Sarah <Dunham.Sarah@epa.gov>; Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>; Grundler, Christopher <grundler.christopher@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** Fwd: docs

See below on timing. Sorry. Let's try to assemble our material by 3:30. Thanks

Sent from my iPhone

Begin forwarded message:

> **From:** "Utech, Dan" <Utech.Dan@epa.gov>
> **Date:** January 29, 2021 at 10:34:59 AM EST
> **To:** "Goffman, Joseph" <Goffman.Joseph@epa.gov>, "Garbow, Avi" <Garbow.Avi@epa.gov>, "Fox, Radhika" <Fox.Radhika@epa.gov>
> **Cc:** "Cassady, Alison" <Cassady.Alison@epa.gov>
> **Subject: RE: docs**

**Ex. 5 Deliberative Process (DP)**

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> **From:** Utech, Dan
> **Sent:** Thursday, January 28, 2021 8:32 PM
> **To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Garbow, Avi <Garbow.Avi@epa.gov>; Fox, Radhika <Fox.Radhika@epa.gov>
> **Cc:** Cassady, Alison <Cassady.Alison@epa.gov>
> **Subject:** docs

Joe and Avi – docs attached. Radhika, I should explain what these are so let me know if you have any time this evening. Best, Dan

Message

**From:** Grundler, Christopher [grundler.christopher@epa.gov]
**Sent:** 1/22/2021 9:10:20 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC:** Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject:** Heads Up/Close Hold

Joe/Tomas:

**Ex. 5 Deliberative Process (DP)**

Chris

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
202.343.9140 (o)
734.645.5221 (m)

Message

**From**: Shaw, Betsy [Shaw.Betsy@epa.gov]
**Sent**: 1/29/2021 4:45:51 PM
**To**: Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Dunham, Sarah [Dunham.Sarah@epa.gov]; Grundler, Christopher [grundler.christopher@epa.gov]; Edwards, Jonathan [Edwards.Jonathan@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]; Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: OAR Grants
**Attachments**: OAR_grant_programs_10-09-20.pdf

Hi all,

Sending along the master list of OAR grants in case that prompts any additional ideas for today's firedrill.

**Ex. 5 Deliberative Process (DP)**

Thanks,

Betsy

Message

**From:** POLITICO Pro Trade [alert@email.politicopro.com]
**Sent:** 1/24/2021 12:07:47 AM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Biden and Boris Johnson talk alliance, climate, Covid

**Biden and Boris Johnson talk alliance, climate, Covid**

By Ben Leonard

01/23/2021 07:06 PM EST

President Joe Biden spoke with U.K. Prime Minister Boris Johnson on Saturday, with trade, climate and Covid discussed among other topline issues.

"Great to speak to President @JoeBiden this evening," Johnson wrote in a tweet Saturday. "I look forward to deepening the longstanding alliance between our two countries as we drive a green and sustainable recovery from COVID-19."

Johnson congratulated Biden for his inauguration and praised Biden's decision to reenter the Paris climate agreement, the COVAX program on expanding vaccine access and the World Health Organization, Johnson's office said in a readout of the call.

"They also discussed the benefits of a potential free deal between our two countries, and our Prime Minister reiterated his intention to resolve existing trade issues as soon as possible," Johnson's office said in the statement. "Building on the UK and US' long history of cooperation in security and defence, the leaders re-committed to the NATO alliance and our shared values in promoting human rights and protecting democracy."

Johnson, a conservative populist and one-time firm ally of former President Donald Trump, had sought to put distance in their relationship after Biden won the presidential election, with Johnson releasing a statement condemning Trump's actions amid the Jan. 6 assault on the U.S. Capitol.

Johnson-backed Brexit has altered the longstanding "special relationship" between the U.S. and the U.K.

"When you wanted to get something done with Europe, you made the first or perhaps second call to London," Charles Kupchan, who served as a senior National Security Council European affairs official in both the Obama and Clinton administrations, previously told POLITICO.

In 2021, "you're still going to call London, but that call will be lower down in the queue. Britain doesn't have a seat at the table anymore," due to Brexit, he said.

"Biden is seeking to strengthen and renew ties with the EU, and Britain is not going to be a part of that," a person familiar with Biden's thinking previously told POLITICO.

Trump and former U.K. Prime Minster Theresa May famously had a difficult relationship. May said recently she "never knew what to expect" from Trump, who was also a frequent critic of the EU bloc before the U.K.'s ultimate exit Jan. 31.

Trump abruptly canceled a planned trip to London with May in January 2018. When he visited May for the first time, he was highly critical of May in an interview with a tabloid published during the trip. Johnson succeeded May as leader of the Conservative Party and prime minister in July 2019.

On Friday, Biden spoke with President Andrés Manuel López Obrador of Mexico and Canadian Prime Minister Justin Trudeau.

The calls come as Biden attempts to begin his quest to "restore dignified leadership at home and respected leadership on the world stage" after Trump's America First approach to international relations.

*To view online*:
https://subscriber.politicopro.com/trade/article/2021/01/biden-and-boris-johnson-talk-alliance-climate-covid-2030180

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Message

**From:** POLITICO Pro [alert@email.politicopro.com]
**Sent:** 1/27/2021 9:25:00 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Biden climate orders include focus on transportation, infrastructure

**Biden climate orders include focus on transportation, infrastructure**

By Tanya Snyder

01/27/2021 04:24 PM EST

President Joe Biden put forward a sweeping executive order on climate Wednesday, including a shift to clean vehicles and an end to oil and gas subsidies.

**The order included:**

— A shift to zero-emission vehicles for federal, state, local, and tribal government fleets, including vehicles of the United States Postal Service;
— A "pause" on new oil and natural gas leases on public lands or in offshore waters pending a comprehensive review;
— The elimination of federal subsidies for fossil fuels;
— A sustainable infrastructure initiative with the White House Council on Environmental Quality and OMB working to ensure that federal infrastructure investment reduces climate pollution;
— A reversal of Trump-era permitting rules that stopped federal agencies from considering the effects of greenhouse gas emissions and climate change in their environmental reviews;
— The establishment of a Civilian Climate Corps;
— An environmental justice initiative working to ensure that 40 percent of the benefits of federal investments in energy, transit and other programs flow to disadvantaged communities; and
— Inclusion of the DOT secretary on task forces, working groups and interagency councils focused on climate, environmental justice and the economic revitalization of coal and power plant communities.

**What's next:** Most elements of the order demand action within the next two to three months.

Read more on Biden's climate initiative here.

*To view online*:
https://subscriber.politicopro.com/sustainability/whiteboard/2021/01/biden-climate-orders-include-focus-on-transportation-infrastructure-3986643

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Message

**From**: Agri-Pulse Communications [noreply@agri-pulse.com]
**Sent**: 3/15/2021 4:58:52 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: One week from today - Register now for the Ag & Food Policy Summit!

One week from today - Register now for the Ag & Food Policy Summit!

View this email in your browser

## One week from today!

## Register now for the Ag & Food Policy Summit

As the climate policy debate ramps up in Congress and the incoming Biden administration, there are a variety of ideas about how to measure, incentivize and regulate more sustainable practices. The 2021 Agri-Pulse Ag & Food Policy Summit will offer a chance to engage with a wide variety of policy makers and industry experts about what changes may be on the horizon. This year's virtual summit will feature three half-day sessions.

Click here to view the latest program

Click here to learn more and register for the event

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## Day 2 speakers:

## Day 3 speakers:

## Sponsors of the 2021 Agri-Pulse Ag & Food Policy Summit include:

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**Bronze:** Ag Council of America, American Sugar Alliance, American Seed Trade Association, Elanco, Farmer Mac, John Deere, National Association of State Departments of Agriculture, Nationwide, National Crop Insurance Services, National Farmers Union, National Milk Producers Federation, U.S. Dairy Export Council, Pivot Bio, and Truterra.

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Message

**From**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Sent**: 1/21/2021 8:14:01 PM
**To**: Dunham, Sarah [Dunham.Sarah@epa.gov]
**CC**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: Re: meeting request

Thank you Sarah! I defer to your expertise and Joe's on how to proceed, but this sounds great to me.

**Ex. 5 Deliberative Process (DP)**

Best,

Tomás

Sent from my iPhone

On Jan 21, 2021, at 2:15 PM, Dunham, Sarah <Dunham.Sarah@epa.gov> wrote:

**Ex. 5 Deliberative Process (DP)**

And if there are other aspects, or more specific parts of above that we should include for a first discussion, please let me know.

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Thursday, January 21, 2021 1:55 PM
**To:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Cc:** Dunham, Sarah <Dunham.Sarah@epa.gov>
**Subject:** RE: meeting request

Please do. Thanks.

**From:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Sent:** Thursday, January 21, 2021 1:51 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>

**Cc:** Dunham, Sarah <Dunham.Sarah@epa.gov>
**Subject:** Re: meeting request

Thanks Joe. Happy to help here. Should I reach out to Melissa to suggest this approach?

Sent from my iPhone

On Jan 21, 2021, at 1:14 PM, Goffman, Joseph <Goffman.Joseph@epa.gov> wrote:

**Ex. 5 Deliberative Process (DP)**

**From:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Sent:** Thursday, January 21, 2021 1:06 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** Fwd: meeting request

Hi Joe, FYI

Sent from my iPhone

Begin forwarded message:

**From:** "Segall, Craig@ARB" <Craig.Segall@arb.ca.gov>
**Date:** January 21, 2021 at 6:42:39 AM EST
**To:** "Hoffer, Melissa" <hoffer.melissa@epa.gov>
**Cc:** "Carbonell, Tomas" <Carbonell.Tomas@epa.gov>, "Fine, Philip" <Fine.Philip@epa.gov>, arroyo.vicki@epa.gov, "Cliff, Steve@ARB" <Steve.Cliff@arb.ca.gov>, "Corey, Richard@ARB" <richard.corey@arb.ca.gov>, "Peter, Ellen M. @ARB" <ellen.peter@arb.ca.gov>, "Gordon, Jessica@ARB" <Jessica.Gordon@arb.ca.gov>, "Brehler, Pippin@ARB" <Pippin.Brehler@arb.ca.gov>
**Subject: Re: meeting request**

Sounds good. I'm booked 3-4 Scotland time, otherwise free.

**From:** Hoffer, Melissa <hoffer.melissa@epa.gov>
**Sent:** Thursday, January 21, 2021 3:33 AM
**To:** Segall, Craig@ARB <Craig.Segall@arb.ca.gov>
**Cc:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Fine, Philip <Fine.Philip@epa.gov>; arroyo.vicki@epa.gov <arroyo.vicki@epa.gov>; Cliff, Steve@ARB <Steve.Cliff@arb.ca.gov>; Corey, Richard@ARB <richard.corey@arb.ca.gov>; Peter, Ellen M. @ARB <ellen.peter@arb.ca.gov>; Gordon, Jessica@ARB <Jessica.Gordon@arb.ca.gov>; Brehler, Pippin@ARB <Pippin.Brehler@arb.ca.gov>
**Subject:** Re: meeting request

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

That sounds right, Craig. Let's speak today regarding next steps.

Melissa

Sent from my iPhone

On Jan 21, 2021, at 5:28 AM, Segall, Craig@ARB <Craig.Segall@arb.ca.gov> wrote:

Dear All:

Congratulations, first of all! Second, as the recent EO establishes (Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis | The White House) there's much work ahead. In light of the tight deadlines on reconsidering the SAFE rules, the direction to consult with states, and CARB's particular role, we'd like to suggest a meeting as soon as possible. We would suggest we start by discussing the SAFE rule state of play, and activities the President has now directed to consider rescinding both parts of the rule.

As time allows, it would also be valuable to set further meetings focusing on other areas where the states are either plaintiffs in ongoing litigation (e.g., the recent remand of the ACE rule, the PM and ozone NAAQS, etc) or have major policy interests (e.g., transforming the freight system). It seems to me that we may want to start with the policy level at OAR/OGC/OPP and CARB, but welcome ideas. I think the team here is available from today forward.

Best,
Craig

Craig Segall
Assistant Chief Counsel
California Air Resources Board
1001 I Street Sacramento, CA 95814
VOIP: 916-720-2974
Craig.Segall@arb.ca.gov
Pronouns: he/him

<image001.png>

Message

**From:** POLITICO Pro Energy [alert@email.politicopro.com]
**Sent:** 1/29/2021 4:30:28 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Court strikes down EPA ozone-related trading program

## Court strikes down EPA ozone-related trading program

By Alex Guillén

01/29/2021 11:29 AM EST

The D.C. Circuit Court of Appeals on Friday vacated a key trading provision included in a rule implementing the 2015 ozone air quality standard.

**Background:** EPA in 2018 issue a rule (Reg. 2060-AS82) to implement the 2015 ozone standard of 70 parts per billion. Ozone is not emitted directly by human activity but rather forms when precursor pollutants — nitrogen oxides and volatile organic compounds — interact with sunlight.

The 2018 rule included an "interprecursor trading program" that allowed state permitting authorities to satisfy offset requirements by swapping reductions of NOx for reductions of VOCs, or vice versa. That would allow a source that needed to offset NOx emissions, for example, to have the option to instead reduce its VOC emissions by a comparable amount determined by a set of calculations.

The Sierra Club and other environmental groups challenged the interprecursor trading program, as well as three other provisions.

**The ruling:** A three-judge panel agreed with the environmental groups that the Clean Air Act does not allow for such a trading program. Congress would have used different language in key statutory passages if it wanted EPA to allow interprecursor trading for offsets, wrote Judge David Tatel, joined by Gregory Katsas and Harry T. Edwards.

"The plain language of the statute thus requires that increased VOC emissions be offset with reductions in VOC emissions, and the same is true for NOx emissions under most circumstances," Tatel wrote.

The panel struck down two other provisions as well.

One allowed states to demonstrate they achieved air quality milestones via implementation-based measures instead of qualitative data. That amounted to an unreasonable interpretation of the law, the panel ruled.

The court also vacated requirements for contingency measures that must be included in state air plans in the event they miss their attainment deadlines. The 2018 rule allowed for measures that were already implemented to count as contingency plans. But Congress banned previously implemented measures from qualifying as contingency measures, the panel ruled.

However, the court rejected the green groups' challenge to a fourth provision that allowed states to choose between two alternative baseline years when demonstrating their progress. EPA "acted reasonably" there, the court concluded.

*To view online*:
https://subscriber.politicopro.com/energy/article/2021/01/court-strikes-down-epa-ozone-related-trading-program-2031409

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Message

**From:** POLITICO Pro Agriculture [alert@email.politicopro.com]
**Sent:** 1/28/2021 4:35:46 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Stabenow aims for climate bill as she takes control of Senate Ag

**Stabenow aims for climate bill as she takes control of Senate Ag**

By Liz Crampton

01/28/2021 11:34 AM EST

Incoming Senate Agriculture Chair Debbie Stabenow intends to move forward "soon" on a bipartisan bill that would set up a certification program at the Agriculture Department to help pay farmers who participate in voluntary carbon markets.

**The approach:** Stabenow, speaking with reporters on Thursday, said that addressing climate change is a top priority as she takes control of the Agriculture Committee.

The Michigan Democrat wants to see that done through the passage of the bipartisan Growing Climate Solutions Act, S. 3894 (116), which she introduced last year with Republican Sen. Mike Braun . The bill would provide technical support for farmers to give them information to be able to enter private carbon markets, such as verification of third-party entities farmers can work with in the carbon credit process.

"We can provide voluntary, producer-led opportunities for our farmers and foresters that would allow them to calculate their emissions and create new sources of income through the adoption of practices that store more carbon in soil," Stabenow said.

She noted that increasing weather changes, such as rapid warming of the Great Lakes in her home state, is threatening farmers' businesses and the overall economy.

"This is very serous and I feel a great sense of urgency to get started on the things that need to be done," she said. "I'm going to look for whatever vehicle will allow us to do that and supporting our farmers by creating a new market as quickly as we can."

**The 2023 farm bill:** Stabenow is also eyeing the upcoming farm bill reauthorization as an opportunity to ramp up USDA's conservation programs as part of the federal government's effort to confront climate change.

She identified increasing funding for certain pilot programs boosted in the 2018 farm bill, such as the Conservation Innovation Grants initiative that encourages public and private partnerships to address natural resource concerns on working lands.

*To view online*:
https://subscriber.politicopro.com/agriculture/whiteboard/2021/01/stabenow-aims-for-climate-bill-as-she-takes-control-of-senate-ag-3986666

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Message

**From**: Nunez, Alejandra [Nunez.Alejandra@epa.gov]
**Sent**: 3/13/2021 12:09:40 AM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Kim, Eun [Kim.Eun@epa.gov]
**Subject**: RE: Two QFRs for your review

Thank you, Joe. Will do.

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Friday, March 12, 2021 7:09 PM
**To:** Nunez, Alejandra <Nunez.Alejandra@epa.gov>
**Cc:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Kim, Eun <Kim.Eun@epa.gov>
**Subject:** RE: Two QFRs for your review

Thanks for doing this. Given that these are written questions, I would get rid of the phrase highlighted below. Otherwise, this looks fine. Thanks, again.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Nunez, Alejandra <Nunez.Alejandra@epa.gov>
**Sent:** Friday, March 12, 2021 7:02 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Kim, Eun <Kim.Eun@epa.gov>
**Subject:** Two QFRs for your review

Hi Joe,

Tomas and I are done reviewing the QFRs and Eunjung is entering comments and edits in Sharepoint. Before we finalize the review, we wanted you to take a look at these two questions. Please let us know if you have any comments.

Thanks.

Senator Inhofe (both)

**Ex. 5 Deliberative Process (DP)**

# Ex. 5 Deliberative Process (DP)

Message

**From:** POLITICO Pro Energy [alert@email.politicopro.com]
**Sent:** 1/28/2021 4:26:37 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** McConnell blasts Biden's 'piecemeal Green New Deal'

## McConnell blasts Biden's 'piecemeal Green New Deal'

By Anthony Adragna

01/28/2021 11:25 AM EST

Senate Minority Leader Mitch McConnell roundly slammed President Joe Biden's early climate change actions as a threat to jobs around the country, foreshadowing the challenges Biden will face in convincing Republicans to enact major portions of his agenda.

"There's nothing green about a tsunami of pink slips for American workers or carting Canadian crude [oil] around in trucks and trains instead of a pipeline," McConnell said in floor remarks. "This piecemeal Green New Deal is the wrong prescription — wrong for the environment, wrong for national security and, most of all, for the working Americans who will soon be formerly-working Americans if this keeps up."

McConnell, who never used the phrase "climate change" in his remarks, asserted Biden's policies would provide "no meaningful impact on global temperatures, just applause at those international conferences where the participants all assemble by private jets." He singled out Biden's rejoining the Paris climate accord, revoking a permit for the Keystone XL pipeline and ordering pause on new leasing on public lands for particular criticism.

**Context:** Democrats, led by Biden, have argued the transition to a clean energy economy will generate millions of jobs, and they vowed to support communities that produced fossil fuels in the transition to new economies.

"A key plank of our Build Back Better Recovery Plan is building a modern, resilient climate infrastructure and clean energy future that will create millions of good-paying union jobs — not 7, 8, 10, 12 dollars an hour, but prevailing wage and benefits," Biden said Wednesday. "We can put millions of Americans to work modernizing our water systems, transportation, our energy infrastructure to withstand the impacts of extreme climate."

But those reassurances have landed with a thud among lawmakers in states like Kentucky, Louisiana, Montana, Wyoming and Texas.

"Kentucky paid dearly for the first round of these liberal policies under President Obama," McConnell said. "We have no desire to be subjected to a sequel."

*To view online*:
https://subscriber.politicopro.com/energy/whiteboard/2021/01/mcconnell-blasts-bidens-piecemeal-green-new-deal-3986667

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Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/28/2021 4:17:49 PM
**To**: Weekly Report Group [Weekly_Report_Group@epa.gov]
**CC**: Shaw, Betsy [Shaw.Betsy@epa.gov]; DeLuca, Isabel [DeLuca.Isabel@epa.gov]; Millett, John [Millett.John@epa.gov]; Rakosnik, Delaney [rakosnik.delaney@epa.gov]; Clarke, Deirdre [clarke.deirdre@epa.gov]; Burch, Julia [Burch.Julia@epa.gov]; Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Haman, Patricia [Haman.Patricia@epa.gov]; Grundler, Christopher [grundler.christopher@epa.gov]; Spenillo, Justin [Spenillo.Justin@epa.gov]; Shoaff, John [Shoaff.John@epa.gov]; Thundiyil, Karen [Thundiyil.Karen@epa.gov]; Dunham, Sarah [Dunham.Sarah@epa.gov]; Morgan, Ruthw [morgan.ruthw@epa.gov]; Edwards, Jonathan [Edwards.Jonathan@epa.gov]; Cherepy, Andrea [Cherepy.Andrea@epa.gov]; Kocchi, Suzanne [Kocchi.Suzanne@epa.gov]; Koerber, Mike [Koerber.Mike@epa.gov]; Sandfoss, Kristina [Sandfoss.Kristina@epa.gov]; Senter, Stephen [Senter.Stephen@epa.gov]; Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: OAR Weekly Report

Please find below, OAR's report for the week ending January 29, 2021. Thank you and welcome!

**Ex. 5 Deliberative Process (DP)**

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Message

**From**: Paul Billings [Paul.Billings@lung.org]
**Sent**: 1/26/2021 9:39:04 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; utech.daniel@EPA.gov; Cassady, Alison [Cassady.Alison@epa.gov]; Adhar, Radha [Adhar.Radha@epa.gov]
**CC**: Laura Kate Bender [Laura.Bender@lung.org]
**Subject**: 26 Health & Medical Group a Declaration on Climate and Health
**Attachments**: ATT00001.txt

Today, in anticipation of the Biden Administration's announcements on climate tomorrow, the American Lung Association and 25 other national health and medical organizations are sharing a Declaration on Climate and Health to President Joe Biden and Congress. It declares climate change a health emergency and calls upon decision-makers to take immediate action to protect public health from air pollution and climate change, prioritizing the communities most impacted by pollution.

The groups signing the declaration are:

1. Allergy & Asthma Network
2. Alliance of Nurses for Healthy Environments
3. American Academy of Pediatrics
4. American Association of Community Psychiatrists
5. American College of Physicians
6. American College of Preventive Medicine
7. American Lung Association
8. American Public Health Association
9. Association of Schools and Programs of Public Health
10. Asthma and Allergy Foundation of America
11. Children's Environmental Health Network
12. Climate for Health
13. Columbia Climate & Health Program
14. Global Climate and Health Alliance
15. Health Care Without Harm
16. Medical Society Consortium on Climate & Health
17. Medical Students for a Sustainable Future
18. National Association of County and City Health Officials
19. National Association of Pediatric Nurse Practitioners
20. National Environmental Health Association
21. National League for Nursing
22. National Medical Association
23. National WIC Association
24. Physicians for Social Responsibility
25. Public Health Institute
26. Society for Public Health Education

We would welcome the opportunity to discuss further. Please let me know if you have any questions, and thank you.

Paul

**Paul Billings**
National Senior Vice President | Public Policy

**American Lung Association**
1331 Pennsylvania Ave NW #1425 | Washington DC 20004
D: 202-785-3988
Lung HelpLine: 1-800-LUNGUSA
Lung.org | Paul.Billings@Lung.org
Pronouns: He/Him/His

Message

**From:** POLITICO Pro [alert@email.politicopro.com]
**Sent:** 1/25/2021 5:26:11 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Pallone vows 'accelerating' push for ambitious climate action

**Pallone vows 'accelerating' push for ambitious climate action**

By Anthony Adragna

01/25/2021 12:24 PM EST

House Energy and Commerce Chair Frank Pallone said on Monday that the Democratic-led Congress intends to include major climate change provisions as part of an infrastructure package in the coming months.

"Our committee and myself are really accelerating our efforts to address climate change," Pallone (D-N.J.) told a virtual roundtable in New Jersey. "Within another month or so there'll be a major infrastructure initiative as part of an effort to bring it back and revise the economy, and that'll have a lot of the things that were in" last year's House-passed infrastructure bill H.R. 2 (116).

**Word of caution:** Pallone said his committee's sweeping climate change legislative framework from last Congress — called the CLEAN Future Act — would serve as the "blueprint" for additional action this year, though he cautioned the scope of any legislation could be more limited if Democrats decided to advance their priorities through budget reconciliation, which allows legislation to advance through thee Senate with a simple majority.

"We're going to try to be ambitious, but I got to be honest and say that we're still dealing with a Senate that's 50-50," he said.

He said he expected Biden to pursue dual tracks for legislation that could include climate change-related provisions.

"Biden's probably going to work with us and announce an overall general authorization package, similar to the CLEAN Future Act and it'll have things in it that don't come under our jurisdiction, as well," Pallone said. "But at the same time we would try to move the money part and the tax part under either a budget reconciliation or some other vehicle ... It's going to probably be all at the same time."

**Budget reconciliation warning:** The New Jersey Democrat expressed doubt a clean energy standard that mandates the share of energy that is derived from different energy sources could be structured in a way to be included in legislation considered under reconciliation. That's been a key source of division among Democratic circles.

"If you have a clean electricity standard that mandates that you move towards [energy distributions] by 2035 or 2050, that's authorization and that's a lot harder to justify and probably wouldn't survive under the so called Byrd rule," Pallone said, referring to the arcane rule that limits what provisions can be included as part of budget reconciliation.

Pallone said he was not explicitly ruling out carbon pricing or cap and trade provisions in the discussions, though he doubted those ideas could achieve political consensus. He noted the committee's legislation last year was silent on those policies.

"It is a political choice," Pallone said. "We're not opposed to it. It's just that we want to see what we can get a consensus on."

**Victory lap on end-of-year bill:** Pallone hailed climate-friendly provisions included in a massive end-of-year spending package, H.R. 133 (116), as a "downpayment" on additional climate action this Congress, singling out a compromise to phase down the use of hydrofluorocarbons as especially significant.

He said Senate Republicans blocked provisions on environmental justice, H.R. 5986 (116), boosting the resiliency of shorelines to the impacts of climate change and restricting the ability of pipeline companies to use eminent domain during construction, but vowed to push again for them this Congress.

"With the key departments of EPA and Interior being led by people who are themselves environmental justice advocates, we can kind of address this on two fronts: one through agency action and executive action, but at the same time trying to get these legislative initiatives passed," Pallone said, referring to environmental justice legislation specifically.

*To view online*:
https://subscriber.politicopro.com/energy/article/2021/01/pallone-vows-accelerating-push-for-ambitious-climate-action-2030393

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Message

**From:** POLITICO Pro Energy [alert@email.politicopro.com]
**Sent:** 1/27/2021 7:25:36 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** On China, Kerry says U.S. won't trade other issues for climate wins

## On China, Kerry says U.S. won't trade other issues for climate wins

By Zack Colman

01/27/2021 02:24 PM EST

Special Presidential Climate Envoy John Kerry said the U.S. would not compromise on major existing disputes with China to secure victories on climate change, underscoring the complex relationship between the world's two largest economies and greenhouse gas emitters.

**The details:** Kerry's comments at a Wednesday White House press briefing showed how relations with China have deteriorated since the two nations collaborated to deliver momentum crucial for sealing the 2015 Paris climate agreement.

"We have serious differences with China on some very, very important issues," Kerry said. "The issues of theft of intellectual property and access to markets, the South China Sea — run the list, we all know them. Those issues will never be traded for anything that has to do with climate."

But Kerry noted cooperation with China on climate is essential for preventing the world from crossing a dangerous threshold that would bake in catastrophic changes. China is the world's leading global greenhouse gas emitter, accounting for 24 percent of the world's total carbon dioxide pollution, with the U.S. second at 13 percent, according to the International Energy Agency.

"Climate is a critical standalone issue that we have to deal on," Kerry said. "So it's urgent that we find a way to compartmentalize and move forward."

**Background:** China also supplies 70 percent of the world's finance for coal-fired power plants, the highest-emitting energy source, Kerry said in an earlier Wednesday speech at the World Economic Forum. That means China's contribution to global emissions registers extends outside its own borders.

Chinese President Xi Jinping committed in September 2020 to achieving domestic net-zero carbon emissions by 2060, while President Joe Biden has set a goal for hitting that mark in the U.S. by 2050.

The U.N. Intergovernmental Panel on Climate Change said nations must eliminate emissions by 2050 to avoid cementing irreversible climate change.

*To view online*:
https://subscriber.politicopro.com/energy/article/2021/01/on-china-kerry-says-us-wont-trade-other-issues-for-climate-wins-2031086

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Message

**From**: Lewis, Josh [Lewis.Josh@epa.gov]
**Sent**: 1/26/2021 9:21:07 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: RE: Message from Joe Goffman, Acting Assistant Administrator for OAR

Hi Joe,

Welcome back! I appreciate all of what you said below. Looking forward to seeing you on the screen tomorrow for the OAQPS All Hands!

Josh

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Tuesday, January 26, 2021 10:35 AM
**To:** OAR-WIDE-EVERYONE <OARWIDEEVERYONE@epa.gov>
**Subject:** Message from Joe Goffman, Acting Assistant Administrator for OAR

Dear OAR Colleagues –

No one will enjoy a greater honor or privilege than the honor and privilege I now enjoy of returning to your side as your colleague. As some of you may recall, from 2009-2017, I served as OAR's Associate Assistant Administrator for Climate and Senior Counsel, which was the best experience of my career. Happy as I am to occupy a new role, now as OAR's Principal Deputy Assistant Administrator and current Acting Assistant Administrator, simply being back here with you all is what makes this return such a pleasure.

First, I would like to thank you all – and by "all" I mean every single person who works in OAR – for your service to the public and for your ongoing dedication and commitment to the mission of the Office of Air and Radiation and of the Environmental Protection Agency. No matter what your job here is, you have earned, and will continue to earn, the unending gratitude of our fellow Americans for the energy and care you devote to protecting the air we breathe, our health, and our quality of life. Of course, you are not here in quest of "thanks" and I'm pretty sure that when you look in the mirror you don't see a hero, but you're entitled both to the "thanks" and to seeing yourselves that way. You are certainly my heroes – every single one of you.

That's not an exaggeration. This has been a difficult year for our country and the world. Since March, the pandemic has brought hard times, fear, and illness to our communities, friends and families. Many of you may have been touched in some way by the hardships and tragedies this year has brought and we are here as colleagues to support you however we can; virtually everyone has had to cope with challenges none of us imagined having to face a year ago.

From everything I've seen and heard, OAR employees' resilience, ingenuity and perseverance has shone through, and that's a tremendous source of comfort. Maintaining your characteristic commitment to our mission with the utmost professionalism while adapting to these tough times should give us all confidence that we can face the challenges, and harvest the opportunities, 2021 puts in our path and continue to deliver for the American people. After all, the OAR culture I knew when I was here last doubtless will propel us forward again: bringing out the best in each other and understanding that there is no success outside the success we all create and share in together.

In his note to all of us last week, EPA Chief of Staff Dan Utech introduced himself and members of the new leadership team who have arrived so far. He also called our attention to some of President Biden's executive orders. One in particular strikes to the core of our mission at OAR. The Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, says, "it is the policy of my Administration to listen to the science; to improve public health and protect our environment; to ensure access to clean air and water; to limit

exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; to reduce greenhouse gas emissions; to bolster resilience to the impacts of climate change; … and to prioritize … environmental justice." It's as if President Biden were addressing EPA and OAR directly. Clearly, this is an amazing moment for us at OAR when our work will be even more vital and more highly valued in the coming months and years.

It is also my great pleasure to introduce Tomás Carbonell, who has joined the OAR leadership team as the Deputy Assistant Administrator for Stationary Sources. Tomás comes to EPA from the Environmental Defense Fund, where he was the Senior Counsel and Director of Regulatory Policy for that organization's clean air program. From 2008-2012, Tomás was an Associate at Van Ness Feldman, LLP, where he counseled diverse clients on federal legal and regulatory matters related to climate change, clean energy, and environmental and electricity regulation. He has a J.D. from Yale University, degrees in Environmental Change and Management and Development Economics from the University of Oxford, and bachelors' degrees in Chemical Engineering, Economics, and Multidisciplinary Studies from North Carolina State University. Please join me in welcoming Tomás, and please stay tuned for more introductions in the near future.

Very soon, via "Teams," we will have the chance to talk to and hear from each other directly as we get "all hands" meetings on the calendar with each of your offices. Please think about how you want to use that time to surface your concerns and share your suggestions for the best practices to continue or adopt in our work together going forward. A little later on we will also be engaging with the regions and states, the Office of General Counsel, the Office of Policy and other program offices as well as the public and our stakeholders.

Looking forward to connecting face-to-face

Thank you all very much for being here.

Stay safe and take care of yourselves and each other.

All best,
Joe

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From**: Millett, John [Millett.John@epa.gov]
**Sent**: 1/29/2021 3:21:58 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**CC**: DeLuca, Isabel [DeLuca.Isabel@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]; Shaw, Betsy [Shaw.Betsy@epa.gov]; Monroe, Scott [Monroe.Scott@epa.gov]; Shoaff, John [Shoaff.John@epa.gov]
**Subject**: OTAQ All Hands Meeting - Monday at 10am
**Attachments**: 2021-January OTAQ All Hands themes and talking points.docx; OTAQ All Hands - Detailed Agenda.docx

Hi Joe and Tomás – attached are the talking points and detailed agenda for the OTAQ all-hands meeting. OTAQ used the OAQPS template, so they don't stray far from the previous all hands meetings. There are questions from OTAQ staff at the end of the talking points along similar lines as previous meetings, too, but they're definitely worth a look. Scott and Betsy may want to have a look at those, too.

Happy to add, subtract or change anything in the talkers -- just let me know.

Thanks –

John

Message

**From**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Sent**: 1/26/2021 3:20:43 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: FW: Climate website
**Attachments**: Comms Briefing_11-17-20.pptx

FYI, some info that Chris shared yesterday re OAP's thinking on the climate website relaunch

**From:** Grundler, Christopher <grundler.christopher@epa.gov>
**Sent:** Monday, January 25, 2021 4:03 PM
**To:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Subject:** RE: Climate website

Hey Tomás:

**Ex. 5 Deliberative Process (DP)**

Talk soon

Chris

Christopher Grundler, Director,
Office of Atmospheric Programs
U.S. Environmental Protection Agency
202.343.9140 (o)
734.645.5221 (m)

**From:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Sent:** Monday, January 25, 2021 10:08 AM
**To:** Grundler, Christopher <grundler.christopher@epa.gov>
**Subject:** Climate website

Hi Chris – hope you had a good weekend! Again, it was great to chat on Friday. Thank you for making the time.

I am really thrilled about the relaunch of EPA's climate website that OAP has been planning. I was wondering if you have a brief description of what's new or major features of the new website? Please don't generate anything new on my account; just thought you might have a summary of what's planned. Thanks!

Tomás

Message

**From:** POLITICO Pro [alert@email.politicopro.com]
**Sent:** 3/12/2021 10:03:50 AM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Kerry leans on banks to back up their climate promises with cash

**Kerry leans on banks to back up their climate promises with cash**

By Zack Colman

03/12/2021 05:00 AM EST

Climate envoy John Kerry is prodding major U.S. banks privately to announce commitments for climate-friendly finance as part of the administration's climate change policy rollout at President Joe Biden's Earth Day summit next month, according to people familiar with the conversations.

The push — which could include a new executive order on climate finance — comes as Kerry's team and the White House scramble to assemble potential deliverables for Biden's April 22 Climate Leaders Summit, where countries will be watching for the new president to take action to put the U.S. at the forefront of global efforts to fight climate change.

Kerry is leveraging personal relationships with Wall Street players as well as banks' broad public promises to help fund climate efforts that they made alongside their pledges to achieve net-zero emissions by 2050 or align with the goals of the Paris Climate Agreement.

"There's an urgency in the timing," said Rachel Kyte, who led sustainable development at the World Bank and was its special envoy for climate change. "It's a political hot potato that Kerry is dealing with."

Kerry has pitched banks on creating a U.S. net-zero banking alliance following the climate commitments from six major Wall Street banks, according to two people familiar with the discussions. Citi, Wells Fargo, Bank of America, Morgan Stanley and Goldman Sachs all set 2050 net-zero goals and JPMorgan Chase has said its lending would be aligned with the Paris agreement although Kerry and his team are pushing for more specific financial commitments as part of this effort.

Kerry also wants clear near-term actions from banks by 2030, which would align with the Biden administration's timeline for the new emissions target it intends to submit as part of the Paris Climate Agreement process.

A Wall Street banker would not discuss specifics of what Kerry has asked, but confirmed that "the big U.S. banks are obviously discussing with his team directly."

"It's trying to figure out collectively whether there's more that can be said," the person said. An official at another Wall Street bank said Kerry made similar asks of that financial institution.

Daniel Firger, managing director of Great Circle Capital Advisors, said so far what that banks have publicly pledged on climate is "vague," and Kerry is now leading a "disambiguation" effort.

"No one knows what they mean yet, including Kerry's team. But this is where the rubber hits the road," said Firger, who has called for more climate financing from Wall Street. "It's going to get quite fraught very quickly."

In meetings with the bankers, Kerry has made an appeal that the public sector alone cannot catalyze the trillions of dollars of investment needed to tame rising emissions, especially in developing nations making investment decisions in electricity and transportation infrastructure that will last decades.

The White House met with environmental and Wall Street watchdog groups on March 9 to discuss its approach to potential financial sector regulations and executive actions to limit risk from climate change-fueled shocks. Groups on the call included the Center for American Progress, Public Citizen, Rainforest Action Network, Sierra Club and 350.org, among others.

A person who participated in the virtual meeting with domestic climate chief Gina McCarthy, her deputy, Ali Zaidi, National Economic Council Director Brian Deese and his deputy, Bharat Ramamurti, said the administration is considering issuing an executive order on climate finance for the April 22 summit.

The Wall Street official, who was not in the meeting, said mandatory disclosure of material climate risks for publicly listed companies is "probably going to be the first mover," given the body of work already done at the Securities and Exchange Commission for Obama-era voluntary guidelines. Environmental activists, however, have said such rules are merely a starting point.

"From what we've been hearing, the plan is to go beyond just disclosures," said Collin Rees, a senior campaigner with Oil Change International, a group that attended the March 9 meeting.

Climate activists want Biden and Kerry to put more pressure on these Wall Street players. They contend banks' commitments to green their lending practices are too vague and full of loopholes, and they worry financial institutions will opt for questionable solutions such as purchasing carbon offsets to allow them to continue to finance fossil fuel infrastructure.

"It seems like so far [the Biden administration is] excited about the voluntary commitments that banks have agreed to and they are talking about that," Alexis Goldstein, senior policy analyst with Americans for Financial Reform, whose group participated in the March 9 call, said of the Biden administration. "Our hope is they will push them beyond what they have already preemptively said they would do. A reach goal."

Kerry's efforts to have included pressing his friends in top positions, including Bank of America's CEO Brian Moynihan and Vice Chair Anne Finucane who oversees the bank's sustainable investing arm. Kerry also chaired a global advisory council for Bank of America after leaving the Obama administration.

Bank of America declined to comment on the details of the discussions, but confirmed talks were taking place.

"We have helped Secretary Kerry get a sense of the extent that leading banks are committed to the transition to a low-carbon, sustainable future," spokesperson Bill Halldin said.

Kerry has also brought in personnel to help with that task, hiring Mark Gallogly, an investor and Democratic donor, to head business outreach.

Kerry's moves run concurrently to those of Mark Carney, the former Bank of England governor who is leading finance efforts for U.N. climate talks slated for Glasgow, Scotland, in November. Carney, too, is calling on financial heavyweights to develop more concrete clean finance plans.

The U.S. climate envoy held meetings with the full treasury teams in the U.K. and EU during his recent European tour.

"Clearly, Kerry is trying to move the needle on the finance sector," said Alden Meyer, a senior associate at E3G, a think tank.

Kerry must also get the rest of the world on board, Meyer noted. The U.S. will play a leading role in that discussion at the G20, where it will co-chair a sustainable finance effort with China. Delivering something consequential when the world's eye is trained on the U.S. for Biden's summit would send a clear message as nations recover from the coronavirus pandemic and head into a busy diplomatic season en route to November's climate talks, he said.

"What Kerry's team is doing is exploring what are going to be the mechanisms and platforms that allow there to be public and private investment at scale," said Kyte, who is now the dean at Tufts University's Fletcher School. "There is a growing dissatisfaction, cynicism and anger in developing countries that they're being told what they can't do but not being given help for what they are supposed to do."

*Stephanie Murray contributed to this report.*

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**Sent:** 1/27/2021 7:11:44 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Transition 2021: Granholm hammers jobs message to fossil fuel-state senators

**Transition 2021: Granholm hammers jobs message to fossil fuel-state senators**

By Eric Wolff, Kelsey Tamborrino

01/27/2021 02:09 PM EST

Jennifer Granholm, faced with fossil fuel-state senators wary of the Biden administration's full-court press on climate change, repeatedly sought to assure the committee at her confirmation hearing Wednesday that fossil fuel workers wouldn't be left behind, even going so far as to suggest that the Energy Department will look to encourage clean energy equipment makers to locate in fossil fuel states.

The former Michigan governor, under consideration for Energy secretary, also leaned on her own personal experiences as a politician, saying she thinks President Joe Biden nominated her "because I am obsessed with creating good-paying jobs in America."

"Having been the governor of Michigan when the automotive industry was on its knees, I understand what it's like to look into the eyes of men and women who have lost jobs through no fault of their own," Granholm said during a confirmation hearing before the Senate Energy and Natural Resources Committee.

Her appearance marks the first of Biden's energy and environmental nominees to come before the Senate. Granholm, a staunch clean energy advocate, is expected to play a key role in the Biden administration as it seeks to combat climate change and achieve net-zero greenhouse gas emissions by 2050.

Her insistence that DOE's work must focus on squeezing greenhouse gas emissions out of the economy is a sharp break from with former Energy Secretaries Rick Perry and Dan Brouillette, who promised to expand U.S. fossil energy production and exports wherever possible. But she and her predecessors would likely have agreed on a requirement to help blue-collar workers currently in the fossil fuel industries and the communities that depend on them.

Senators from both parties who represent states that rely on fossil fuel production peppered her with questions about how their constituents, many of whom rely directly or indirectly on the coal, natural gas and oil industries for their livelihoods, will thrive even as the administration accelerates the transition to clean energy. That includes incoming Energy Chair Joe Manchin (D-W.Va.), former Chair Lisa Murkowski (R-Alaska), and the committee's new top Republican John Barrasso (R-Wyo.), illustrating the bipartisan needle Granholm must thread.

"There's an awful lot of states that have been heavy lifters for a lot of years, who have done the heavy lifting to get the country where they are today," Manchin said. "People feel they've been left behind, so in those areas that have been ravaged because of the market changes — and the market's changing, we know that and people are coming to realize that — how do we keep them in an opportunity situation?"

Granholm, who has touted her experience during the Great Recession facilitating the auto industry's transition into electric vehicles, emphasized Biden's commitment in a "Buy American" executive order on Monday and a

climate change executive order issued on Wednesday as pillars that will ensure clean energy manufacturing happens in the U.S.

During the hearing, she also touted "place-based" solutions to greening the economy, essentially promising to use DOE's authorities to facilitate locating clean energy manufacturing in states that have historically relied on fossil fuel production and refining to boost their economies.

"Why aren't we building these big wind turbines in America?" she said. "Place-based strategies are critical for areas that have been left behind and that's exactly what the executive order from Joe Biden today has committed to fix."

She added that the order "created a requirement that we lead by example in the federal government and it is the Department of Energy that will be working on making sure that we are buying American, creating demand in America for American-made products and that we are deploying them on the vast complexes inside of the federal government."

During the hearing, Granholm committed to focusing on three missions at DOE: securing the nation through the National Nuclear Security Administration and clean-up of the United States' "Cold War legacy"; supporting the scientific work at the department's 17 national labs, including on climate change and emissions reductions; and deploying that research to create jobs.

Granholm also referenced a White House "SWAT team" dedicated to communities that will lose jobs as the U.S. moves away from fossil fuels. The White House did not immediately respond to requests for more details on this group.

Barrasso pressed Granholm on an advanced battery company in Michigan which during her time as governor was awarded billions in grants under the Obama administration but ultimately filed for bankruptcy and was bought by a Chinese company.

"In short, American taxpayers spent close to $400 million to subsidize a technology transfer basically to the Chinese," Barrasso said.

Granholm pushed back by saying that the state would not pay out to firms that don't deliver. But she used the opportunity to tout the role unused funds through DOE's loan program can play — money that her last four predecessors allowed to languish.

"I hope that we don't look at some failures along the way as a reason not to invest in technologies that banks are not going to invest in because they haven't been deployed yet," she said.

She added that some companies' failures due to market reasons or China's entrance into the market should not be reasons to stall U.S. competitiveness.

"We better believe that China is in this game, they are aggressively competing," she said. "States individually are bringing a knife to a gunfight and without a federal partner in making sure that we can get these jobs in America, then we will be losing globally."

Granholm will push forward a Brouillette initiative to slash 2020 energy storage costs by 90 percent by 2030, a key to making electric vehicles affordable and further slashing emissions from the electric grid. She called the agency's "Grand Challenge" an "Earth Shot," in reference to DOE's "SunShot" initiative that drove down solar panel production costs.

But she was vague in response to questions related to approving export licenses for new LNG terminals under the Natural Gas Act, which had been a top priority for both of former President Donald Trump's Energy secretaries.

"I would certainly abide by that act, including issues related to whether something is in the public interest, what the economic and what the geopolitical concerns are," she said. She later added, "I would work with natural gas providers to reduce greenhouse gases at the point of production."

The former governor also said the Biden administration opposed the use of Yucca Mountain for the storage of nuclear waste and committed to looking for alternatives through a return to consent-based siting.

The Trump administration tried repeatedly to get Congress to appropriate funding to resume licensing for Yucca Mountain until last year, when Trump, in an about-face, pledged to find "innovative approaches" to nuclear waste storage.

Granholm also expressed an earnest interest in working with FERC to develop transmission lines in order to link population centers to rural areas with consistent wind and sun, though her collaborative language stood in contrast to the last administration. Perry exercised a rarely used DOE authority to propose a coal bailout rule directly to FERC only to watch it get rejected unanimously by the commission in 2018.

"I'm very eager to work with FERC to get transmission lines ASAP," Granholm said. "I feel like this conversation that's been had for years, to bring power like wind from North Dakota to load centers. This is a very high priority to make this happen."

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**Sent:** 1/27/2021 7:04:53 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Biden brings back Obama's top EPA lawyer

**Biden brings back Obama's top EPA lawyer**

By Annie Snider

01/27/2021 02:01 PM EST

The Biden administration is bringing back the former top EPA lawyer who helped craft major Obama-era environmental rules to serve as senior counselor to the agency administrator.

**The details:** Avi Garbow will bring a deep legal and regulatory expertise to the Biden EPA as it seeks to aggressively address climate change and environmental justice, while reversing the Trump administration's environmental rollbacks.

Garbow served as EPA general counsel from 2013 to 2017, playing a key role in the crafting of virtually every major regulation of that era, from the Clean Power Plan and the Waters of the U.S. rule to rules governing coal ash and air pollutants. He has most recently worked as "environmental advocate" for the outdoor retailer Patagonia.

**Other appointees:** The Biden administration also named a handful of other appointees to EPA:

— **Dorien Paul Blythers** to be deputy chief of staff for operations. Blythers served as regional political director for Vice President Kamala Harris' presidential campaign.

— **Kathleen Lance** to be director of scheduling and advance for the administrator. Lance most recently served at North Carolina's Department of Environmental Quality as special assistant to secretary Michael Regan, now Biden's nominee to lead EPA.

— **Fernando Mercado-Violand** to be deputy White House liaison. Mercado-Violand most recently worked as deputy state and political director for the Biden-Harris campaign in Virginia.

**What's next:** Additional appointees are expected to be announced in the coming days.

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ECOS

Environmental Council of the States
1250 H Street NW, Suite 850 | Washington, DC 20005
(202) 266-4920 | www.ecos.org

December 21, 2020

Dear U.S. EPA Agency Review Team:

Americans can be justly proud of our nation's environmental protection system. In the 50-year history of the major federal environmental statutes, the United States has made significant progress in achieving cleaner air and water and in cleaning up contaminated land. That success rests on a unique partnership between the federal government and the states. The U.S. Environmental Protection Agency (EPA) takes the lead in research and development, in setting national minimum standards, and in assuring that state programs are meeting those standards. The states are the primary implementers of the environmental protection programs, having taken on the delegated authority for the vast majority of programs under the federal statutes. Together, these complementary roles form the basis for our national enterprise for environmental protection.

While great progress has been made, significant challenges remain, and new threats emerge as the products we use in society evolve and as our scientific knowledge advances. As a nation we will continue to set new environmental goals, but those goals cannot be met unless we maintain and strengthen the effective partnership between the states and the federal government.

The Environmental Council of the States (ECOS) is the national nonprofit, nonpartisan association of state, territorial, and District of Columbia (hereinafter referred to collectively as "state") environmental agency leaders. The mission of ECOS is to improve the capability of state environmental agencies and their leaders to protect and improve human health and the environment of the United States of America.

ECOS has more than 25 years of history of leadership on environmental issues of national importance and of playing a critical role in promoting a more effective relationship among and between state and federal agencies. ECOS provides a forum for proactive early engagement, collaboration, and exchange of views and experiences among states and with our federal partners. In that role, we facilitate state input to EPA on budget priorities and the development of regulations. We identify and highlight implementation challenges and offer solutions.

As the country transitions to a new federal administration led by President Joe Biden, ECOS stands ready to strengthen the state-federal partnership upon which our mutual success depends. We recommit to a constructive relationship with EPA and our other federal partners to promote the most effective and efficient accomplishment of our shared goals.

In this document, we offer for consideration a number of priority areas that states feel will be critical to the achievement of the best possible results in the protection of public health and the environment for the American people. Several of these issues are "fundamental" issues, or those that have faced policy makers in the past and likely will do so for years in the future. Others we see as current

**Patrick McDonnell**
Pennsylvania Department of Environmental Protection
ECOS President

**Ben Grumbles**
Maryland Department of the Environment
ECOS Vice President

**Myra Reece**
South Carolina Department of Health and Environmental Control
ECOS Secretary-Treasurer

**Jim Macy**
Nebraska Department of Environment and Energy
ECOS Past President

**Donald Welsh**
ECOS Executive Director

challenges for which new approaches and augmented efforts will be needed in the near term.

We welcome opportunities to discuss this letter, and to further share the views and concerns of our members. Dialogue or discussions can be arranged through ECOS Executive Director Don Welsh via email (dwelsh@ecos.org) or by calling (202) 266-4929.

FUNDAMENTAL POLICY ISSUES

Federal Financial Support for Program Implementation

Adequate federal financial support to states is key to the success of the national environmental protection system.

The federal environmental statutes enacted by Congress envisioned that states would assume authority for the programs and that the federal government would provide financial assistance to states for their implementation. States have in fact received delegation or authority for the overwhelming majority of eligible programs, and have been implementing them for many years.

States receive support for the operation of these programs through the State and Tribal Assistance Grants (STAG). In Fiscal Year (FY) 2002, the enacted funding level for these grants was $1.1 billion. Eighteen years later, in FY 2020, the enacted funding level was also $1.1 billion. In light of rising costs, these years of flat funding constitute a significant real reduction in available resources. This occurred while new regulations and new program requirements have added to the workload.

States supplement the federal assistance with general revenues appropriated by their own legislatures along with other revenue streams such as permit fees. ECOS' recent analysis of state environmental budgets shows that on average, 73% of the funding comes from states sources and 27% comes from federal support. States use these combined funds to carry out the core environmental protection functions such as permitting, conducting compliance inspections and enforcement, remediating contaminated sites, monitoring, and reporting, in addition to addressing local needs, such as assisting communities and businesses in meeting environmental responsibilities.

With the federal contribution remaining flat, or declining in real terms, states have struggled to meet these obligations and to keep up with new threats to public health and the environment. Economic impacts from the COVID-19 pandemic are already being felt by most states, and further impacts are anticipated. Reduced general revenues in the states, and particularly reduced revenue from permit fees, will compound the challenge for state environmental agency leaders. Furthermore, environmental permitting and oversight is a key component of rebuilding the economy.

The federal government must provide adequate financial support to state environmental agencies to establish sound financial footing following the pandemic and to ensure the long-term viability of the national environmental protection system. We must also make every effort to reduce or eliminate

ineffective or redundant requirements to focus resources on environmental results.

Water Infrastructure Investment Needs

Replacing and modernizing our nation's aging drinking water and wastewater infrastructure continues to be a critical need in protecting public health and the environment.

Policy makers have known for some time that in many places around our nation, the infrastructure on which we rely to treat wastewater and provide safe drinking water is aging and in need of repair and replacement. Recent assessments indicate a need for infrastructure investments of more than $271 billion for wastewater and more than $472 billion for drinking water. Long-standing challenges such as eliminating sewer overflows and reducing sources of lead in drinking water have now been joined by efforts to identify and remove per- and polyfluoroalkyl substances (PFAS) from drinking water and wastewater.

The Clean Water and Drinking Water State Revolving Funds have been among the most successful and cost-effective programs enacted by Congress and carried out by the states and the EPA. The revolving loan programs allow every federal dollar to be leveraged into as much as three dollars of infrastructure investment. The Water Infrastructure Finance and Innovation Act and related programs provide additional resources and tools to meet this critical national need. States have worked to develop innovative strategies to deploying this funding and helping both large and small communities to pay for needed projects.

Distressed urban areas and small communities are particularly challenged to afford operation, maintenance, and replacement of these assets. Meeting our shared clean water and drinking water goals will require additional investment in these effective tools and continued state-federal partnership in developing innovative approaches to allow the funds to get to the communities that need them most. Federal research and development resources can be used to assist states in finding cost-effective treatment solutions for all communities, particularly small and economically challenged ones.

Investments in drinking water, wastewater, stormwater, and green infrastructure generate job growth, health improvements, and economic benefits. ECOS looks forward to working with the new administration to advance these critical priorities.

State-Federal Implementation

State and federal agencies must work together effectively and cooperatively in the implementation of environmental programs delegated to the states. Both the federal government and state governments have their own particular responsibilities in delivering environmental protection.

The federal government not only takes the lead in research and the setting of minimum national standards, but also assures the integrity of our system through oversight and accountability. ECOS and EPA have worked to improve the oversight process so that it is based on clearly defined measures applied through

consistent processes. We have worked together to better define roles and responsibilities and to provide for agreed-upon steps for elevation when disagreements occur. We encourage the continuation of these efforts to assure that deficiencies can be identified and corrected, processes that add no value can be eliminated, and disputes and differences can be resolved quickly.

States generally take the lead in program implementation including permitting, compliance monitoring, and enforcement, with the federal government retaining its own authorities in these areas. We have worked to reduce duplication of effort through early consultation and coordination on compliance activities and other program efforts where states and the federal government have shared responsibilities.

States and EPA have also made strides in "leaning" business practices to increase efficiency and reduce unnecessary steps. Resource constraints have always been a challenge, and the economic impacts of the recent pandemic will likely multiply that challenge for many states. More than ever, we must continue these efforts to efficiently deliver environmental results.

Each state faces its own unique circumstances, challenges, and opportunities. While working to meet consistent national standards, states also continue to need sufficient flexibility to address state priorities. Successful examples include the National Environmental Performance Partnership System, which recently celebrated its 25th anniversary, under which states can minimize administrative burdens and gain flexibility while maintaining the emphasis on measuring and reporting environmental results. The multipurpose grants that Congress has appropriated in recent years are especially helpful, particularly when distributed with the maximum ability for states to direct them toward priority needs.

In a number of individual instances, states and EPA Regions have negotiated innovative alternative strategies to meet program performance obligations in ways that were more efficient and/or more effectively addressed state-specific conditions. ECOS and the EPA should cooperate to catalogue these innovations and make them available in other states, regions, and programs where they might also apply.

Modernizing the Delivery of Environmental Protection

We must make the best use of new tools and advanced technologies to efficiently deliver better environmental results for the American people.

New technologies have dramatically transformed the way that society functions and the way in which we live our daily lives. States and EPA can harness these technologies to enable smarter, faster, and more effective environmental protection. Truly transformative improvements are only possible with close collaboration across the diverse partners who share responsibility for human health and the environment. States and EPA need committed leadership and cooperation from every quarter to spark and manage this change.

EPA, states, and tribes created the E-Enterprise for the Environment initiative to drive program modernization through collaborative leadership and joint governance. The E-Enterprise Leadership Council (EELC) is co-chaired by EPA's

Deputy Administrator, a state environmental commissioner, and a tribal representative. This executive leadership is essential to driving meaningful change throughout our programs and organizations. E-Enterprise leaders have produced a Digital Strategy that presents a shared vision to better coordinate investments in information systems. The strategy provides a set of principles and strategic actions for building an environmental enterprise that is customer-centric, information-centric, and based on shared platforms and services. EPA, states, and tribes are using these principles to unlock access to quality data and deliver better environmental outcomes and more responsive services to the public and the regulated community.

The Digital Strategy is also providing important guideposts for process and information technology system modernizations in the drinking water, National Pollutant Discharge Elimination System, and air programs. These initiatives will replace aging data systems to help safeguard drinking water and protect the health of the nation's water and air resources. These modernizations are a high priority, and states and EPA need sufficient resources to see them through to completion.

Many state environmental agencies have also been working with EPA to pioneer the use of remote video compliance monitoring. Spurred in part by the challenges presented by the COVID-19 pandemic, states see this as a potential resource multiplier in enhancing their compliance monitoring capacity. Artificial intelligence, unmanned aerial vehicles, and advanced software tools provide a host of new opportunities to revolutionize environmental programs.

Harnessing the full potential of these technologies requires close collaboration and partnership. EPA, states, and tribes should renew and expand their commitment to E-Enterprise for the Environment. That commitment should include fully engaged executive leadership, cross-program participation, support for funding and resources, and operational flexibility to develop and test new tools.

Measuring and Communicating Environmental Results

The effective management of environmental programs, as well as the public's trust and confidence in the state-federal environmental system, rests on our ability to measure and communicate tangible environmental results.

Improvements in the quality of the air and water, reductions in the risk to human health, and increases in healthy and vibrant ecosystems are the reasons for our environmental protection efforts. Too often we have judged success on program outputs like number of permits issued or enforcement actions taken because those are easier to measure. Both decision makers and the public can be misled when outputs are equated with success.

ECOS Results is a suite of common measures for states to report and explain their progress toward environmental outcomes. Developed by ECOS in collaboration with the EPA, ECOS Results now includes the participation of 46 states reporting on some or all of the measures. This tool serves not only to enhance public understanding, but also provides Congress and stakeholders with straightforward and easily accessible measures to better understand progress.

The federal government has also developed many measures of both program outputs and results. The states and the federal government must continue the commitment to measuring results and communicating them clearly. These measures must be used by decision makers to guide resource choices toward programs that deliver the best results. These measures must also be communicated regularly and clearly to the public so that they have a better basis to judge progress and inform their choices as citizens.

CURRENT CHALLENGES

PFAS and Emerging Contaminants

New chemicals of concern, which may have previously been unregulated, present a significant challenge to the nation's environmental protection system. PFAS, a group of chemicals often called "forever" chemicals due to their persistence in the environment, are one major example of this type of threat to public health and the environment.

The research capacity of the federal government is an indispensable tool in setting standards and in developing long-term remedies. The existence of particular areas with significant levels of contamination often prompts states to seek to move forward with their own regulations in advance of federal standards. Early consultation and cooperation among states and EPA will promote the sharing of information and environmental data, as well as technical and regulatory approaches as they are being developed. Federal leadership in research and standard setting can promote the adoption of effective strategies and reduce the risk communication challenges associated with varying state standards. While drinking water standards are often a key area of focus, impacts on cleanup and remediation, stream health, and waste disposal are also important areas where EPA leadership is needed.

As new contaminants of concern are likely to continue to emerge, a regular and well-defined process for consultation and cooperation would help decision makers at all levels to more quickly initiate effective steps to confront issues as they arise.

Diversity and Environmental Justice

States feel strongly that our national environmental protection system must provide equal protection to all communities. States have been working to ensure that all communities have access to environmental data and other information that allow them to participate effectively in evaluating choices and decisions that affect their lives and neighborhoods.

EPA can help states in working to meet these challenges through support for improved monitoring, mapping, and toxicological information that will help us better understand impacts in all communities. E-Enterprise for the Environment offers an excellent forum for cooperative efforts among states, tribes, and EPA in developing these tools and technologies that meet the needs on the front lines of our programs.

Messages about environmental risk and regulatory requirements should be community specific and targeted to situations faced by individuals and communities.

EPA can assist states as they develop risk communication tools that meet communities where they are.

An important part of meeting these goals is ensuring that our environmental agencies reflect the communities for which they work. Innovative recruitment and hiring practices can promote inclusion. Joint efforts between environmental agencies and professionals with academic programs in high schools, colleges, and universities can be an important tool in attracting more people of all backgrounds into environmental careers. People in all communities want their children to be safe and healthy, and people from all communities should be involved in the mission of environmental protection.

EPA should work in consultation with states in developing tools and initiatives to address these challenges, and provide support to states as they advance justice, equity, and inclusion programs.

Risk Communication

Accurately characterizing environmental risks and communicating them clearly is critical to assuring the public that they are being effectively protected. The availability of many sources of information, including environmental data of differing levels of quality through social media and other internet platforms, places greater emphasis on the need to provide answers promptly and accurately.

Effective risk communication needs to be tailored to the needs of specific communities impacted by environmental threats. Priority should be given to expanding our capacity to collect, analyze, and explain risk information. Members of the public are rightly anxious for answers to their questions and concerns when confronted with an environmental risk. Cooperation between federal, state, and local officials is required to meet the public's expectation.

Rapid response teams comprised of state and federal experts with site-specific messages would increase our capacity to meet this need and to improve the public's understanding of risks.

Emergency Preparedness and Response

There are few areas of the nation that have not been impacted by storms, flooding, wildfires, or other emergencies that, in addition to public safety concerns, present threats to public health and the environment. State and local governments are the first responders, but preparedness and consequence management require close coordination and cooperation among local governments, state governments, and federal agencies such as EPA and the Federal Emergency Management Agency. While many states have more experience than they might like in meeting these emergencies, federal resources are often required when the scope of the emergency is large. Governments at all levels must be committed to the teamwork necessary to protect the public and to remedy the environmental impacts of these emergencies.

More than just preparedness and response, our national system must recognize and take advantage of opportunities to make our infrastructure more resilient. We need to improve the resilience of infrastructure to cope with increased pressures,

whether they come from changing land use patterns, local and regional circumstances, or weather and climate impacts. Regulatory barriers or administrative requirements that impede effective responses or prevent more resilient infrastructure choices must be removed.

CONCLUSION

Overcoming the environmental challenges that we face, whether long-standing or more recently encountered, will require vision, innovation, and flexibility on the part of all of the partners in our shared national environmental protection system. We cannot hope to achieve the goals that we envision and that the American people deserve without adequate and sustainable funding. We must continue to improve our working partnership to remove pointless friction and wasteful duplication of effort.

At this unique time in our history, the pandemic we are fighting seems destined to spur long-lasting changes in how we live our lives and how we conduct business. Our environmental protection system will likely have to adapt to new patterns of interaction and changed systems for obtaining public input, inspecting regulated sources, and engaging our partners. We will need to consider the organization of environmental agencies and determine how best to deliver environmental results in this new setting. While these organizational issues may add to our shared list of challenges, adjusting old patterns may present opportunities to overcome some old problems.

ECOS is able to serve the states as a forum for the exchange of experiences and innovations and a resource to expand the capacity of state agency leadership. ECOS also has a long history of working with our partners at EPA and other federal agencies to provide collective feedback on budget priorities and on policies and regulations under consideration. We stand ready to continue that service to our members and to the public as we transition to new federal leadership.

Sincerely,

Patrick McDonnell
ECOS President

Message

**From:** Campbell, Ann [Campbell.Ann@epa.gov]
**Sent:** 3/12/2021 10:55:52 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Fwd: FOR YOUR SIGNATURE: Correction Notice - Test Methods and Performance Specifications CMS#OAR-21-000-1914 FRL#10018-97-OAR
**Attachments:** Test Methods correction POST IT NOTE_02-12-2021 Revised.docx; 10018-97-OAR_ADMIN.docx; Test Methods correction_fr-cover-form-02-12-2021.pdf; FP1028Request.pdf; FR Typesetting Request_2nd Test Methods corr notice fundedjh.pdf; RE: FOR YOUR REVIEW: Correction Notice - Test Methods and Performance Specifications CMS#OAR-21-000-1914 FRL#10018-97-OAR

Ann (Campbell) Ferrio
Chief of Staff
Office of Air and Radiation
(202) 566-1370

Begin forwarded message:

**From:** "Campbell, Ann" <Campbell.Ann@epa.gov>
**Date:** February 22, 2021 at 8:17:00 AM EST
**To:** "Goffman, Joseph" <Goffman.Joseph@epa.gov>
**Cc:** "Carbonell, Tomas" <Carbonell.Tomas@epa.gov>
**Subject: FOR YOUR SIGNATURE: Correction Notice - Test Methods and Performance Specifications CMS#OAR-21-000-1914 FRL#10018-97-OAR**

Joe, the attached is ready for your **DIGITAL** signature. Tomas has reviewed and concurred (attached) and provided the summary below. There is no specific deadline associated with this action. As a reminder, this is a Federal Register Notice and must be signed digitally and remain in Word for the OFR to accept the document for publication. Instructions for signing are below.

**Summary**

The attached final rule consists of technical corrections to a final rule that was published on October 7, 2020, which corrected and updated EPA regulations prescribing test methods for various sources of air pollution. Due to errors in the amendatory language in the original Federal Register notice, the October 7 rule did not properly effectuate certain updates to Methods 4 and 5 in Appendix A-3 of EPA's Part 60 regulations. The present final rule would correct the amendatory language to ensure the updates to Methods 4 and 5 are codified in the CFR. This is an essentially ministerial action that would make no other changes to the October 7 rule.

**Digital Signature Instructions**

- Save the document to your computer then reopen the saved document.
- Go to File >> Info >>Protect Document >> Select Add a Digital Signature
- A pop up box will appear; under Commitment Type, select Approved this document; at the bottom of the box click sign
- Simply close the document and attach in an email to Ann

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation

Office: 202 566 1370

---

**From:** Mcquilkin, Wendy <Mcquilkin.Wendy@epa.gov>
**Sent:** Wednesday, February 17, 2021 1:15 PM
**To:** Campbell, Ann <Campbell.Ann@epa.gov>
**Cc:** OAQPSREGPROCESSING <OAQPSREGPROCESSING@epa.gov>
**Subject:** Correction Notice - Test Methods and Performance Specifications CMS#OAR-21-000-1914 FRL#10018-97-OAR
**Importance:** High

TO: THE IMMEDIATE FOR REVIEW AND CONCURRENCE FOR THE AAs SIGNATURE.

Attached is a correction notice for the Test Methods and Performance Specifications rulemaking for AA signature. The files are located in CMS at OAR-21-000-1914 and FR Dailies (10018-97-OAR). All pre-signature reviews have been completed by OP, AQAD and OAQPS IO.

Amber Iglesias
202-564-3175

***Wendy***

Wendy Mcquilkin
USEPA - OAR/OAPPS
1200 Pennsylvania Ave, NW
Washington, DC 20460
Rm 5442S WJC North – MC 6103A
(202) 564-1348
Prejudice is a burden that confuses the past, threatens the future and renders the present inaccessible – Dr. Maya Angelou

*Current as of 3/7/2016*

# Cover Form and Checklist for *Federal Register* (FR) Document Submissions to the Office of Policy (OP)

## Section 1: Tracking information

Contact name: Lula Melton Office/Region: OAR

Contact phone and email: (919) Ex. 6 Personal Privacy (PP); melton.lula@epa.gov

Docket # *(if applicable)*: EPA-HQ-OAR-2018-0815 FRL # *(if applicable)*: 10018-97-OAR

Name of document: Test Methods and Performance Specifications for Air Emission Sources; Correction

Name of File:

Other Information (alternate contacts, etc.):

Kelly Brown; brown.kelly@epa.gov

Is this action subject to the Congressional Review Act (CRA)?
For questions associated with the CRA, consult the attorney assigned to your action, or visit http://intranet.epa.gov/actiondp/documents/craguidance15-10-15.pdf. Yes ☐ No ☐

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Explain other:

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☐ **We need OFR to REVIEW and APPROVE the IBR contained in this rule**.
The relevant IBR memo or letter and materials are attached.

☐ **We need to MANAGE the FR publication of multiple FR documents.** This document must (choose one) (choose one) the following FR document (choose one)

Title:

Docket # *(if applicable)*:

FRL *(if applicable)*: 10018-97-OAR Published on *(if applicable)*:

☐ **We need OFR to confirm their receipt of this FR document:** Select this option ONLY if you need to ask OFR to provide a confirmation of receipt in order to document EPA's compliance with a legal requirement to submit the document to OFR by a specific date.

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*The following section provides formatting requirements for materials included in a submission package. Requirements are based on OFR's Document Drafting Handbook. Failure to adhere to these requirements could delay the publication of your document.*

- [ ] 1. EPA's Billing Code is present **(6560-50-P)** on original and each copy, on the first page of each document in the upper right corner.
- [ ] 2. The **title** is concise, does not contain overly specific information, and does not contain legal citations.
- [ ] 3. The **SUMMARY** section is no longer than one page.
- [ ] 4. The **SUMMARY** section does not contain legal citations *(i.e., CFR citations, FR citations, USC citations, etc.).*
- [ ] 5. The **DATES** section is labeled "**DATES**" *(Not "EFFECTIVE DATES", etc.).*
- [ ] 6. The **Table of Contents**, if included, matches the headings in the preamble.
- 7. **Signature Block – Original Paper Version***
  - [ ] a. The signature block contains a legible date.
  - [ ] b. The signer's name and title are typed or printed under the signature line.
  - [ ] c. *(if applicable)* "Acting" is added, in front of the title, if a person other than the official holder of that title is acting in that capacity. *(Note: no "for" is permitted in the signature block)*
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  - [ ] e. No White-Out or corrective tape is used on the signature page.
- 8. **Signature Block – Word File***
  - [ ] a. The signature page matches items 7a – c above.
  - [ ] b. The date is spelled out, with a period at the end. *(Example: "February 6, 2014.")*
- [ ] 9. A rewritable CD **(CD-RW)** is included with the package. *(CD-R or DVD-RW are not acceptable)*
- 10. The CD-RW contains:
  - [ ] a. the **(1) most recent Word version** of document that (2) **matches the original**,
  - [ ] b. a scanned copy of the typesetting request form, and
  - [ ] c. a scanned copy of the (signed) signature page.
- [ ] 11. The **original** document is **single-sided**, and each **copy** is **double-sided**.
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KELLY BROWN

Digitally signed by KELLY BROWN
Date: 2021.02.12 09:12:11 -05'00'

Date/Signature of Contact Regarding Submitted Package

**ORAL ARGUMENT NOT YET SCHEDULED**

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

No. 15-1056

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HEARTH, PATIO & BARBECUE ASSOCIATION, *et al.*,
*Petitioners*,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
*Respondent*.

---

PETITION FOR REVIEW OF FINAL ADMINISTRATIVE ACTION OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

---

# FINAL BRIEF OF INTERVENORS

**DATED: October 20, 2020**

Timothy D. Ballo
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(202) 745-5209
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*Counsel for American Lung Association, Clean Air Council, and Environment and Human Health, Inc.*

## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), Respondent-Intervenors American Lung Association, Clean Air Council, and Environment and Human Health, Inc. (collectively "Intervenors") hereby certify as follows:

**(A) Parties and Amici:** All parties, intervenors, and amici appearing in this Court are listed in the Brief for Petitioner Hearth, Patio, and Barbecue Association filed June 25, 2020, except that Pellet Fuels Institute is no longer a party.

**(B) Ruling Under Review:** Petitioner seeks review of the final action taken by the U.S. Environmental Protection Agency at 80 Fed. Reg. 13,672 (Mar. 16, 2015) and entitled "Standards of Performance for New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces."

**(C) Related Cases:** Intervenors adopt the statement of related cases set forth in the Brief of Respondent U.S. Environmental Protection Agency.

## CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure and Circuit Rule 26.1, Respondent-Intervenors American Lung Association, Clean Air Council, and Environment and Human Health, Inc. state that they are not-for-profit, non-governmental organizations whose missions include protection of public health and the environment. None of the organizations has any outstanding shares or debt securities in the hands of the public, or any parent, subsidiary, or affiliate that has issued shares or debt securities to the public.

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## GLOSSARY OF ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| EPA | U.S. Environmental Protection Agency |
| HPBA | Petitioner Hearth, Patio, and Barbecue Association |

## STATUTES AND REGULATIONS

Except for those in the Addendum, all pertinent statutes and regulations are contained in the Initial Briefs for Petitioner and Respondent.

## STATEMENT OF THE CASE

This case seeks review of the final rule promulgated by the U.S Environmental Protection Agency ("EPA") entitled "Standards of Performance for New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces," published at 80 Fed. Reg. 13,672 (Mar. 16, 2015) (the "Final Rule"). The Final Rule updates air pollution standards for wood-fired residential heating devices that are significant sources of harmful air pollutant emissions. *See* 40 C.F.R. §§ 60.532, 60.5474. The Final Rule also specifies the testing that manufacturers of devices covered by the standards must conduct on each model line to certify its compliance with the standards. *See id.* §§ 60.533(a), 60.534, 60.5475(a), 60.5476. To enforce the emission standards, EPA follows the Final Rule's audit procedures, which rely on the same test method manufacturers use to certify compliance. *Id.* §§ 60.533(n)(2)(iii), 60.5475(n)(2)(iii).

Petitioner Hearth, Patio, and Barbecue Association ("HPBA") seeks to eliminate EPA's ability to enforce the updated emission standards. HPBA does not contend the emission standards are themselves unlawful, nor does it attack the test methods EPA has adopted and through which HPBA's members certify that their

products comply with the standards. Instead, HPBA asserts that there is too much variability in test results for EPA to rely on audit testing to find that a wood heating device does not comply with the standards. In sum, HPBA's position is that although the test method is accurate enough to identify products that HPBA's members can sell, it is not accurate enough to identify products that they must stop selling.

HPBA's position is an attempt to shift the risk of any variability in the test method entirely onto people who will be exposed to air pollution from wood heating devices. As EPA has found, smoke from wood heating devices contains, among other harmful compounds, fine particulate matter, exposure to which "has been associated with a range of health effects, including aggravation of heart or respiratory problems, changes in lung function and increased respiratory symptoms, as well as premature death." 80 Fed. Reg. at 13,675. These emissions "cause[] many counties in the U.S. to either exceed the EPA's health-based national ambient air quality standards (NAAQS) for fine particles or place[] them on the cusp of exceeding those standards." *Id.* at 13,673.

## SUMMARY OF ARGUMENT

Respondent-Intervenors American Lung Association, Clean Air Council, and Environment and Human Health, Inc. (collectively "Intervenors") embrace, but do not repeat, EPA's argument that the rule under review reasonably

accommodates testing variability, through both the emission standard levels EPA selected and the compliance audit process it prescribed. *See* EPA Br. at 24-36. However, if this Court is persuaded that EPA has failed to explain aspects of its decision to adopt the audit testing regulations included in that rule or to respond to comments opposing that decision, vacatur is not the appropriate remedy. This Court should instead remand the matter to EPA for additional explanation.

## ARGUMENT

### I. EPA acted lawfully in issuing the Final Rule.

Intervenors adopt EPA's argument that the Final Rule reasonably accommodates testing variability, through both the emission standard levels EPA selected and the compliance audit process it prescribed. *See* EPA Br. at 24-36.

### II. If the Court concludes otherwise, remand without vacatur is the appropriate remedy.

Even if the Court determines that EPA has failed to explain aspects of its decision or to respond to significant comments, vacating the compliance audit testing provisions of the Final Rule is not the appropriate remedy. The Court should instead remand the matter to EPA for further explanation.

In deciding whether to vacate a rule, this Court considers both "the seriousness of [the rule's] deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*,

988 F.2d 146, 150-151 (D.C. Cir. 1993). As to the first factor, the Court need only find it plausible that the agency will reach the same result on remand while redressing its failure to explain. *Black Oak Energy, LLC v. FERC*, 725 F.3d 230, 244 (D.C. Cir. 2013) (finding it "plausible that FERC can redress its failure of explanation on remand while reaching the same result"). Moreover, "[a] strong showing of one factor may obviate the need to find a similar showing of the other." *American Bankers Ass'n v. Nat'l Credit Union Admin.*, 934 F.3d 649, 674 (D.C. Cir. 2019). Finally, in cases challenging EPA rules, so long as the rule's "defects are curable" this Court has given great weight to the need to avoid defeating—even temporarily—"the enhanced protection of the environmental values." *U.S. Sugar Corp. v. EPA*, 844 F.3d 268, 270 (D.C. Cir. 2016) (quoting *North Carolina v. EPA*, 550 F.3d 1176, 1178 (D.C. Cir. 2008); *see also Natural Res. Def. Council v. EPA*, 489 F.3d 1250, 1265 (D.C. Cir. 2007) ("Where the court has concluded that a final rule is deficient, the court has traditionally not vacated the rule if doing so would have serious adverse implications for public health and the environment.").

Here, it is clear that EPA could take lawful action on remand to retain the compliance audit provisions HPBA has challenged. The more recent studies of variability discussed in EPA's Brief show there is sufficient evidence to support a determination to retain the existing regulations. *See* EPA Br. at 11-14 (discussing analyses of test result variability from Woodstock Soapstone, Puget Sound Clean

Air Agency, and Brookhaven National Laboratory); *see also* Br. of Amici State of New York, et al. at 16-18 (discussing additional analysis from Northeast States for Coordinated Air Use Management).

Moreover, vacating the compliance audit regulations as HPBA requests would undermine compliance with the Final Rule's emission standards and the environmental values they protect. Supporting Amici have detailed the widespread problems with manufacturers' certifications of compliance with EPA's wood heating device standards and how manufacturers have implemented EPA's test procedures in ways that yield favorable outcomes. *Id.* at 12-13, 16-18. Nor are Amici alone in recognizing that manufacturers have made choices when conducting certification tests that achieve compliance at the risk of generating unrepresentative values. For example, the lead author of the study HPBA relies on to claim EPA's audit testing provisions are unreasonable has suggested the ratings achieved for certification purposes "are biased toward low values," in part because labs select favorable start-up procedures and "may have imposed significantly tighter controls of fuel selection and arrangement than required by [EPA]." JA250 (EPA-HQ-OAR-2009-0734-1643, attachment 9 at 5). If there is no prospect of EPA completing a compliance audit until the agency first goes through a new notice and comment rulemaking to promulgate regulations authorizing such action, manufacturers will have an incentive to continue production of any models that

such audits would likely disclose are violating EPA's standards. In contrast, a remand would allow EPA to address any deficiencies this Court identifies in the agency's justification for its 2015 action in the context of enforcement actions against manufacturers.

## CONCLUSION

For the reasons set out in EPA's Brief and herein, the Court should deny the petition for review.

DATED: October 20, 2020

Respectfully submitted,

/s/ Timothy D. Ballo
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*Counsel for American Lung Association, Clean Air Council, and Environment and Human Health, Inc.*

## CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT

Counsel hereby certifies, in accordance with Federal Rule of Appellate Procedure 32(g)(1) and Circuit Rule 32(e)(2)(B) that the foregoing **Final Brief of Intervenors** contains 1,201 words, as counted by counsel's word processing system, and thus complies with the 9,100 word limit.

Further, this document complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) & (a)(6) because this document has been prepared in a proportionally spaced typeface using **Microsoft Word 2016** using **size 14 Times New Roman** font.

DATED: October 20, 2020

/s/ Timothy D. Ballo
Timothy D. Ballo

# ADDENDUM

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Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter C. Air Programs
Part 60. Standards of Performance for New Stationary Sources (Refs & Annos)
Subpart AAA. Standards of Performance for New Residential Wood Heaters (Refs & Annos)

40 C.F.R. § 60.532

# § 60.532 What standards and associated requirements must I meet and by when?

Effective: April 2, 2020
Currentness

(a) 2015 particulate matter emission standards. Unless exempted under § 60.530(b), each affected wood heater manufactured, imported into the United States, and/or sold at retail on or after May 15, 2015 must be certified to not discharge into the atmosphere any gases that contain particulate matter in excess of a weighted average of 4.5 g/hr (0.010 lb/hr), except that a wood heater manufactured before May 15, 2015 may be imported into the United States and/or sold at retail on or before December 31, 2015. Compliance for all heaters must be determined by the test methods and procedures in § 60.534.

(b) 2020 particulate matter emission standards. Unless exempted under § 60.530(b) or electing to use the cord wood alternative means of compliance option in paragraph (c) of the section, each affected wood heater manufactured or sold at retail for use in the United States on or after May 15, 2020 must not discharge into the atmosphere any gases that contain particulate matter in excess of a weighted average of 2.0 g/hr (0.0044 lb/hr). Compliance for all heaters must be determined by the test methods and procedures in § 60.534.

(c) 2020 cord wood alternative compliance option. Each affected wood heater manufactured or sold at retail for use in the United States on or after May 15, 2020 must not discharge into the atmosphere any gases that contain particulate matter in excess of a weighted average of 2.5 g/hr (0.0055 lb/hr). Compliance must be determined by a cord wood test method approved by the Administrator and the procedures in § 60.534.

(d) Chip wood fuel requirements. Operators of wood heaters that are certified to burn chip wood fuels must only burn chip wood fuels that have been specified in the owner's manual. The chip wood fuel must meet the following minimum requirements:

(1) Moisture content: less than 35 percent;

(2) Inorganic fines: less than or equal to 1 percent;

(3) Chlorides: less than or equal to 300 parts per million by weight;

(4) Ash content: no more than 2 percent;

(5) No demolition or construction waste; and

(6) Trace metals: less than 100 mg/kg.

(e) Pellet fuel requirements. Operators of wood heaters that are certified to burn pellet fuels may burn only pellets that have been specified in the owner's manual and graded under a licensing agreement with a third-party organization approved by the EPA (including a certification by the third-party organization that the pellets do not contain, and are not manufactured from, any of the prohibited fuels in paragraph (f) of this section). The Pellet Fuels Institute, ENplus, and CANplus are initially deemed to be approved third-party organizations for this purpose, and additional organizations may apply to the Administrator for approval.

(f) Prohibited fuel types. No person is permitted to burn any of the following materials in an affected wood heater:

(1) Residential or commercial garbage;

(2) Lawn clippings or yard waste;

(3) Materials containing rubber, including tires;

(4) Materials containing plastic;

(5) Waste petroleum products, paints or paint thinners, or asphalt products;

(6) Materials containing asbestos;

(7) Construction or demolition debris;

(8) Paper products, cardboard, plywood, or particleboard. The prohibition against burning these materials does not prohibit the use of fire starters made from paper, cardboard, sawdust, wax and similar substances for the purpose of starting a fire in an affected wood heater;

(9) Railroad ties, pressure-treated wood or pallets;

(10) Manure or animal remains;

(11) Salt water driftwood or other previously salt water saturated materials;

(12) Unseasoned wood;

(13) Any materials that are not included in the warranty and owner's manual for the subject wood heater; or

(14) Any materials that were not included in the certification tests for the subject wood heater.

(g) Operation of affected wood heaters. The user of an affected residential wood heater must operate the heater in a manner consistent with the owner's manual. The owner's manual must clearly specify that operation in a manner inconsistent with the owner's manual would void the warranty.

(h) Temperature sensor requirement. An affected wood heater equipped with a catalytic combustor must be equipped with a temperature sensor that can monitor combustor gas stream temperatures within or immediately downstream [within 2.54 centimeters (1 inch) ] of the catalytic combustor surface.

**Credits**
[85 FR 18455, April 2, 2020]

SOURCE: 36 FR 24877, Dec. 23, 1971; 50 FR 36834, Sept. 9, 1985; 52 FR 37874, Oct. 9, 1987; 53 FR 2675, Jan. 29, 1988; 57 FR 32338, July 21, 1992; 58 FR 40591, July 29, 1993; 60 FR 65384, Dec. 19, 1995; 62 FR 8328, Feb. 24, 1997; 62 FR 48379, Sept. 15, 1997; 64 FR 7463, Feb. 12, 1999; 65 FR 78275, Dec. 14, 2000; 72 FR 59204, Oct. 19, 2007; 80 FR 13702, March 16, 2015 unless otherwise noted., unless otherwise noted.

AUTHORITY: 42 U.S.C. 7401 et seq.

Current through September 25, 2020; 85 FR 60682.

End of Document

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Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter C. Air Programs
Part 60. Standards of Performance for New Stationary Sources (Refs & Annos)
Subpart AAA. Standards of Performance for New Residential Wood Heaters (Refs & Annos)

40 C.F.R. § 60.534

# § 60.534 What test methods and procedures must I use to determine compliance with the standards and requirements for certification?

Effective: May 15, 2015
Currentness

Test methods and procedures specified in this section or in appendices of this part, except as provided under § 60.8(b), must be used to determine compliance with the standards and requirements for certification under §§ 60.532 and 60.533 and for reporting carbon monoxide emissions and efficiency as follows:

(a)(1) For affected wood heaters subject to the 2015 and 2020 particulate matter emission standards of §§ 60.532(a) and (b), the manufacturer must have an EPA–approved test laboratory conduct testing according to paragraphs (a)(1)(i) or (ii) of this section. The manufacturer or manufacturer's authorized representative must submit a summary and the full test reports with all supporting information, including detailed discussion of all anomalies, whether all burn rate categories were properly achieved, any data not used in the calculations and, for any test runs not completed, the data that were collected and the reason that the test run was not completed. The burn rate for the low burn rate category must be no greater than the rate that an operator can achieve in home use and no greater than is advertised by the manufacturer or retailer. The manufacturer has the option of submitting test results obtained pursuant to either paragraph (a)(1)(i) or (ii) of this section to the Administrator as specified under § 60.537 as part of a request for a certification of compliance.

(i) Conduct testing with crib wood using EPA Method 28R of Appendix A–8 of this part or an alternative crib wood test method approved by the Administrator or the ASTM E2779–10 (IBR, see § 60.17) pellet heater test method to establish the certification test conditions and the particulate matter emission values.

(ii) Conduct testing with cord wood using an alternative cord wood test method approved by the Administrator to establish the certification test conditions and the particulate matter emission values.

(2) For the 2020 cord wood alternative means of compliance option specified in § 60.532(c), the manufacturer must have an EPA–approved test laboratory conduct testing with cord wood using an alternative cord wood test method approved by the Administrator to establish the certification test conditions and the particulate matter emission values.

(b) [Reserved]

(c) For affected wood heaters subject to the 2015 and 2020 particulate matter emission standards specified in § 60.532(a), (b) and (c), particulate matter emission concentrations must be measured with ASTM E2515–11 (IBR, see § 60.17). Four-inch filters and Teflon membrane filters or Teflon-coated glass fiber filters may be used in ASTM E2515–11.

(d) For all tests conducted using ASTM E2515–11 (IBR, see § 60.17) pursuant to this section, the manufacturer and approved test laboratory must also measure the first hour of particulate matter emissions for each test run using a separate filter in one of the two parallel trains. The manufacturer and approved test laboratory must report the test results for the first hour separately and also include them in the total particulate matter emissions per run.

(e) The manufacturer must have the approved test laboratory measure the efficiency, heat output and carbon monoxide emissions of the tested wood heater using Canadian Standards Administration (CSA) Method B415.1–10 (IBR, see § 60.17), section 13.7.

(f) Douglas fir may be used in ASTM E2779–10, ASTM E2780–10 and CSA B415.1–10 (IBR, see § 60.17).

(g) The manufacturer of an affected wood heater model line must notify the Administrator of the date that certification testing is scheduled to begin by email to WoodHeaterReports@epa.gov. This notice must be received by the EPA at least 30 days before the start of testing. The notification of testing must include the manufacturer's name and physical and email addresses, the approved test laboratory's name and physical and email addresses, the third-party certifier name, the model name and number (or, if unavailable, some other way to distinguish between models), and the dates of testing. The laboratory may substitute certification testing of another affected wood heater on the original date in order to ensure regular laboratory testing operations.

(h) The approved test laboratory must allow the manufacturer, the manufacturer's approved third-party certifier, the EPA and delegated state regulatory agencies to observe certification testing. However, manufacturers must not involve themselves in the conduct of the test after the pretest burn has begun. Communications between the manufacturer and laboratory or third-party certifier personnel regarding operation of the wood heater must be limited to written communications transmitted prior to the first pretest burn of the certification test series. During certification tests, the manufacturer may communicate with laboratory personnel only in writing and only to notify them that the manufacturer has observed a deviation from proper test procedures. All communications must be included in the test documentation required to be submitted pursuant to § 60.533(b)(5) and must be consistent with instructions provided in the owner's manual required under § 60.536(g), except to the extent that they address details of the certification tests that would not be relevant to owners or regulators.

SOURCE: 36 FR 24877, Dec. 23, 1971; 50 FR 36834, Sept. 9, 1985; 52 FR 37874, Oct. 9, 1987; 53 FR 2675, Jan. 29, 1988; 57 FR 32338, July 21, 1992; 58 FR 40591, July 29, 1993; 60 FR 65384, Dec. 19, 1995; 62 FR 8328, Feb. 24, 1997; 62 FR 48379, Sept. 15, 1997; 64 FR 7463, Feb. 12, 1999; 65 FR 78275, Dec. 14, 2000; 72 FR 59204, Oct. 19, 2007; 80 FR 13702, March 16, 2015 unless otherwise noted., unless otherwise noted.

AUTHORITY: 42 U.S.C. 7401 et seq.

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Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter C. Air Programs
Part 60. Standards of Performance for New Stationary Sources (Refs & Annos)
Subpart Qqqq. Standards of Performance for New Residential Hydronic Heaters and Forced–Air Furnaces (Refs & Annos)

40 C.F.R. § 60.5474

# § 60.5474 What standards and requirements must I meet and by when?

Effective: April 2, 2020
Currentness

(a) Standards. Unless exempted under § 60.5472, no person is permitted to:

(1) On or after May 15, 2015, manufacture, import into the United States or sell at retail a residential hydronic heater unless it has been certified to meet the 2015 particulate matter emission limits in paragraph (b)(1) of this section, except that a residential hydronic heater that was manufactured on or before May 15, 2015 may be imported into the United States and/or sold at retail on or before December 31, 2015.

(2) On or after May 15, 2020 manufacture or sell at retail a residential hydronic heater unless it has been certified to meet the 2020 particulate matter emission limit in paragraph (b)(2) or (b)(3) of this section.

(3) On or after May 15, 2015, manufacture or sell at retail a residential forced-air furnace unless it complies with the work practice and operating standards in paragraphs (d), (e), (f) and (g) of this section and the owner's manual requirements in Appendix I.

(4) On or after May 16, 2016, manufacture or sell at retail a small residential forced-air furnace unless it has been certified to meet the 2016 particulate matter emission limits in paragraph (b)(4) of this section

(5) On or after May 15, 2017 manufacture or sell at retail a large forced-air furnace unless it has been certified to meet the 2017 particulate matter emission limits in paragraph (b)(5) of this section.

(6) On or after May 15, 2020 manufacture or sell at retail a small or large residential forced-air furnace unless it has been certified to meet the 2020 particulate matter emission limit in paragraph (b)(6) of this section.

(b)(1) 2015 residential hydronic heater particulate matter emission limit: A weighted average of 0.32 lb/mmBtu (0.137 g/MJ) heat output and a maximum per individual burn rate of 18.0 g/hr (0.041 lb/hr) as determined by the test methods and procedures in § 60.5476 or an alternative crib wood or cord wood test method approved by the Administrator.

(2) 2020 residential hydronic heater particulate matter emission limit: 0.10 lb/mmBtu (0.026 g/MJ) heat output per individual burn rate as determined by the crib wood test methods and procedures in § 60.5476 or an alternative crib wood test method approved by the Administrator .

(3) 2020 residential hydronic heater cord wood alternative compliance option for particulate matter emission limit: 0.15 lb/mmBtu (0.026 g/MJ) heat output per individual burn rate as determined by the cord wood test methods and procedures in § 60.5476 or an alternative cord wood test method approved by the Administrator.

(4) 2016 small forced-air furnace particulate matter emission limit: A weighted average of 0.93 lb/mmBtu (0.40 g/MJ) heat output as determined by the test methods and procedures in § 60.5476.

(5) 2017 large forced-air furnace particulate matter emission limit: A weighted average of 0.93 lb/mmBtu (0.40 g/MJ) heat output as determined by the test methods and procedures in § 60.5476.

(6) 2020 forced-air furnace particulate matter emission limit: 0.15 lb/mmBtu (0.026 g/MJ) heat output per individual burn rate as determined by the cord wood test methods and procedures in § 60.5476 or cord wood test methods approved by the Administrator.

(c) [Reserved]

(d) Chip wood fuel requirements. Operators of wood central heaters, including hydronic heaters and forced-air furnaces, that are certified to burn chip wood fuels may only burn wood chips that have been specified in the owner's manual. The chip wood fuel must meet the following minimum requirements:

(1) Moisture content: Less than 35 percent,

(2) Inorganic fines: Less than or equal to 1 percent;

(3) Chlorides: Less than or equal to 300 parts per million by weight;

(4) Ash content: No more than 2 percent;

(5) No demolition or construction waste; and

(6) Trace metals: Less than 100 mg/kg.

(e) Pellet fuel requirements. Operators of wood central heaters, including outdoor residential hydronic heaters, indoor residential hydronic heaters, and residential forced-air furnaces, that are certified to burn pellet fuels may burn only pellets that have been specified in the owner's manual and graded under a licensing agreement with a third-party organization approved by the EPA

(including a certification by the third-party organization that the pellets do not contain, and are not manufactured from, any of the prohibited fuels in paragraph (f) of this section). The Pellet Fuels Institute, ENplus, and CANplus are initially deemed to be approved third-party organizations for this purpose, and additional organizations may apply to the Administrator for approval.

(f) Prohibited fuel types. No person is permitted to burn any of the following materials in an outdoor residential hydronic heater, indoor residential hydronic heater, residential forced-air furnace or other affected central heater:

(1) Residential or commercial garbage;

(2) Lawn clippings or yard waste;

(3) Materials containing rubber, including tires;

(4) Materials containing plastic;

(5) Waste petroleum products, paints or paint thinners, or asphalt products;

(6) Materials containing asbestos;

(7) Construction or demolition debris;

(8) Paper products; cardboard, plywood or particleboard. The prohibition against burning these materials does not prohibit the use of fire starters made from paper, cardboard, saw dust, wax and similar substances for the purpose of starting a fire in an affected central heater;

(9) Railroad ties or pressure treated lumber;

(10) Manure or animal remains;

(11) Salt water driftwood or other or other previously salt water saturated materials;

(12) Unseasoned wood;

(13) Any materials that are not included in the warranty and owner's manual for the subject heater or furnace; or

(14) Any materials that were not included in the certification tests for the subject heater or furnace.

(g) Operation of affected wood heaters. A user must operate an outdoor residential hydronic heater, indoor residential hydronic heater, residential forced-air furnace or other affected central heater in a manner consistent with the owner's manual. The owner's manual must clearly specify that operation in a manner inconsistent with the owner's manual would void the warranty.

(h) Temperature sensor requirement. An affected wood heater equipped with a catalytic combustor must be equipped with a temperature sensor that can monitor combustor gas stream temperatures within or immediately downstream [within 2.54 centimeters (1 inch)] of the catalytic combustor surface.

**Credits**
[85 FR 18455, April 2, 2020]

SOURCE: 36 FR 24877, Dec. 23, 1971; 50 FR 36834, Sept. 9, 1985; 52 FR 37874, Oct. 9, 1987; 53 FR 2675, Jan. 29, 1988; 57 FR 32338, July 21, 1992; 58 FR 40591, July 29, 1993; 60 FR 65384, Dec. 19, 1995; 62 FR 8328, Feb. 24, 1997; 62 FR 48379, Sept. 15, 1997; 64 FR 7463, Feb. 12, 1999; 65 FR 78275, Dec. 14, 2000; 72 FR 59204, Oct. 19, 2007; 80 FR 13715, March 16, 2015, unless otherwise noted.

AUTHORITY: 42 U.S.C. 7401 et seq.

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Subpart Qqqq. Standards of Performance for New Residential Hydronic Heaters and Forced–Air Furnaces (Refs & Annos)

40 C.F.R. § 60.5476

# § 60.5476 What test methods and procedures must I use to determine compliance with the standards and requirements for certification?

Effective: May 15, 2015
Currentness

Test methods and procedures specified in this section or in appendices of this part, except as provided under § 60.8(b), must be used to determine compliance with the standards and requirements for certification under §§ 60.5474 and 60.5475 and for reporting carbon monoxide emissions and efficiency. The EPA will post all approved alternative test methods on the EPA Web site. The manufacturer or the manufacturer's authorized representative must submit a summary and the full test report with all supporting information, including detailed discussion of all anomalies, whether all burn rate categories were properly achieved, any data not used in the calculations and, for any test runs not completed, the data that were collected and the reason that the test run was not completed. The burn rate for the low burn rate category must be no greater than the rate that an operator can achieve in home use and no greater than is advertised by the manufacturer or retailer.

(a) Canadian Standards Administration (CSA) Method B415.1–10, sections 13.7–13.10 (IBR, see § 60.17), must be used to measure the thermal efficiency and CO emissions of outdoor and indoor residential hydronic heaters and forced-air furnaces, except that the burn rates specified in Method 28WHH must be used for hydronic heaters.

(b) Testing conducted with continuously fed biomass as the fuel(s) must be conducted according to the relevant section of the ASTM E2618–13 (IBR, see § 60.17) or adaptations approved by EPA. The EPA will post all approved alternative test methods on the EPA Web site.

(c)(1) For outdoor and indoor residential hydronic heaters to be tested under the 2015 particulate matter emission standards in § 60.5474(b)(1), the manufacturer must have an EPA–approved test laboratory use:

(i) Method 28WHH;

(ii) Method 28WHH PTS;

(iii) ASTM E2618–13 (IBR, see § 60.17) (using crib wood); or

(iv) EN 303–5 (IBR, see § 60.17), only for units sold with thermal storage.

(2) For outdoor and indoor residential hydronic heaters to be tested under the 2020 particulate matter emission standards in § 60.5474(b)(2), the manufacturer must have an EPA–approved test laboratory use:

(i) Method 28WHH;

(ii) Method 28WHH PTS; or

(iii) ASTM E2618–13 (IBR, see § 60.17) (using crib wood).

(3) If the heater is equipped with full or partial heat storage, the manufacturer, retailer and installer must not sell or install the heater with less heat storage capacity than is used in the certification test.

(4) The manufacturer and approved laboratory must make the following adjustments to the methods listed in paragraphs (a), (c)(1) and (2) of this section:

(i) For ASTM E2618–13 (IBR, see § 60.17), the burn rate categories specified in Method 28WHH must be used;

(ii) For EN 303–5 (IBR, see § 60.17), the organic compounds must be included as part of the PM.

(iii) For ASTM 2618–13 (IBR, see § 60.17) Appendix A1 for full thermal storage certification tests, the test must use the large scale as required in the test method unless the manufacturer requests a variance, in advance of testing, contingent upon measuring flue gas temperature, oxygen and CO, using a simple electronic spreadsheet calculator to estimate efficiency and conducting a comparison to the delivered efficiency to determine if a more detailed examination should be made.

(5) For particulate matter emission concentrations measured with ASTM E2515–11 (IBR, see § 60.17), four-inch filters and Teflon membrane filters or Teflon-coated glass fiber filters may be used.

(6) For all tests conducted using ASTM 2515–11 (IBR, see § 60.17) pursuant to this section, the manufacturer and approved test laboratory must also measure the first hour of particulate matter emissions for each test run using a separate filter in one of the two parallel trains. The manufacturer and approved test laboratory must report the test results for the first hour separately and also include them in the total particulate matter emissions per run.

(d)(1) For hydronic heaters subject to the 2020 cord wood alternative compliance option specified in § 60.5474(b)(3), the manufacturers must have the approved laboratory conduct cord wood testing using the test methods listed below:

(i) Method 28WHH;

(ii) Method 28WHH PTS; or

(iii) ASTM E2618–13 (IBR, see § 60.17) (using cord wood).

(2) If the heater is equipped with full or partial heat storage, the manufacturer, retailer and installer must not sell or install the heater with less heat storage capacity than is used in the certification test.

(3) The manufacturer and approved laboratory must make the following adjustments to the methods listed in (d)(1) of this section:

(i) For ASTM E2618–13 (IBR, see § 60.17), use the burn rate categories specified in Method 28WHH;

(ii) For all methods, report the results separately per burn rate category.

(e) For forced-air furnaces, use CSA Method B415.1–10 (IBR, see § 60.17) to measure the heat output (mmBtu/hr) and particulate matter emission rate (lb/mmBtu heat output), except use the burn rate categories in Method 28WHH for the 2020 particulate matter emission standards. For the 2020 particulate matter emission standards, report the particulate matter, efficiency and CO emission results separately per burn rate category.

(f) For affected wood heaters subject to the particulate matter emission standards, emission concentrations must be measured with ASTM E2515–11 (IBR, see § 60.17), except for the 2015 certification tests using EN303–5 (IBR, see § 60.17). As required in paragraph (c)(4)(ii) of this section, the manufacturer and approved laboratory must add the organic gases to the PM for EN 303–5. Four-inch filters and Teflon membrane filters or Teflon-coated glass fiber filters may be used in ASTM E2515–11. Method 5H is not allowed for certification testing.

(g) Douglas fir may be used in ASTM E2618–13 and CSA B415.1–10 (IBR, see § 60.17).

(h) The manufacturer of an affected central heater model line must notify the Administrator of the date that certification testing is to begin, by email, to WoodHeaterReports@epa.gov. This notice must be at least 30 days before the start of testing. The notification of testing must include the manufacturer's name and physical and email addresses, the approved test laboratory's name and physical and email addresses, third-party certifier name, the model name and number (or, if unavailable, some other way to distinguish between models), and the dates of testing. The laboratory may substitute certification testing of another affected central heater on the original date in order to ensure regular laboratory testing operations.

(i) The approved test laboratory must allow the manufacturer, the manufacturer's approved third-party certifier, the EPA and delegated state regulatory agencies to observe certification testing. However, manufacturers must not involve themselves in the conduct of the test after the pretest burn has begun. Communications between the manufacturer and laboratory or third-party certifier personnel regarding operation of the central heater must be limited to written communications transmitted prior to the first pretest burn of the certification series. During certification tests, the manufacturer may communicate with laboratory personnel only in writing and only to notify them that the manufacturer has observed a deviation from proper test procedures. All communications must be included in the test documentation required to be submitted pursuant to § 60.5475(b)(5) and must

be consistent with instructions provided in the owner's manual required under § 60.5478(f), except to the extent that they address details of the certification tests that would not be relevant to owners or regulators.

SOURCE: 36 FR 24877, Dec. 23, 1971; 50 FR 36834, Sept. 9, 1985; 52 FR 37874, Oct. 9, 1987; 53 FR 2675, Jan. 29, 1988; 57 FR 32338, July 21, 1992; 58 FR 40591, July 29, 1993; 60 FR 65384, Dec. 19, 1995; 62 FR 8328, Feb. 24, 1997; 62 FR 48379, Sept. 15, 1997; 64 FR 7463, Feb. 12, 1999; 65 FR 78275, Dec. 14, 2000; 72 FR 59204, Oct. 19, 2007; 80 FR 13715, March 16, 2015, unless otherwise noted.

AUTHORITY: 42 U.S.C. 7401 et seq.

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**ORAL ARGUMENT NOT YET SCHEDULED**
**Case No. 15-1056**

United States Court of Appeals
for the District of Columbia Circuit

HEARTH, PATIO & BARBECUE ASSOCIATION, et al.,

*Petitioners*,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

*Respondent.*

ON PETITION FOR REVIEW OF FINAL ACTION OF THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

# BRIEF OF STATES OF NEW YORK, ALASKA, CONNECTICUT, ILLINOIS, MARYLAND, MINNESOTA, NEW JERSEY, OREGON, RHODE ISLAND, VERMONT, AND WASHINGTON, AND THE PUGET SOUND CLEAN AIR AGENCY AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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Dated: September 21, 2020

## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel of record certifies as follows:

**A. Parties.** All parties, intervenors, and amici are listed in the Brief for Petitioner Hearth, Patio, and Barbecue Association, except that Pellet Fuels Institute is no longer a party, and the amici joining this brief are the States of New York, Alaska, Connecticut, Illinois, Maryland, Minnesota, New Jersey, Oregon, Rhode Island, Vermont, and Washington, and the Puget Sound Clean Air Agency.[1]

**B. Rulings Under Review.** References to the agency action at issue appear in the Brief for Petitioner Hearth, Patio, and Barbecue Association.

**C. Related Cases.** This Court granted Pellet Fuels Institute's motion to dismiss voluntarily in Case No. 15-1140 and terminated the consolidation of that case with this one.

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[1] No counsel for a party authored this brief in whole or in part, and no person other than the amici curiae contributed money that was intended to fund the preparation or submission of this brief.

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## GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| g/hr | Grams per hour |
| NESCAUM | Northeast States for Coordinated Air Use Management |
| $PM_{2.5}$ | Fine particulate matter |
| Puget Sound | Puget Sound Clean Air Agency |
| Puget Sound Study | Puget Sound Clean Air Agency, *Preliminary Review and Critique of Analyses of NSPS Test Method Variability (Curkeet, 2010) and the Relationship of EPA Certified Values to "In-Home Use" (Houck, 2012)* (Dec. 5, 2012) |
| Response to Comments | U.S. Envtl. Prot. Agency, Response to Comments on Proposed Rule, 'Standards of Performance for New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces, and New Residential Masonry Heaters' (Feb. 2015) |
| Rule | Standards of Performance for New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces, 80 Fed. Reg. 13,672 (Mar. 16, 2015) |

## INTRODUCTION AND INTERESTS OF AMICI

New York, Alaska, Connecticut, Illinois, Maryland, Minnesota, New Jersey, Oregon, Rhode Island, Vermont, Washington, and Washington's Puget Sound Clean Air Agency (Puget Sound) (collectively, the States) submit this amicus brief in support of the Environmental Protection Agency (EPA) in this challenge to a 2015 EPA rule establishing emission and audit standards for wood-burning devices. *See* Standards of Performance for New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces, 80 Fed. Reg. 13,672 (Mar. 16, 2015) (Rule).

The amici States have a compelling interest in protecting their citizens from the emissions of wood-burning devices, which produce multiple pollutants that cause serious health effects. To advance this compelling interest, the amici States have enacted their own measures to mitigate the risks of wood-burning devices, and have participated in efforts to reduce wood-burning device pollutants at the federal level.

EPA promulgated its original federal standards for wood heaters in response to a lawsuit filed by New York. New York and several States later sued to ensure that EPA fulfilled its statutory duty to update the

original standards, resulting in a consent decree that paved the way for the 2015 Rule at issue in this case.

The state studies described in this brief confirm that there is no merit to petitioner Hearth, Patio & Barbecue Association's objections to the audit-testing provisions in the 2015 Rule. As the States' analyses demonstrate, the audit-testing provisions are necessary to ensure compliance with the Rule's emissions standards. Petitioner's testing variability concerns are overblown: those concerns are based on flawed statistical analysis and avoidable testing choices made by the manufacturers themselves. Accordingly, the States urge this Court to uphold the Rule in full, and reject the petitioner's challenge.

## BACKGROUND

### A. Wood Smoke's Harms to the Amici States

Wood-burning devices emit numerous pollutants that endanger public health and welfare, such as fine particulate matter ($PM_{2.5}$), carbon monoxide, polycyclic aromatic hydrocarbons, and polycyclic organic matter. Studies have found that $PM_{2.5}$ emissions from wood-burning devices are associated with significant increases in morbidity and mortality for men,

African-Americans, and low-income persons.[2] Moreover, emerging research shows that long term exposure to $PM_{2.5}$ increases the mortality rate from COVID-19, including in minority and low-income communities.[3]

Carbon monoxide from wood-burning devices can cause headaches, nausea, unconsciousness, and even death.[4] Polycyclic aromatic hydrocarbons from the devices can cause cancer.[5] And polycyclic organic matter from the devices can cause cancer, skin disorders, and respiratory

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[2] *See, e.g.*, Qian Di et al., *Air Pollution and Mortality in the Medicare Population*, 376 New Engl. J. Med. 2513, 2520-21 (2017), https://www.nejm.org/doi/full/10.1056/NEJMoa1702747; *see also* Richard Burnett et al., *Global Estimates of Mortality Associated with Long-Term Exposure to Outdoor Fine Particulate Matter*, 115 Proceedings of Nat'l Acad. of Scis. 9592, 9593 (2018), https://tinyurl.com/yxbo9pmd (estimated 4 million deaths worldwide due to $PM_{2.5}$ exposure in 2015).

[3] Xiao Wu et al., *Exposures to Air Pollution and COVID-19 Mortality in the United States: A Nationwide Cross-Sectional Study* 2, 12 (Apr. 27, 2020), https://www.medrxiv.org/content/10.1101/2020.04.05.20054502v2.

[4] Ctrs. for Disease Control & Prevention, *Carbon Monoxide Poisoning* (last updated Oct. 26, 2016), https://tinyurl.com/yxjmtmvd.

[5] Ctrs. for Disease Control & Prevention, *Toxic Substances Portal: Polycyclic Aromatic Hydrocarbons (PAHs)* (last updated Aug. 28, 2014), http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=121&tid=25.

harms.[6] In addition, greenhouse gases produced by wood-burning devices have adverse climate impacts. *See* 80 Fed. Reg. at 13,674.

The health effects of wood-burning devices are acute in the amici States. The amici States have hundreds of thousands, if not millions, of residents who rely on wood-burning devices for heating. New York alone contains nearly 150,000 homes that use wood as a primary heating source and 500,000 homes that use wood for supplemental heat.[7] In Vermont, 22% of homes use wood as a primary heating source, and 35% of households burn wood for at least some heating.[8]

Wood-burning devices pose a particular risk to residents of rural areas in the amici States. One study found "[v]ery high spikes" in wood

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[6] EPA, *Polycyclic Organic Matter (POM)* (Sept. 23, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/polycyclic-organic-matter.pdf.

[7] N.Y. State Energy Research & Dev. Auth., *New York State Wood Heat Report: An Energy, Environmental, and Market Assessment* 8 (Apr. 2016), https://tinyurl.com/y2vow9w6.

[8] Vt. Dep't of Forests, Parks & Recreation, *Vermont Residential Fuel Assessment for the 2018-2019 Heating Season* 15 (Nov. 2019), https://tinyurl.com/y2vf8b9s; *see also* Wilson Ring, *Vermont No. 1 in Per Capita Wood Stove Emissions*, Burlington Free Press (Mar. 14, 2015), www.burlingtonfreepress.com/story/news/local/2015/03/14/vermont-per-capita-wood-stove-emissions/24784007/.

smoke concentrations in a seven-county rural area of upstate New York, where 26% of the monitored population were exposed to elevated wood smoke posing serious health risks.[9]

### B. The Amici States' History of Supporting Stricter Emissions Limits for Wood-Burning Devices

The amici States have enacted many measures to mitigate the harmful effects of wood-burning devices. New York has launched the Renewable Heat New York program, which provides support and funding for development and demonstration of safer wood heaters.[10] Vermont imposes restrictions on allowable fuels and siting for wood-burning devices, and has promulgated regulations prohibiting the operation or sale of wood heaters that are not certified as meeting the 2015 Rule standards (which otherwise are applicable only to new heaters).[11] Alaska

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[9] N.Y. State Energy Research & Dev. Auth., *Spatial Modeling and Monitoring of Residential Woodsmoke Across a Non-Urban Upstate New York Region* xvii-xix, 4-1 (Feb. 2010), https://tinyurl.com/y5uyf867.

[10] *See* N.Y. State Energy Research & Dev. Auth., *Renewable Heat NY*, https://www.nyserda.ny.gov/All%20Programs/Programs/Renewable%20Heat%20NY.

[11] 16-3 Vt. Code R. 100 § 5-204.

likewise has promulgated regulations prohibiting the installation of wood heaters that are not certified as meeting the 2015 Rule standards.[12] Alaska also relies on certification test results to limit the wood-burning devices qualifying for use in an area of the State with particularly high $PM_{2.5}$ levels.[13] After the Tacoma-Pierce County area was identified as having dangerously high $PM_{2.5}$ levels, Washington and its Puget Sound Clean Air Agency imposed burning restrictions and offered incentives to change out older, dirtier wood-burning devices, which substantially reduced $PM_{2.5}$ levels in the region.[14]

The amici States also have a long history of urging EPA to promulgate standards for wood-burning devices that protect the health of amici's citizens. EPA promulgated the original federal emissions standards for wood heaters in 1988, in response to a lawsuit filed by New York. *See* 53 Fed. Reg. 5873 (Feb. 26, 1988); 40 C.F.R. §§ 60.530-60.539b. In 2012, Puget Sound urged EPA to update the standards for wood-

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[12] Alaska Admin. Code tit. 18, § 50.077.

[13] *Id.*

[14] *See* Wash. Dep't of Ecology, *Progress in Reducing Fine Particulate Air Pollution in Tacoma-Pierce County* 1 (Apr. 2019), https://fortress.wa.gov/ecy/publications/documents/1902009.pdf.

burning devices, including by imposing audit testing procedures.[15] In 2013, New York and several States filed a complaint to force EPA to fulfill its statutory duty to update those standards. *See* Compl., *New York v. McCarthy*, No. 13-cv-1553 (D.D.C. Oct. 9, 2013), ECF No. 1. The States also asked that EPA be required to set emissions standards for wood boilers, which were exempted under the 1988 rule. *Id.* at 7-8. EPA and the States resolved that matter through a consent decree that required EPA to promulgate updated standards. *See* Partial Consent Decree, *New York v. McCarthy*, No. 13-cv-1553 (D.D.C. Apr. 28, 2018), ECF No. 27-1.

When EPA proposed new standards, *see* 79 Fed. Reg. 6330 (Feb. 3, 2014), New York and other States submitted comments urging EPA to adopt a new 1.3 g/hr emissions limit for wood stoves, which was consistent with the proposed rule. The States also urged EPA to adopt a three-to-four-year phase-in schedule, which was faster than the proposed rule's phase-in periods of up to eight years. The States explained that many wood stove models already could achieve EPA's proposed standards

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[15] *See* Letter from Puget Sound to Stephen D. Page, Dir., Office of Air Quality Planning & Standards, EPA (Dec. 5, 2012), https://www.regulations.gov/document?D=EPA-HQ-OAR-2009-0734-0060.

and there was negligible evidence that manufacturers needed more than three-to-four years to comply with the stricter standards.[16]

### C. The 2015 Rule and Petitioner's Challenge

After completing a thorough review of the available data, EPA issued the 2015 Rule at issue in this litigation. To allow manufacturers flexibility, EPA permitted a five-year phase-in period, in two stages. EPA set the emissions limits for wood heaters at 4.5 g/hr beginning in 2015 and at 2.0 g/hr (or 2.5 g/hr if manufacturers tested with cordwood[17]) beginning in 2020—higher than in the proposed rule, to address

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[16] *See* Comments Submitted by New York, Maryland, and Massachusetts on Proposed Standards of Performance for New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces, and New Residential Masonry Heaters at 6 (May 5, 2014), https://www.regulations.gov/document?D=EPA-HQ-OAR-2009-0734-1477; *see also* 79 Fed. Reg. at 6339, 6343; 80 Fed. Reg. at 13,678, 13,681, 13,686-87.

[17] Cordwood has more irregularities than the crib wood that is more commonly used for testing; thus, some commenters argued that cordwood could have more variability in testing results. *See* EPA, *Burn Wise: Cordwood and Crib Wood Testing* (last updated May 15, 2020), https://www.epa.gov/burnwise/cord-wood-and-crib-wood-testing; EPA, Response to Comment on Proposed Rule, 'Standards of Performance for New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces, and New Residential Masonry Heaters,' at 83, 468-69 (Feb. 2015) (Response to Comments), https://tinyurl.com/y6adkawd.

manufacturer concerns. 80 Fed. Reg. at 13,678. EPA also set separate new emissions limits for wood boilers and forced-air furnaces. *See id.* at 13,681.

To be permitted to sell a wood-burning device under the Rule, manufacturers are required to certify their compliance with emissions standards for each model line, based on a certification test. 40 C.F.R. §§ 60.533(b), 60.5475(b). To enforce the emissions standards, EPA renewed audit testing procedures that had originated in the 1988 rules, with only slight variation. *Id.* §§ 60.533(n), 60.5475(n); 80 Fed. Reg. at 13,708, 13721; *see also* EPA Br. at 19-20 (describing minor changes in audit procedures).

Thereafter, petitioner Hearth, Patio & Barbecue Association brought this suit challenging the Rule. In its brief, petitioner claims that the Rule's audit-testing provisions do not account for testing variability—i.e., potential variability in test results at the initial certification stage and the audit stage—and are therefore arbitrary and capricious.[18]

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[18] The Pellet Fuels Institute also filed a petition for review of the Rule, but voluntarily dismissed its petition. *See* Order, *Pellet Fuels Inst. v. EPA*, No. 15-1140 (June 26, 2020), Doc. No. 1849126.

## ARGUMENT

In reviewing an agency decision, "a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency need only "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (quotation marks omitted). "[I]t suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (emphasis omitted).

The amici States agree with EPA that petitioner's challenges to the Rule are meritless, for the reasons stated in EPA's brief. The States file this brief to inform the Court of the States' own research, which underscores that the audit-testing provisions challenged by petitioner are necessary to ensure compliance with emissions standards, and that petitioner exaggerates testing variability as an impediment to reliable auditing.

### A. Audit Testing Is Necessary to Ensure Compliance with the Rule.

The amici States have long emphasized the importance of audit testing to confirm compliance with emissions standards for wood-burning devices.[19] The Northeast States for Coordinated Air Use Management (NESCAUM)—an association of eight States committed to working together to address air pollution—recently explained that "[e]ffective compliance audit testing is needed to ensure the integrity of the emission certification process."[20] Because manufacturers certify their compliance with emissions standards without regulatory oversight, audit testing is necessary to ensure that errors in the certification process—whether willful or unwitting—do not go unchecked. Audit testing also gives consumers confidence that the devices they purchase actually meet the

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[19] *See, e.g.*, Comments of New York State Department of Environmental Conservation on Advance Notice of Proposed Rulemaking, "Standards of Performance for New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces," at 4-5 (Feb. 13, 2019), https://tinyurl.com/y6ky26t8.

[20] Comment Submitted by NESCAUM on Advanced Notice of Proposed Rulemaking for New Source Performance Standards for Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Heaters at 3 (Feb. 12, 2019), https://tinyurl.com/y3vv6vyy.

certified emissions standards. And audit testing promotes a level playing field among manufacturers.

State analyses of manufacturers' certification reports underscore the critical need for audit testing. For instance, the Alaska Department of Environmental Conservation has conducted a systematic review of wood-burning devices that have been certified to be compliant with EPA standards.[21] The Department found that 59% of the certifications had inaccurate certification data, and 64% had certifications based on non-representative testing methods—i.e., methods that were not consistent with ordinary consumer use. What is more, three certifications lacked certification test reports altogether.[22] These results suggest serious

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[21] *See* Alaska Dep't of Envtl. Conservation, Div. of Air Quality, *Air Non-Point & Mobile Sources: Manufacturers & Vendors*, https://dec.alaska.gov/air/burnwise/manufacturers-vendors/#Regulations.

[22] The Department evaluated 128 certifications, and posted two lists with error data. *See* Alaska Dep't of Envtl. Conservation, Div. of Air Quality, *Transition List* (Sept. 14, 2020), https://tinyurl.com/yxl9m8rh; Alaska Dep't of Envtl. Conservation, Div. of Air Quality, *Disapproved List* (Sept. 9, 2020), https://tinyurl.com/y6pd37f3. On these two lists, 75 out of 128 certifications reported data inaccurately (listed as IDU) and 82 out of 128 certifications had non-representative data reported (listed as NR). The lists also identify two certifications as not having a test report

problems in the certification process.[23] And those problems in the certification process in turn demonstrate why EPA must have a way to check on manufacturers—and hold them accountable—through audits.

## B. Testing Variability Does Not Impede Effective Audit Testing.

### 1. Petitioner relies on a flawed statistical analysis of testing variability.

Contrary to petitioner's claims, potential variability in test results at the certification stage and the audit stage do not render the Rule's audit-testing provision problematic. As Washington's Puget Sound Clean Air Agency found in a study on which EPA relied in finalizing the Rule, testing of wood-heating devices is sufficiently precise to make audit

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(one listed as NTR and the other stating "no test report") and one certification that relied on an incorrect test report.

[23] Amici's examination of testing data from other sources confirms these concerns. *See, e.g.*, Intertek, Certificate of Conformity at 15-17 (July 16, 2020), https://tinyurl.com/y662yhcs (lab disregarded unfavorable test runs without replacing them with additional runs); OMNI-Test Laboratories, Inc., Certification Test Report: Catalytic Wood Burning Factory Built Fireplace Model: 42 Apex at 5, 7, 31 (July 20, 2018), https://www.travisindustries.com/docs/EPA/EPA%20Report%2042%20Apex.pdf (lab relied on data showing model emitted negative particulate matter, which is not possible); OMNI-Test Laboratories, Inc., Certification Test Report: Travis Industries, Inc. Model: Large Flush Wood Hybrid Fyre Insert at 5, 7, 35 (June 2018), https://tinyurl.com/yym7cpkh (same).

testing reliable and effective.[24]

Petitioner misplaces its reliance on a study by Rick Curkeet, which petitioner proffers as evidence of the problem of testing variability. EPA appropriately relied on Puget Sound's demonstration that there were serious flaws in the Curkeet study.[25] As Puget Sound's analysis showed, the Curkeet study suffers from three main defects. First, the Curkeet study incorrectly applied statistics applicable to a normal distribution to data that was not normally distributed.[26] Second, the Curkeet study improperly divided its dataset and drew conclusions from data that were

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[24] *See* Response to Comments at 236; Puget Sound, *Preliminary Review and Critique of Analyses of NSPS Test Method Variability (Curkeet, 2010) and the Relationship of EPA Certified Values to "In-Home Use" (Houck, 2012)* (Dec. 5, 2012) (Puget Sound Study), https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OAR-2009-0734-0060&fp=true&ns=true.

[25] Rick Curkeet & Robert Ferguson, *EPA Wood Heater Test Method Variability Study: Analysis of Uncertainty, Repeatability and Reproducibility Based on the EPA Accredited Laboratory Proficiency Test Database* (Oct. 6, 2010), https://tinyurl.com/y4bq27g6.

[26] Puget Sound Study at 6-7. Normal-distribution statistics apply when the distribution of values falls along a predictable bell-curve. *See, e.g.*, *Palmer v. Shultz*, 815 F.2d 84, 93-94 (D.C. Cir. 1987). In contrast, where the data points are not normally distributed, statisticians use different tests that do not assume that the data falls on a bell curve. *See, e.g.*, *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1164 (Fed. Cir. 2018).

not representative of the dataset as a whole, allowing particularly extreme values to be highlighted and taken out of context.[27] Finally, the Curkeet study conflated absolute difference in values with a confidence interval, leading to a dramatic overestimate of uncertainty.[28] Based on these problems with the Curkeet study, EPA reasonably discounted Curkeet's conclusions.[29] EPA further noted that it performed its own analysis of the data, and found that the Curkeet study was inconsistent with that analysis.[30]

EPA's explanation of why it decided to discount the Curkeet study satisfied its legal obligations. "EPA specifically analyzed and responded" to the study, and identified the flaws that led EPA to reject the study's conclusions. *See International Fabricare Inst. v. EPA*, 972 F.2d 384, 394 (D.C. Cir. 1992). The Court's role is only to ensure that EPA looked at the data and made a reasoned decision—as it did here. *See State Farm*, 463 U.S. at 43.

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[27] *See* Puget Sound Study at 9.

[28] *See id.* at 9-10.

[29] Response to Comments at 236.

[30] *Id.*

### 2. Testing variability is largely attributable to manufacturers' own testing choices.

NESCAUM's analysis shows that testing variability may be minimized if manufacturers use a reliable certification test and scrupulously follow that test method. In issuing the Rule, EPA required labs to follow a certification method designated Method 28R, but allowed for approval of alternative test methods. 40 C.F.R. §§ 60.534(a)(1)(i), 60.5476; 80 Fed. Reg. at 13,709. At the request of manufacturers, EPA approved ASTM 3053, an industry-developed test, as an alternative test method.[31] But using ASTM 3053 produces more variability than Method 28R because ASTM 3053 contains fewer specific instructions. To illustrate, where Method 28R states that manufacturers should use fuel logs that are no less than 5/6 the length of the firebox, ASTM 3053 contains no such limitations.[32]

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[31] *See* Letter from Steffan Johnson, EPA, to Justin White, Hearthstone QHPP, Inc. (Feb. 28, 2018), https://tinyurl.com/y2hfp58w.

[32] *Compare* EPA, *Air Emission Measurement Center (EMC): Method 28 – Certification and Auditing of Wood Heaters* § 7.1.4 (Aug. 4, 2017), https://www.epa.gov/emc/method-28-certification-and-auditing-wood-heaters, *with* ASTM Int'l, *Standard Test Method for Determining Particulate Matter Emissions from Wood Heaters Using Cordwood Test Fuel*, https://www.astm.org/Standards/E3053.htm.

A NESCAUM study shows the testing variability that may result from ASTM 3053.[33] NESCAUM tested six wood stoves, including five that used ASTM 3053 for their certifications and one that used Method 28R. NESCAUM replicated the results of the stove certified using Method 28R—in other words, there was no substantial testing variability using that method. However, two of the five stoves using ASTM 3053 had high variability between the certification test results and NESCAUM's results. NESCAUM determined that these stoves used non-typical fueling approaches, such as by burning short logs or logs stacked in unusual ways, which likely explained the variation in test results.[34]

NESCAUM noted that manufacturers could generate more reliable ASTM 3053 test results by conducting certification tests in a manner that was more representative of consumers' ordinary use of the stoves. [35] For example, the manufacturer of one of the stoves in NESCAUM's study used the ASTM 3053 test for certification, but with a representative

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[33] Memorandum from Barbara Morin & Lisa Rector, NESCAUM, to the NESCAUM Board of Directors Concerning the Reproducibility of Test Results in Step 2 Stoves (Sept. 4, 2020), https://tinyurl.com/y6js5wnn.

[34] *Id.* at 4-7.

[35] *Id.* at 8-9.

testing technique (by loading the stove as a consumer would). NESCAUM found that that stove emitted almost exactly the amount in NESCAUM's test that the stove was certified to emit.[36]

NESCAUM concluded that it was able to reproduce certification test results using either Method 28R or ASTM 3053 with little if any testing variability so long as the certification tests were conducted in a manner representative of consumer use. In sum, amici's experiences and analyses confirm that the Rule's audit provisions provide a reliable—and necessary—mechanism for ensuring compliance with the Rule's emissions standards.[37]

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[36] *Id.*

[37] *Id.*

## CONCLUSION

For the reasons stated above, the Court should uphold the Rule and dismiss the petition in its entirety.

Dated: September 21, 2020
Albany, New York

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, William P. Ford, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 3,352 words and complies with the typeface requirements and length limits of Rules 29 and 32(a)(5)-(7) and the corresponding local rules.

/s/ *William P. Ford*

## CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing document with the Court's CM/ECF system on September 21, 2020. I certify that all parties and counsel of record in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: September 21, 2020
Albany, NY

/s/ Nicholas C. Buttino

Appointment

**From**: Patrick, Monique [Patrick.Monique@epa.gov]
**Sent**: 1/29/2021 1:39:50 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Chaudhary, Dimple [Chaudhary.Dimple@epa.gov]; Srinivasan, Gautam [Srinivasan.Gautam@epa.gov]; Marks, Matthew [Marks.Matthew@epa.gov]; Palmer, Karen [Palmer.Karen@epa.gov]; Hogan, Stephanie [Hogan.Stephanie@epa.gov]; Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Lassiter, Penny [Lassiter.Penny@epa.gov]
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**Subject**: Landfill CH4
**Attachments**: MSW Landfills Ba rule.Litigation.Background - Meeting with Petitioners.docx
**Location**: Microsoft Teams Meeting

**Start**: 1/29/2021 2:30:00 PM
**End**: 1/29/2021 3:00:00 PM
**Show Time As**: Tentative

**Required Attendees**: Goffman, Joseph; Chaudhary, Dimple; Srinivasan, Gautam; Marks, Matthew; Palmer, Karen; Hogan, Stephanie; Tsirigotis, Peter; Lassiter, Penny
**Optional Attendees**: Rakosnik, Delaney; Campbell, Ann; Razor, Lila; Hooks, Samantha; Monique Patrick

POC: Monique Patrick

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# Microsoft Teams meeting

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Message

**From**: Millett, John [Millett.John@epa.gov]
**Sent**: 3/15/2021 2:48:55 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Kim, Eun [Kim.Eun@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]; Shoaff, John [Shoaff.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]
**CC**: DeLuca, Isabel [DeLuca.Isabel@epa.gov]; Stevens, Katherine [stevens.katherine@epa.gov]
**Subject**: CSAPR comms materials
**Attachments**: Revised CSAPR Update Internal Questions and Answers.docx; Revised CSAPR Update Internal State Data Fact Sheet.docx; Revised CSAPR Update Factsheet for Final Rule.docx; Revised CSAPR Update Talking Points.docx

These are going to the regions ahead of their noon call with CAMD today. Internal q/a and talking points, plus fact sheets planned to be posted along with the rule.

---

**From:** LaCount, Melanie <LaCount.Melanie@epa.gov>
**Sent:** Monday, March 15, 2021 10:43 AM
**To:** Millett, John <Millett.John@epa.gov>
**Cc:** Haeuber, Richard <Haeuber.Richard@epa.gov>; Ashley, Jackie <Ashley.Jackie@epa.gov>
**Subject:** RE: Status of comms materials

John – here is what we are about to share with the regions

- Overview factsheet
- Internal Q&As
- Internal State Data Factsheet
- Internal Talking Points

Let me know if you have any questions!
Thanks,
Melanie

---

**From:** Millett, John <Millett.John@epa.gov>
**Sent:** Monday, March 15, 2021 9:40 AM
**To:** LaCount, Melanie <LaCount.Melanie@epa.gov>
**Cc:** Haeuber, Richard <Haeuber.Richard@epa.gov>
**Subject:** RE: Status of comms materials

**Ex. 5 Deliberative Process (DP)**

a-dated bullets fashion.

---

**From:** LaCount, Melanie <LaCount.Melanie@epa.gov>
**Sent:** Monday, March 15, 2021 9:14 AM
**To:** Millett, John <Millett.John@epa.gov>
**Cc:** Haeuber, Richard <Haeuber.Richard@epa.gov>
**Subject:** RE: Status of comms materials

Just to clarify - he doesn't need additional Q&A?

**From:** Millett, John <Millett.John@epa.gov>
**Sent:** Monday, March 15, 2021 9:13 AM
**To:** LaCount, Melanie <LaCount.Melanie@epa.gov>
**Cc:** Haeuber, Richard <Haeuber.Richard@epa.gov>
**Subject:** RE: Status of comms materials

He's good with your approach.

---

**From:** LaCount, Melanie <LaCount.Melanie@epa.gov>
**Sent:** Monday, March 15, 2021 9:08 AM
**To:** Millett, John <Millett.John@epa.gov>
**Cc:** Haeuber, Richard <Haeuber.Richard@epa.gov>
**Subject:** RE: Status of comms materials

OK, please keep me posted. Thanks!

---

**From:** Millett, John <Millett.John@epa.gov>
**Sent:** Monday, March 15, 2021 8:06 AM
**To:** LaCount, Melanie <LaCount.Melanie@epa.gov>
**Cc:** Haeuber, Richard <Haeuber.Richard@epa.gov>
**Subject:** RE: Status of comms materials

Thanks and whoa Nellie, Melanie – saw this earlier, just replying now. I'll fill Joe in on status at the 9 am. We should be good.

---

**From:** LaCount, Melanie <LaCount.Melanie@epa.gov>
**Sent:** Monday, March 15, 2021 1:09 AM
**To:** Millett, John <Millett.John@epa.gov>
**Cc:** Haeuber, Richard <Haeuber.Richard@epa.gov>
**Subject:** FW: Status of comms materials
**Importance:** High

John – please see my update below, esp the note following the Q&A re: Joe's points. Here is the nearly-final draft Q&A in case it is helpful – along with the factsheet, I think we cover his concerns, but he may want more historical context. I will send the finals asap in the morning.

---

**From:** LaCount, Melanie
**Sent:** Monday, March 15, 2021 1:06 AM
**To:** Hooper, Daniel <hooper.daniel@epa.gov>; Harvey, Reid <Harvey.Reid@epa.gov>; Stenhouse, Jeb <Stenhouse.Jeb@epa.gov>; Lifland, David <Lifland.David@epa.gov>; Fisher, Brian <Fisher.Brian@epa.gov>; Murray, Beth <Murray.Beth@epa.gov>
**Cc:** Haeuber, Richard <Haeuber.Richard@epa.gov>; Liu, Kimberly <Liu.Kimberly@epa.gov>; Hollerbach, Kevin <hollerbach.kevin@epa.gov>
**Subject:** Status of comms materials
**Importance:** High

Here is an update on where the materials stand. All are in the RCU comms directory.

- **Revised CSAPR Update Factsheet:** No comments outstanding. Needs one final, clear-eyed review just for certainty. I can do this in the morning.
- **State Data Factsheet:** Ditto
- **Talking points:** Ditto

- **Q&A:** One comment outstanding – from Dan Schramm on page 8 re: the impact of the rule on coal-fired plants.

Ex. 5 Deliberative Process (DP)

- **Web page:** Drafted and in good shape. We can start loading final docs into the draft version once we are ready.
- **Recall Factsheet** No comments outstanding.
- **Bank Conversation Factsheet:** No comments outstanding.
- **Safety Valve Factsheet:** No comments outstanding.

Let me know of you have any questions.

Melanie LaCount
Communications Director
US EPA Clean Air Markets Division
202.343.9587 office
202.641.5147 cell

Message

**From**: Kabanda, Thierry [Kabanda.Thierry@epa.gov]
**Sent**: 1/25/2021 4:31:17 PM
**To**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC**: Rakosnik, Delaney [rakosnik.delaney@epa.gov]
**Subject**: FW: Material for today's Light-duty Vehicle meeting with OAR and OGC leadership
**Attachments**: SAFE 1 and 2 Briefing for the OAR and OGC leadership , Final.docx

Hey Tomas,

Here are some material for today's 3:30PM. You should have also received it from the OAR Briefing.

**From:** Charmley, William <charmley.william@epa.gov>
**Sent:** Monday, January 25, 2021 10:54 AM
**To:** OAR Briefings <OAR_Briefings@epa.gov>
**Cc:** OTAQ Materials <OTAQMaterials@epa.gov>; Orlin, David <Orlin.David@epa.gov>; Srinivasan, Gautam <Srinivasan.Gautam@epa.gov>; Simon, Karl <Simon.Karl@epa.gov>
**Subject:** Material for today's Light-duty Vehicle meeting with OAR and OGC leadership

Please find attached material for today's 3:30 – 4:15pm meeting "Light-duty Vehicle SAFE 1 and 2" meeting.

Message

**From**: Rakosnik, Delaney [rakosnik.delaney@epa.gov]
**Sent**: 1/27/2021 5:44:23 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**CC**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Grundler, Christopher [grundler.christopher@epa.gov]; Dunham, Sarah [Dunham.Sarah@epa.gov]
**Subject**: RE: Welcome back, Joe!

Hi Joe,

If you want to take this meeting, I'll certainly reply back. Please let me know if you want to take this.

Many thanks!

Delaney Rakosnik
Staff Assistant
Immediate Office of the Assistant Administrator
Office of Air and Radiation, USEPA
Room 5406A, 1200 Pennsylvania Avenue NW
Washington, DC 20460
Voice: 202-564-0935
Email: rakosnik.delaney@epa.gov

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Wednesday, January 27, 2021 12:39 PM
**To:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Rakosnik, Delaney <rakosnik.delaney@epa.gov>
**Cc:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>; Grundler, Christopher <grundler.christopher@epa.gov>; Dunham, Sarah <Dunham.Sarah@epa.gov>
**Subject:** FW: Welcome back, Joe!

Please see below. I think we need a personalized and more specific response to this one – and probably should accept the invitation. Please advise with additional thoughts. Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Miles Keogh <mkeogh@4cleanair.org>
**Sent:** Wednesday, January 27, 2021 12:22 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>; Rakosnik, Delaney <rakosnik.delaney@epa.gov>
**Subject:** Welcome back, Joe!

Dear Joe,

First of all: congratulations! I can't tell you how gratified I am to see you at EPA again, partly because of your deep expertise but also because of the good experience I had back when I was at NARUC working with OAR when you were

there. As my mom sometimes says, "it's great to know a guy, it's better when you like him." Welcome back, I hope things are off to a great start for you so far.

I'd love to connect with you to figure out the best way for NACAA to put a strong bridge in place between our agencies and your office to advance our shared priorities.

First and most urgently, we're having a virtual board and committee chairs meeting on Thursday, February 18, and I'd like to invite you (and whoever else makes sense from OAR at that time) to zoom into that meeting for an hour to accomplish some of that early bridge-building. Do you think that might be possible? I'm looking at 2-3 pm, but anytime in the afternoon that fits your schedule, I can make work. (Aside - I'm copying Delaney Rakosnik and Ann Campbell so they're aware of the ask – thanks in advance, friends!)

Second, as political appointees start to get named and confirmed at EPA, we'd like to work with y'all on some of the shared priorities that we included in NACAA's transition recommendations and that we're seeing roll out rapidly from the Biden-Harris Administration. (I know you've seen it already, but I've linked it here to make it easy to find). I'd like to flag that as the next Administrator, Deputy Administrator, and an AA for Air are confirmed, we'd be honored and excited to have our leadership connect with them about how we can work together on advancing clean air and addressing climate damage – and I think NACAA has a lot to offer to them as well. I hope you'll keep that in mind, and that we can be resources to each other for that.

Finally, I'm really excited for the work ahead! Please reach out to me anytime I can be of help to you. The air directors on the NACAA roster are legitimately excited to work together with EPA in the coming years, and I am too. Whatever I can do to support you as things start rolling ahead, please count on it! I'm reachable at all hours at 571-970-6795, which you should feel welcome to use anytime.

Wishing you well, Miles

Miles E. Keogh
Executive Director
National Association of Clean Air Agencies
1530 Wilson Blvd Suite 320
Arlington VA 22209
(571) 970-6795
mkeogh@4cleanair.org
www.4cleanair.org

Message

**From:** Campbell, Ann [Campbell.Ann@epa.gov]
**Sent:** 1/26/2021 2:41:20 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**CC:** Rakosnik, Delaney [rakosnik.delaney@epa.gov]; Kabanda, Thierry [Kabanda.Thierry@epa.gov]
**Subject:** Meeting with David Doniger (Climate and Clean Energy Program) re: Power Plant Plans & CBD NAAQS Petition
**Attachments:** Climate and Clean Energy Program_012621.rtf

Joe, Tomas – for recordkeeping purposes (and often for rulemaking dockets) we must keep a record of all transactions with external stakeholders. We've developed the attached sign in sheet to meet this need simply. I have filled it in with the information we have currently have regarding who will be in attendance and what they wish to discuss to give you a leg up. If you could confirm the information already populated in the sheet and/or remove/add additional information, that would be helpful. Don't worry too much about getting email addresses. Please let me know if you have any questions.

Climate and Clean Energy Program...

---

**Subject:** Meeting with David Doniger (Climate and Clean Energy Program) re: Power Plant Plans & CBD NAAQS Petition
**Location:** Microsoft Teams Meeting

**Start:** Tue 1/26/2021 4:00 PM
**End:** Tue 1/26/2021 4:30 PM

**Recurrence:** (none)

**Meeting Status:** Meeting organizer

**Organizer:** Goffman, Joseph
**Required Attendees:** Carbonell, Tomas; Tsirigotis, Peter; Mike Koerber (Koerber.Mike@epa.gov)

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Microsoft Teams meeting

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Date: January 26, 2021

Meeting: **Climate and Clean Energy Program**

Rule(s) Discussed: Power Plants & CBD NAAQS Petition

Written Materials? Yes/ No

| NAME | ORGANIZATION | EMAIL |
|---|---|---|
| Joe Goffman | EPA/OAR | |
| Tomas Carbonell | EPA/OAR | |
| David Doniger | Climate and Clean Energy Program | |
| John Walke | Climate and Clean Energy Program | |
| Ben Longstreth | Climate and Clean Energy Program | |
| Starla Yeh | Climate and Clean Energy Program | |
| Peter Tsirigotis | EPA/OAR/OAQPS | |
| Mike Koerber | EPA/OAR/OAQPS | |
| | | |
| | | |
| | | |

Message

**From:** POLITICO Pro [alert@email.politicopro.com]
**Sent:** 1/26/2021 2:34:07 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** BlackRock sets net-zero goal for 2050

**BlackRock sets net-zero goal for 2050**

By Zack Colman

01/26/2021 09:29 AM EST

BlackRock, the world's largest asset manager, said it hopes to guide its portfolio to net-zero emissions by 2050 by pushing the companies in which it's invested to do the same — while threatening to divest from laggard firms.

**Details:** The announcement in CEO Larry Fink's annual letter to clients laid out expectations the company has for clients to document and reduce their emissions. It said it will introduce a "heightened scrutiny model" to firms that fail to make adequate progress, including actions such as voting against management and "flag these holdings for potential exit in our discretionary active portfolios."

The bulk of BlackRock's investments, however, are passive, giving the company less less direct say over how it implements many of its climate pledges.

BlackRock said it would begin to track the Scope 3 emissions — those caused by end-users — of their entire investment portfolio this year. It will also publish its share of investments that are currently aligned with a net-zero path, roll out new investment products in areas like electric vehicles, and incorporate climate modeling into its market assumptions.

"We also believe that climate transition creates a historic investment opportunity," Fink wrote. "With the world moving to net zero, BlackRock can best serve our clients by helping them be at the forefront of that transition."

**Context:** Environmental and financial watchdog groups offered qualified praise of the steps, saying the letter lacked details such as whether BlackRock would permit carbon offsets, a climate accounting mechanism that has attracted derision for its spotty track record in reducing emissions.

"This doesn't rise to the visionary leadership we need from the world's largest investor in coal, oil and gas, and deforestation-linked commodities," said Gaurav Madan, senior forests and lands campaigner at Friends of the Earth, which operates in the BlackRock's Big Problem coalition.

The steps are the latest iteration of BlackRock's evolving strategy on climate change. Fink last January said he would put sustainability and climate at the heart of BlackRock's strategy, including voting against company boards for insufficient action to reduce emissions and pulling actively managed funds from coal firms.

That 2020 letter was credited with pushing a number of companies and trade associations to adopt their own climate pledges. But critics say BlackRock did not always live up to its vows to vote against management with weak climate plans.

*To view online*:
https://subscriber.politicopro.com/energy/article/2021/01/blackrock-sets-net-zero-goal-for-2050-2030671

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Arlington, VA 22209
USA

Message

**From**: Grundler, Christopher [grundler.christopher@epa.gov]
**Sent**: 1/28/2021 4:23:37 AM
**To**: Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]
**CC**: Harvey, Reid [Harvey.Reid@epa.gov]; Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: Re: CSAPR Update Options Selection

Touché

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
(202) 343-9140 (Office)
(734) 645-5221 (Mobile)

On Jan 27, 2021, at 10:12 PM, Tsirigotis, Peter <Tsirigotis.Peter@epa.gov> wrote:

It's past 10 pm so I don't know how regular the order is...

On Jan 27, 2021, at 10:05 PM, Grundler, Christopher <grundler.christopher@epa.gov> wrote:

The return of regular order !

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
(202) 343-9140 (Office)
(734) 645-5221 (Mobile)

On Jan 27, 2021, at 10:01 PM, Harvey, Reid <Harvey.Reid@epa.gov> wrote:

On Jan 27, 2021, at 10:00 PM, Goffman, Joseph <Goffman.Joseph@epa.gov> wrote:

Got a late-evening dialogue going on the finer points of the ADP during my first week back! Yay! My work is done here.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>
**Sent:** Wednesday, January 27, 2021 9:59 PM
**To:** Harvey, Reid <Harvey.Reid@epa.gov>
**Cc:** Grundler, Christopher <grundler.christopher@epa.gov>; Goffman, Joseph <Goffman.Joseph@epa.gov>; Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Subject:** Re: CSAPR Update Options Selection

**Ex. 5 Deliberative Process (DP)**

On Jan 27, 2021, at 9:53 PM, Harvey, Reid <Harvey.Reid@epa.gov> wrote:

**Ex. 5 Deliberative Process (DP)**

Reid

PS - like you, I'm glad the team is re-united!

On Jan 27, 2021, at 9:32 PM, Grundler, Christopher <grundler.christopher@epa.gov> wrote:

**Ex. 5 Deliberative Process (DP)**

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
(202) 343-9140 (Office)
(734) 645-5221 (Mobile)

On Jan 27, 2021, at 9:27 PM, Tsirigotis, Peter <Tsirigotis.Peter@epa.gov> wrote:

**Ex. 5 Deliberative Process (DP)**

On Jan 27, 2021, at 9:06 PM, Goffman, Joseph <Goffman.Joseph@epa.gov> wrote:

Wow. Maybe it is like riding a bicycle?? Well, I wish. Got lucky this time. In any event, please do not hesitate to prompt, prod, or intervene as required for success. Thank you.

PS Hi, Reid. So very glad we're back together.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Grundler, Christopher

<grundler.christopher@epa.gov>
**Sent:** Wednesday, January 27, 2021 8:47 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>; Harvey, Reid <Harvey.Reid@epa.gov>
**Subject:** Re: CSAPR Update Options Selection

Joe-

**Ex. 5 Deliberative Process (DP)**

Copying Reid if he'd like to add anything

C

Christopher Grundler,
Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
(202) 343-9140 (Office)
(734) 645-5221 (Mobile)

On Jan 27, 2021, at 8:13 PM, Goffman, Joseph <Goffman.Joseph@epa.gov> wrote:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation

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mental
Protecti
on
Agency

Message

**From**: Millett, John [Millett.John@epa.gov]
**Sent**: 3/15/2021 2:24:22 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**CC**: DeLuca, Isabel [DeLuca.Isabel@epa.gov]; Stevens, Katherine [stevens.katherine@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: CSAPR -- q/a, fact sheets
**Attachments**: Internal Questions and Answers for Final Rule DRAFT.docx; State Data Fact Sheet for Final Rule DRAFT.docx; Revised CSAPR Update Factsheet for Final Rule DRAFT.docx

The remaining CSAPR comms products are attached. Q/a are intended to be internal. The fact sheets will be posted along with the rule. There may be another round forthcoming, but we don't expect major edits. CAMD plans to share with the ADDs ahead of their special purpose call today at noon.

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/29/2021 2:24:56 AM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: Re: READING: Calendar & Materials January 29, 2021

**Ex. 5 Deliberative Process (DP)**

Have good evening.

Ann (Campbell) Ferrio
Chief of Staff
Office of Air and Radiation
(202) 566-1370

On Jan 28, 2021, at 9:22 PM, Goffman, Joseph <Goffman.Joseph@epa.gov> wrote:

# Ex. 5 Deliberative Process (DP)

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Campbell, Ann <Campbell.Ann@epa.gov>
**Sent:** Thursday, January 28, 2021 9:18 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** Re: READING: Calendar & Materials January 29, 2021

Of course. My apologies. I thought Thierry and Delaney were doing this already. I will address it.

Ann (Campbell) Ferrio
Chief of Staff
Office of Air and Radiation
(202) 566-1370

On Jan 28, 2021, at 9:11 PM, Goffman, Joseph <Goffman.Joseph@epa.gov> wrote:

Deliverance! Thank you! Please serve this up every afternoon/evening. It will be immensely, immensely helpful if Tomas, Deputy AA #2, and I can count on receiving every day one, single email from you (or someone you designate) with all of the read-ahead materials in one place. It will be life-changing. Thanks, again.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Campbell, Ann <Campbell.Ann@epa.gov>
**Sent:** Thursday, January 28, 2021 8:51 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** READING: Calendar & Materials January 29, 2021

Joe, attached are the materials I have received for tomorrow's meetings. Let me know if this helps. And let me know if you need anything else.

<image001.gif>

**Goffman, Joseph Calendar**
Goffman.Joseph@epa.gov
On Friday, January 29, 2021
Time zone: (UTC-05:00) Eastern Time (US & Cana
(Adjusted for Daylight Saving Time)

<image002.gif>

**January 2021**

Su Mo Tu We Th Fr Sa
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<image004.gif> Busy
<image005.gif> Tentative
<image006.gif> Free
<image007.gif> Out of Office
<image008.gif> Working Elsewhere
<image009.gif> Outside of Workin Hours

## January 2021

<image002.gif>

<image010.gif> **Fri, Jan 29**

| | | |
|---|---|---|
| <image009.gif> | **Before 8:00 AM** | **Free** |
| <image006.gif> | **8:00 AM – 8:30 AM** | **Free** |
| <image004.gif> | 8:30 AM – 9:00 AM | Check-In |
| <image004.gif> | 9:00 AM – 9:30 AM | Air Issues Meeting |
| <image004.gif> | 9:30 AM – 10:00 AM | Landfill CH4 |

| | | |
|---|---|---|
| <image004.gif> | 10:00 AM – 10:30 AM | Management Round Table |
| <image004.gif> | 10:30 AM – 11:00 AM | OAR/ARLO Discussion |
| <image004.gif> | 11:00 AM – 11:45 AM | AIM Act – NODA (Materials attached) |
| <image006.gif> | **11:45 AM – 12:00 PM** | **Free** |
| <image004.gif> | 12:00 PM – 12:30 PM | One-on-One with Sarah Dunham |
| <image004.gif> | 12:30 PM – 1:00 PM | One-on-One with Jon Edwards |
| <image004.gif> | 1:00 PM – 2:00 PM | Overview of Key OAQPS Priority Topics (Materials attached) |
| <image006.gif> | 2:00 PM – 2:45 PM | Appointees IT Training (Option 1) |
| <image006.gif> | **2:45 PM – 3:00 PM** | **Free** |
| <image004.gif> | 3:00 PM – 4:00 PM | Briefing: PFAS Hot Issues (Materials attached) |
| <image004.gif> | 4:00 PM – 4:30 PM | Introductory Video-Call: Michael Regan and Joe Goffman (We provi your bio at Kathleen Lance's request) |
| <image004.gif> | 4:30 PM – 5:00 PM | To Discuss CRA |
| <image004.gif> | 5:00 PM – 5:30 PM | Check-In |
| <image004.gif> | 5:30 PM – 6:00 PM | Cars Working Group |
| <image009.gif> | **After 6:00 PM** | **Free** |

<image002.gif>

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Appointment

**From**: Patrick, Monique [Patrick.Monique@epa.gov]
**Sent**: 1/22/2021 3:12:15 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Culligan, Kevin [Culligan.Kevin@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**CC**: Campbell, Ann [Campbell.Ann@epa.gov]; Rakosnik, Delaney [rakosnik.delaney@epa.gov]; Patrick, Monique [Patrick.Monique@epa.gov]

**Subject**: Methane CRA/DC Circuit ACE
**Location**: Microsoft Teams Meeting

**Start**: 1/22/2021 8:00:00 PM
**End**: 1/22/2021 8:30:00 PM
**Show Time As**: Tentative

**Required Attendees**: Goffman, Joseph; Tsirigotis, Peter; Culligan, Kevin; Carbonell, Tomas
**Optional Attendees**: Campbell, Ann; Rakosnik, Delaney; Monique Patrick

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# Microsoft Teams meeting

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Message

**From:** Grundler, Christopher [grundler.christopher@epa.gov]
**Sent:** 1/29/2021 10:17:57 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**CC:** Newberg, Cindy [Newberg.Cindy@epa.gov]; Kocchi, Suzanne [Kocchi.Suzanne@epa.gov]
**Subject:** Review Draft: HFC Baseline NODA
**Attachments:** OD-review-HFC Baseline NODA 1.29.21.docx

**Flag:** Follow up

Joe and Tomás:

Thanks for the discussion today on the HFC NODA. Attached is the current draft for your review. It's not long. Note that

**Ex. 5 Deliberative Process (DP)**

Enjoy your weekend,

Chris

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
202.343.9140 (o)
734.645.5221 (m)

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/29/2021 2:22:54 AM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: FOR YOUR APPROVAL: Briefing Doc for Options Selection - Revised CSAPR Update Rule - Monday, February 1 (11 am - 12 pm)
**Attachments**: Final_Administrator Briefing_Revised CSAPR Update_Options Selection_02.01.21.docx

Joe, attached for your final approval are the materials for the Acting Administrator's briefing on Monday. The deadline for submission is typically 2p the day prior to the briefing (i.e., 2p tomorrow).

Ann (Campbell) Ferrio
Chief of Staff
Office of Air and Radiation
(202) 566-1370

Message

**From:** POLITICO Pro [alert@email.politicopro.com]
**Sent:** 1/25/2021 3:26:02 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** In a first, corporations unite behind organized energy markets

**In a first, corporations unite behind organized energy markets**

By Nancy Vu

01/25/2021 10:03 AM EST

Walmart, Johnson & Johnson, Amazon and dozens of other large corporations on Monday asked the Biden administration to expand organized wholesale energy markets to speed delivery of clean and renewable energy and lower the cost of electricity to large buyers.

The policy statement, developed by the Renewable Energy Buyers Alliance, is the first of its kind from the membership association, which was founded in 2019 to connect more than 200 large power users — including corporations in healthcare, technology and manufacturing — to energy providers and service providers.

**Details:** The group called on the administration to expand wholesale markets to deliver cheaper and more efficient clean energy, support policies to catalyze clean energy production, and increase federal funding for clean energy research and development.

Under the proposal, FERC would be empowered to give big energy buyers more leverage in the market, which the group said would effectively spur investment in clean energy.

"Without organized markets, then we're just sitting around waiting for a 100 percent clean energy standard to happen to us," Miranda Ballentine, CEO of the Renewable Energy Buyers Alliance, said in an interview. "Our members are not really interested in waiting around for the government to do it to them. They want to use their procurement power to make it happen faster, and we need organized markets to do that."

The plan also calls for the federal government to update the current patchwork of clean energy policies.

**It's a big deal:** The policy proposal is backed by some of the world's biggest brands, with millions of employees, trillions of dollars in combined revenue and enormous influence in Washington. The signatories cut across sectors and include Cargill, McDonald's, Microsoft and Nestle.

Corporations are embracing clean and renewable energy because it's good for business and morale, Ballantine said.

"Let's be real, commercial and industrial energy customers are the second-largest cause of energy-related greenhouse gas emissions in the United States," Ballentine said. "They know they're causing climate change and they want to solve it because it's good for their business and because it's their responsibility to do so."

President Joe Biden has made climate policy a central theme of his administration and wants to make the U.S. carbon-neutral by 2050.

*To view online*:
https://subscriber.politicopro.com/sustainability/whiteboard/2021/01/in-a-first-corporations-unite-behind-organized-energy-markets-3986574

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USA

Message

**From**: Kim, Eun [Kim.Eun@epa.gov]
**Sent**: 3/12/2021 10:22:59 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC**: Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: READING: Materials for Monday, March 15, 2021
**Attachments**: Chevron Platform Decommissioning Part 2 paper 03112021.docx; ChevronRevisedLetter_03112021.docx; Orsted Cable Laying Vessel Paper _03-11-2021.docx; CAAAC Briefing-3-11-21_Final.docx; FW: For Joe's Reading Folder: Signed Wildland Fire MOU

---

**Goffman, Joseph Calendar**
Goffman.Joseph@epa.gov
On Monday, March 15, 2021
Time zone: (UTC-05:00) Eastern Time (US & Canada)
(Adjusted for Daylight Saving Time)

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**March 2021**

| Su | Mo | Tu | We | Th | Fr | Sa |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | 29 | 30 | 31 | | | |

Busy — Tentative — Free
Out of Office — Working Elsewhere — Outside of Working Hours

## March 2021

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### Mon, Mar 15

| | | |
|---|---|---|
| | **Before 8:00 AM** | **Free** |
| | **8:00 AM – 9:00 AM** | **Free** |
| | 9:00 AM – 9:30 AM | Management Roundtable |
| | 9:30 AM – 10:00 AM | Air Issues Meeting |
| | 10:00 AM – 10:30 AM | Scheduling Meeting |
| | 10:30 AM – 11:15 AM | Informational Briefing on Outer Continental Shelf (OCS) Permitting Issues Part 2 (materials attached, 3 docs) |
| | 11:15 AM – 12:00 PM | OAQPS Weekly |
| | **12:00 PM – 1:45 PM** | **Free** |
| | 1:45 PM – 3:00 PM | CAAAC Session (materials attached, 1 doc) |
| | 2:00 PM – 3:00 PM | Senior Staff Meeting |

| | | |
|---|---|---|
| ■ | 3:00 PM – 3:45 PM | OAP Weekly |
| ■ | 3:45 PM – 4:00 PM | General Chris F/Joe |
| ■ | 4:00 PM – 5:00 PM | Briefing: Wildland Fire Leadership Council (WFLC) report (email attached with docs) |
| ■ | 5:00 PM – 5:30 PM | Connecting on oil and gas |
| □ | **After 5:30 PM** | **Free** |

---

Eunjung Kim
Special Assistant
Office of Air and Radiation
(202) 815-7252

Appointment

**From**: Koerber, Mike [Koerber.Mike@epa.gov]
**Sent**: 1/26/2021 2:16:33 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]

**Subject**: Accepted: Meeting with David Doniger (Climate and Clean Energy Program) re: Power Plant Plans & CBD NAAQS Petition
**Location**: Microsoft Teams Meeting

**Start**: 1/26/2021 9:00:00 PM
**End**: 1/26/2021 9:30:00 PM
**Show Time As**: Busy

Message

**From**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Sent**: 1/22/2021 2:03:04 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: CH4 CRA

# Ex. 5 Deliberative Process (DP)

Tomás

Biotechnology Innovation Organization

January 22, 2021

The Honorable Joseph R. Biden, Jr.
President
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear President Biden:

On behalf of the Biotechnology Innovation Organization (BIO), the nearly 1000 companies, universities, and biotech organizations we represent comprised of millions of scientists, researchers and entrepreneurs, congratulations on your historic inauguration. BIO pledges to work with you and your Administration to advance the cause of truth and scientific innovation to address the four overlapping and compounding crises of the COVID-19 crisis, the resulting economic crisis, the climate crisis, and the racial equality crisis.

On the climate crisis, BIO applauds you for rejoining the Paris Agreement on your first day in office. As you begin to take immediate action in the first ten days of your administration to address the climate crisis, BIO urges the federal government to support pioneering technology breakthroughs that reduce greenhouse gas emissions in manufacturing, transportation, and agricultural supply chains to build a stronger, more resilient, and environmentally sustainable economy. BIO recommends the following actions to address the climate crisis:

1. **Leverage the Regulatory System to Quickly Deploy Climate-Positive Biotechnologies**

   Biotechnology is already contributing to reductions in greenhouse gas emissions in agriculture, manufacturing, and transportation. Yet, it has the potential to yield significantly more environmental benefits if we leverage the regulatory system to quickly review and speed adoption of new technologies that can sustainably grow the economy and help reduce greenhouse gas emissions. We have seen the impact of this approach on innovative technologies like synthetic biology and gene editing, which have helped to mobilize COVID cures and therapies. To realize the full climate-positive potential of biotechnologies and products, the Biden Administration should:

   - Direct agencies to expedite regulatory pathways for biotechnologies and products that advance environmental, animal, and public health goals.
   - Ensure environmental regulation of manufacturing recognizes the environmental benefits of utilizing renewable chemicals throughout such processes.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200
202.488.6307
bio.org

## 2. Buy "Green"

Biobased manufacturing uses biology to convert agricultural and other renewable or waste feedstocks into everyday consumer products, thus reducing our dependence on petrochemicals and growing a green American economy that is more resilient and self-sustaining. A new approach to manufacturing will also help rebuild our national economy and workforce in a way that addresses climate change and enhances human health through improved air quality. To deploy biobased technologies and products and create more sustainable supply chains, we should take immediate steps to:

- Direct federal agencies and their contractors to buy biobased products.
- Redirect or reallocate available funds to existing federal programs to promote the use and consumption of biobased products.
- Encourage or incentivize the use of existing or future COVID-19 relief and recovery funding to purchase biobased products to meet the demand for personal protection equipment, sterilizing, and cleaning products, and with respect to broader efforts to "build back better."

## 3. Deploy Sustainable Fuels

Liquid biofuels provide a readily available technology for reducing transportation air pollution and enabling value-added agriculture to be a key part of the solution to climate change. Supporting the production and deployment of sustainable fuels is essential to significantly reducing emissions in automobiles, planes, ships, and other forms of transportation, while also creating quality jobs across rural America. Specifically, the Biden Administration should:

- Cease issuance of Renewable Fuel Standard (RFS) Small Refinery Exemptions to unqualified refineries.
- Build on the success of the RFS to develop and implement a Low Carbon Fuel Standard that is technology and feedstock neutral and ensures agriculture and biofuels are part of the solution to reducing emissions.
- Direct agencies to advance stalled pathways and facility registrations for advanced and cellulosic biofuel technologies.
- Instruct federal agencies and their contractors to purchase sustainable fuels in both ground and air transportation.

## 4. Regain America's Global Leadership against Climate Change

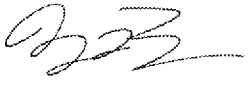
The United States must reestablish its global leadership in the fight to halt climate change through increased engagement with international allies, and by re-joining international agreements to decrease greenhouse gas emissions. Further, as the United States works with its allies to set new and ambitious climate agendas, it is imperative that biotechnology be treated and incentivized as a key solution to climate change and sustainable

development. Three critical actions to support U.S. global leadership on climate change are:

- Maintain American global leadership in innovation and broaden access to such innovations around the world, strengthen global rules on intellectual property, remove tariff and non-tariff barriers to the trade of biotechnology products, encourage regulatory harmonization, and enable the free flow of biological data across borders.
- Place biotechnology at the center of U.S. trade policy to achieve sustainability and address challenges like climate change through innovation and technology.

By proactively advancing biotechnology, we can take bold and drastic action to address the climate crisis. We join the Nation in optimism that your Administration marks a new opportunity for science to guide our response to the climate crisis and return our Nation and the world to health and prosperity.

Yours sincerely,



Michelle McMurry-Heath
President and CEO
Biotechnology Innovation Organization

Biotechnology Innovation Organization

# FIGHTING CLIMATE CHANGE THROUGH BIOTECHNOLOGY INNOVATION

In order to meet climate change commitments, it is crucial to lead with science and U.S. innovation. The federal government can support pioneering technology breakthroughs that reduce greenhouse gas emissions in manufacturing, transportation, and agricultural supply chains to build a stronger, more resilient, and environmentally sustainable economy. BIO supports comprehensive climate change legislation and recommends the following executive actions that can be taken immediately to jumpstart efforts to address climate change:

## LEVERAGE THE REGULATORY SYSTEM TO QUICKLY DEPLOY CLIMATE-POSITIVE BIOTECHNOLOGIES

Biotechnology is already contributing to reductions in greenhouse gas emissions in agriculture, manufacturing, and transportation. Yet, it has the potential to yield significantly more environmental benefits if we leverage the regulatory system to quickly review and speed adoption of new technologies that can sustainably grow the economy and help reduce greenhouse gas emissions. We have seen the impact of this approach on innovative technologies like synthetic biology and gene editing, which have helped to mobilize COVID-19 cures and therapies. To realize the full climate-positive potential of biotechnologies and products, the Biden Administration should:

- **Direct** agencies to expedite regulatory pathways for biotechnologies and products that advance environmental, animal, and public health goals.
- **Ensure** environmental regulation of manufacturing recognizes the environmental benefits of utilizing renewable chemicals throughout such processes.

## BUY "GREEN"

Biobased manufacturing uses biology to convert agricultural and other renewable or waste feedstocks into everyday consumer products, thus reducing our dependence on petrochemicals and growing a green American economy that is more resilient and self-sustaining. A new approach to manufacturing will also help rebuild our national economy and workforce in a way that addresses climate change and enhances human health through improved air quality. To deploy biobased technologies and products and create more sustainable supply chains, we should take immediate steps to:

- **Direct** federal agencies and their contractors to buy biobased products.
- **Redirect** or reallocate available funds to existing federal programs to promote the use and consumption of biobased products.
- **Encourage** or incentivize the use of existing or future COVID-19 relief and recovery funding to purchase biobased products to meet the demand for personal protection equipment, sterilizing, and cleaning products, and with respect to broader efforts to "build back better."

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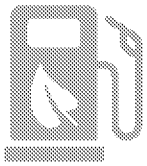
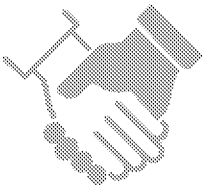
# FIGHTING CLIMATE CHANGE THROUGH BIOTECHNOLOGY INNOVATION



## DEPLOY SUSTAINABLE FUELS

Liquid biofuels provide a readily available technology for reducing transportation air pollution and enabling value-added agriculture to be a key part of the solution to climate change. Supporting the production and deployment of sustainable fuels is essential to significantly reducing emissions in automobiles, planes, ships, and other forms of transportation, while also creating quality jobs across rural America. Specifically, the Biden Administration should:

- **Cease** issuance of Renewable Fuel Standard (RFS) Small Refinery Exemptions to unqualified refineries.
- **Build** on the success of the RFS to develop and implement a Low Carbon Fuel Standard that is technology and feedstock neutral and ensures agriculture and biofuels are part of the solution to reducing emissions.
- **Direct** agencies to advance stalled pathways and facility registrations for advanced and cellulosic biofuel technologies.
- **Instruct** federal agencies and their contractors to purchase sustainable fuels in ground, air, and marine transportation.



## REGAIN AMERICA'S GLOBAL LEADERSHIP AGAINST CLIMATE CHANGE

The United States must reestablish its global leadership in the fight to halt climate change through increased engagement with international allies, and by re-joining international agreements to decrease greenhouse gas emissions. Further, as the United States works with its allies to set new and ambitious climate agendas, it is imperative that biotechnology be treated and incentivized as a key solution to climate change and sustainable development. Three critical actions to support U.S. global leadership on climate change are:

- **Rejoin** the Paris Accords and reaffirm United States leadership within the United Nations and other multinational entities.
- **Maintain** American global leadership in innovation, broaden access to such innovations around the world, strengthen global rules on intellectual property, remove tariff and non-tariff barriers to the trade of biotechnology products, encourage regulatory harmonization, and enable the free flow of biological data across borders.
- **Place** biotechnology at the center of U.S. trade policy to promote sustainability and address challenges like climate change through innovation and technology.

# DRIVING AMERICAN GLOBAL HEALTH & CLIMATE LEADERSHIP THROUGH BIOTECHNOLOGY

DECEMBER 2020

Biotechnology Innovation Organization

Biotechnology Innovation Organization

The United States leads the world in developing technologies that will solve the health and economic crises caused by COVID-19, fight climate change, and improve access to nutritious food. Because of cutting-edge science and a growing understanding of biology and genetics, the U.S. biotechnology sector is uniquely valuable in the context of confronting these global challenges. Biotechnology is also a significant contributor to U.S. economic growth and is creating thousands of high paying jobs in cities and towns across the country.

In recent years, however, America's position as the global leader has come under attack. As countries race to secure access to these technologies, governments are working to weaken global rules and international organizations, instead of investing in innovation. Such efforts undermine the core economic incentives needed to advance science, putting American innovation at risk. Government and industry must work collectively to bolster U.S. leadership. BIO recommends several foreign policy actions that will restore our standing as a global leader on biotechnology, enhance economic growth and job creation, and lay the groundwork for leveraging science and American innovation to solve society's biggest and most pressing challenges.

# BIO'S GLOBAL LEADERSHIP

## CORE ELEMENTS OF AN EFFECTIVE U.S. INTERNATIONAL AGENDA

U.S. leadership in biotechnology is a cornerstone of U.S. economic and national security, and provides a platform from which to exercise global leadership on key issues. To accelerate this process, BIO recommends policies and actions in three categories:

- Enhancing American leadership in global health and pandemic preparedness
- Advancing American trade strategies that enhance the life sciences and grow U.S. bioeconomy jobs
- Driving global climate solutions through American science

## GLOBAL HEALTH AND PANDEMIC PREPAREDNESS

COVID-19 underscores the strategic importance of the biotechnology sector. As the world struggles to get control of this virus, we will need a broad array of treatments and vaccines to enable a return to normal. U.S. biotechnology innovators and their durable global partnerships are advancing an unprecedented effort to combat the disease. Multiple breakthroughs have already been commercialized or are close to commercialization, and we are currently witnessing successful vaccine administration across the world. This industry leadership occurred despite the U.S. government's global disengagement, including its withdrawal from the World Health Organization (WHO).

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## *Restore U.S. membership and leadership in the WHO*

- Re-engage the U.S. broadly within the WHO to:
  - → Coordinate an international response to the ongoing COVID-19 pandemic, including through efforts like the "ACT-Accelerator" initiative and COVAX Facility.
  - → Drive successful WHO workstreams aimed at applying lessons learned through COVID-19 to future pandemic preparedness, including:
    - Engaging in the review of the WHO's International Health Regulations
    - Enhancing global transparency on outbreaks of new epidemics
    - Removing obstacles to information sharing and data about emerging pathogens
    - Advancing "One Health" collaboration that underscores the connectivity between human, animal, and environmental health
  - → Establish global norms for emerging biotechnologies, including genome editing, that will be instrumental in solving numerous public health, environmental, and nutritional challenges resulting from climate change.
- Work collaboratively with allies to restore the WHO's core mission on public health while streamlining the organization's cumbersome process of engagement with external stakeholders, including the biotechnology sector.

## *Enhance and expand global access to medicines and related health products*

As the originator of most new biomedical innovations in the world, the U.S. has a special responsibility to lead global efforts to provide access to new treatments and cures to patients, while preserving the engine of innovation. U.S. biotech innovators are committed to expanding access to their products globally, but international rules protecting intellectual property rights are critical both to the development of new products and to their launch around the world. The launch of 800 COVID-19 related projects and cross-border collaborations in just a few months demonstrates that commitment and the underlying importance of incentives for innovation, including intellectual property protections. The U.S. should take the following steps to enhance and expand access, with a particular focus on promoting equity:

- Lead efforts to build the capacity and ability to deliver needed medical treatments to underserved populations, including establishing regional centers of excellence.
- Advance global harmonization of efficient, science-based regulatory systems for transformative health products, centered on the U.S. Food and Drug Administration (FDA) "gold standard." Harmonization will lead to faster, more efficient, and safer development of transformative treatments and cures for patients everywhere. To achieve this, the U.S. should:
  - → Partner with leaders of other stringent regulatory agencies to promote broader global harmonization of regulatory best practices through the International Council on Harmonization (ICH).
  - → Use the ICH as the forum for driving the development of regulatory standards for new technologies (e.g., gene and cell therapies, gene editing).
  - → Build capacity for regulatory "reliance" on stringent regulatory agency decisions and effective cross-national pooling of resources within low- and middle-income countries.

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## TRADE STRATEGIES TO ENHANCE LIFE SCIENCES AND GROW THE U.S. BIOECONOMY

Executing thoughtful and creative trade strategies is among the most effective means to enhance global science-based collaboration while growing the U.S. bioeconomy. An open global trading and investment system benefits innovators and researchers everywhere by establishing a fair, level playing field for all. Trade agreements help to establish national policies that promote the development of and access to disruptive and transformative biotechnologies that will be required to effectively confront serious public health, environmental, and nutritional challenges.

Yet, the United States has backtracked in recent years to protect "defensive" economic interests at the expense of emerging and innovate sectors, such as biotechnology. Further, the United States has ceded much of its leadership and credibility at global institutions such as the World Trade Organization (WTO).

The support for innovation and cross-border collaboration in the world trading system is challenged by inward-looking, nationalistic models based on imitating or even stealing leading technologies. U.S. leadership is essential to preserve and expand the pro-innovation, pro-collaboration nature of that system. To do so, the United States must reassert its influence within the global trading system by leading efforts to place science and technology at the core of its global economic and strategic interests. Doing so will result in the growth of American bioeconomy jobs and better position us to effectively confront big global challenges. We have an obligation – industry and government – to leverage American strengths and work collectively to remove barriers that restrict the development of the global biotech ecosystem. Specific recommendations include:

### *Recommit to American leadership in global trade*

- Reengage within the **WTO**, leveraging American influence to reform the institution and lead efforts to launch new initiatives focused on liberalizing trade and establishing rules to enable a revolution in science and technology.
- Continue to hold **China** accountable, pressing for critical market-based reforms, intellectual property protection and science-based regulation, working with allies as feasible.
- Enforce existing U.S. trade agreements, including implementation of key agricultural biotechnology provisions of the **U.S.-Mexico-Canada (USMCA)** trade agreement.
- Proactively engage **Europe** on science-based climate and sustainable farming, manufacturing, health, and transportation solutions, asserting the valuable and proven role of biotechnology as a means to achieve climate-positive successes in these sectors.

*Leverage the **U.S.-UK trade agreement** to establish a new trade policy model that enhances both nations' life science strengths and bioeconomy growth potential by:*

→ Establishing strong intellectual property and data flow protections

→ Enhancing commitments to science-based regulations and approaches

→ Growing access to transformative biotechnologies and products to underserved communities

→ Partnering to leverage both nations' economic strength to confront anti-innovation efforts in other parts of the world that weaken society's efforts to fight climate change

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*Leverage Trade Policy to Confront Global Challenges:*

- Commit to advancing transformative biotechnologies that are required to meet global public health, environmental, and nutrition challenges through bilateral and multilateral trade agreements and ensuring a fair and level playing field abroad for U.S. innovators.
- Maintain long-standing U.S. trade policy commitments to intellectual property, which is critical to risk-taking and investment in pre-profit companies at the heart of BIO's membership, as incorporated into Trade Promotion Authority.
- Establish rules for digital trade to ensure data related to life-sciences and technology research and development can flow across borders without compromising personal privacy concerns.
- Proactively confront regulatory systems in other countries that do not facilitate access to transformative biotechnologies and products.
- Work creatively with advanced economies to ensure that the world economic system rewards and sustains global incentives for biotechnology innovation in a way that is fair and balanced.

## ADVANCING GLOBAL CLIMATE SOLUTIONS

The COVID-19 pandemic is exposing the vulnerabilities in our nation's capacity to respond to crisis, maintain supply chains, and withstand economic downturn. At the same time, this crisis highlights the breakthrough potential of science when it is unleashed. We must apply these learnings as we take bold and drastic action to address climate change, the next imminent threat to our society. From an international standpoint, BIO recommends the following actions:

- Proactively advance biotechnology as a valuable tool to combat climate change through broad trade strategy approaches and efforts to reengage in multilateral forums.
- Build broad global support for the U.S. government's recent regulatory modernization for agricultural biotechnology.
- Build a coalition of countries to push back on international treaties such as the Convention on Biological Diversity and the Nagoya Protocol that tend to stifle the adoption of biotechnology and frustrate research and development.
- Rejoin the Paris Accords and provide active leadership to the United Nations and other global organizations to ensure that science and technology are positioned to overcome climate challenges.

## CONCLUSION

U.S. biotechnology innovation will provide significant contributions in our effort to address health, nutrition, and environmental challenges. To protect small innovators and give rise to more American-developed solutions, however, the U.S. must modernize its trade policy objectives to be better positioned within the life-science ecosystem.

Because the U.S. has pulled back its role as the international leader over the past few years, it is critical that the US take steps to restore global leadership, particularly in areas where it has pulled back in recent years.

Biotechnology Innovation Organization

## FACTS AND FIGURES

*US Global leadership stats:*

- US is still the leader — **57% of new meds**
- In 2019, US represented **66% of global biotech** VC financing (EU — 16%, China 15%) But China is catching up — went from less than 1% of global VC financing in 2010, to almost 15% in 2019 (i.e., a 3000% increase in 9 years)

*Threats abroad*

- To reduce the potential for trade disruption in agriculture, biotech companies often delay commercialization of new products in the United States until China and Europe have approved the same products. A recent study estimates Chinese delays between 2011 and 2016 reduced farm income by **$5 billion** and U.S. GDP by **$7 billion**.
- Chinese (and potentially other country policies) aim to replace U.S. biotech medicines with locally developed ones by unfair practices such as requiring US companies to do R&D and manufacture locally in order to have access to their market. In addition, while intellectual property laws have improved, enforcement is still weak, so that US developed innovations are being unfairly appropriated abroad.

*U.S. crop biotech acreage, US exports of biotech crops, contribution to US GDP (INFORMA REPORT)*

- According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), biotech-enhanced farming systems **saved 452 million acres of lands** from plowing and cultivation, and decreased use of pesticides by **8.2 percent since 1996**.

*Climate leadership*

- By 2025, California's Low Carbon Fuel Standard, in combination with Cap & Trade, will result in:
  - → Savings of **$8.3 billion** in pollution-related health costs
  - → Prevention of **600 heart attacks** and **880 premature deaths** caused by air pollution
  - → Prevention of **38,000 asthma attacks** and almost **75,000 lost workdays**
  - → Reduction of criteria pollutant emissions by almost **180,000 tons**
- The use of biofuels, primarily used in passenger cars, has resulted in significant greenhouse gas reductions, with cumulative CO2 savings of nearly **600 million metric tons** (mmt) since the RFS was enacted.
- Compared to gasoline, biofuel from energy crops can reduce emissions by **101 to 115 percent**.
- The USDA found that the development of renewable chemicals and biobased products removed **12.7 mmt of CO2** from the manufacturing sector in 2016 alone.
- The USDA estimates that the biobased economy contributes **$393 billion** to the overall U.S. economy, generating **4.2 million jobs**.

# BIOTECHNOLOGY INNOVATION ORGANIZATION

## Spurring a Bio-Revolution in 2021 and Beyond

October 2020

Biotechnology Innovation Organization

## EXECUTIVE SUMMARY

Biotechnology is playing an essential role in helping the United States respond to the COVID-19 pandemic. The continued growth of bio-based technologies and solutions will enable the United States to rebound from the current crisis stronger than before, and smoothly transition to mitigating climate change, spurring technological innovation, and creating new opportunities for job growth. Biotechnology can be at the heart of a new, resilient American economy.

Bio-innovation is occurring across the country every day. During the pandemic, industry partners in states such as North Carolina, Wisconsin, and Michigan are leading research around COVID-19 solutions. Significant work is also being conducted to help the U.S. meet climate goals by reducing our agricultural carbon footprint and lowering our dependence on foreign resources. When it comes to bio-innovation, technology, and manufacturing, the U.S. has a great legacy in states such as Pennsylvania, North Carolina, Michigan, Minnesota, Wisconsin, and Iowa, where scientists and research institutions partner to develop cures for newly discovered diseases, sustainable food and farming, and biological alternatives to petrochemicals, fossil fuels, and plastics. This legacy also provides a foundation for the U.S. to formulate a cohesive COVID-19 response, create a strong bio-based climate solutions portfolio, and produce meaningful outcomes to gaps in patient access to healthcare.

**This paper will outline the critical work of BIO's diverse member companies to respond to three of the most pressing challenges currently facing our country and the world:**

1. The COVID-19 pandemic
2. Climate change and environmental degradation
3. Access to healthcare

For each of these issues, we will discuss the progress that has already been made by the biotechnology industry, the potential that biotechnology has to do more, and the public policies that are necessary to unleash this potential.

## BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) WHO WE ARE

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO is unique because it represents an entire technology, rather than a specific industry or sector. **In 2020, BIO members are operating at the intersection of biology and technology to heal, feed, and fuel our planet in more sustainable and environmentally friendly ways.** BIO advances policies that promote science and innovation, ensure patients have robust and equitable access to new treatments and cures, and transition our food systems and broader economy to be more resilient and self-sustaining through bio-based solutions.

The vast majority of our approximately 1,000 members are small companies engaged in some of the most challenging, cutting-edge research in the world. They typically have no marketed products and no profits, and thus are heavily reliant on private capital to fund their work. They take risks to develop the next generation of biomedical breakthroughs for the millions of patients suffering from diseases for which there currently are no effective cures or treatments.

By operating at the nexus of environmental, human, and animal health, BIO is uniquely positioned to develop smart, multi-faceted, and coordinated strategies that draw upon deep understanding and expertise across sectors. It is at this nexus that BIO advances policies to promote scientific breakthroughs.

**The COVID-19 pandemic has highlighted the breakthrough potential of science when it is unleashed. At the same time, however, we have witnessed the troubling imbalances in access to that science.** We now face the reality that our medicine development, public health, energy, and food supply paradigms are not fit to withstand or adequately respond to current or future threats.

In response to these realities, and as we work to end the current crisis, BIO is doubling down on its goal of delivering justice through science. To do so, we aim to foster an innovation ecosystem that unleashes the transformative potential of science, take steps to ensure that the gains from transformative sciences are broadly shared, and lead the way to usher in a new economic future powered by the Bio-Revolution.

# BIOTECHNOLOGY: LEADING COVID-19 RESPONSE & RECOVERY

## Background

The importance of biotechnology has never been more evident than during the COVID-19 pandemic. Since the beginning of the pandemic, BIO has been working closely with the federal government and dozens of our member companies to accelerate the response to COVID-19 and combat the health and economic repercussions of this crisis. Rapid progress is being made in this fight, largely due to the unprecedented response of the biotechnology industry in driving innovation to find therapies and vaccines. But more can and must be done to accelerate this fight and better prepare for future public health crises.

## Biotech Achievements

Since January, our innovators have invested substantial financial and personnel resources to launch more than 700 unique drug development programs aimed at preventing or treating COVID-19, with more than 200 of these already in clinical trials. Furthermore, our companies are collaborating like never before — putting aside their narrow commercial interests to share data, expertise, capacities, and capabilities with other companies — to accelerate development of the most promising drug candidates.

While the federal government has been an important partner in this endeavor, BIO companies are doing most of this work at their own risk. Contrary to some news reports, vaccines and therapies being developed with partial government support represent only 1% of these products. And while most headlines are focused on the work of large companies, most of these products are originating from smaller biotech developers largely based in the United States. This is true of most innovative drug development across disease areas, but it is particularly important to highlight in our fight against COVID-19.

There is also incredible collaboration taking place between industry and key government agencies, which is critical during a pandemic and must be expanded upon. BIO member companies are working closely with U.S. government agencies, non-government entities, and the World Health Organization to identify the most pressing needs in the areas of vaccination, diagnostics, antivirals, and other treatments.

Biotechnology companies have been able to respond so quickly to this pandemic because the United States has the most robust innovative R&D and investment ecosystem in the world. And that itself is no accident, but rather the result of decades of smart, bipartisan public policy that fostered its creation — from substantial investments in basic research and scientific infrastructure, to strong intellectual property and technology transfer systems; from science- and risk-based regulation, to a market-based system of competition based on value.

Based on everything we have learned over the past six months, BIO is making the following recommendations for an improved COVID response framework in the short term and for a more prepared public health system in the future.

## Policy Recommendations

### SHORT-TERM

- Support the development of a wide range of therapeutic and vaccine candidates targeting the COVID-19 virus through funding partnerships, rapid sharing of relevant scientific information, and greater clarity from government agencies on the types and characteristics of medicines most in need of development.
- Put in place measures that inspire confidence among the public health community and the public at large in the safety and efficacy of COVID vaccines and therapeutics.
- Coordinate between government regulators and industry partners to provide flexibility in site registrations and technology transfer approvals, so that manufacturing capacity does not become an obstacle in effectively addressing the pandemic.

- Ensure there is zero patient cost-sharing for COVID therapeutics across government and commercial insurance programs, and for the uninsured.
- Establish a comprehensive, clear, and fully funded strategy for the prompt and equitable allocation, distribution, and administration of COVID vaccines and therapeutics.
- Maintain the coordination mechanisms that accelerated our initial response to the virus, including R&D efforts such as Operation Warp Speed and ACTIV, beyond the first wave of vaccines and therapeutics to ensure a robust arsenal of treatments.

**LONG-TERM**

- Put in place an improved government preparedness and response protocol for infectious disease outbreaks, which includes:
  - ✓ A system for sharing all relevant scientific data and information as quickly as possible with researchers in academia and industry, including how and where to obtain critically needed research tools and supplies;
  - ✓ Real-time assistance to help small and mid-size biotech companies navigate the federal approval process for therapeutics and vaccines;
  - ✓ A streamlined process to identify and support the research that shows most promise and that merits government support;
  - ✓ Robust funding and incentives to maintain a steady state of emerging infectious disease R&D;
  - ✓ Adequate appropriations for procurement of emerging infectious disease countermeasures, including fully funding BARDA, the Project BioShield SRF, and the SNS; and
  - ✓ Funding and incentives to enhance and make more resilient U.S. domestic manufacturing capacity for vaccines and other biological products, without imposing counterproductive and unrealistic supply chain restrictions or mandates.

In the face of this global health crisis, the U.S. biotech industry is responding as only it can. Our companies are working to address this crisis as quickly and as safely as possible to save lives, reopen businesses and schools, and get the American people back to work. The United States must learn from this crisis to build a more prepared country moving forward.

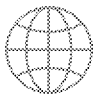
**Biotech COVID-19 Response**

**782 unique drug programs** have been launched over the last ten months in response to COVID-19

52% originated in the United States

72% originated from small companies

**741 of these initiated drug programs remain active,** and 10 have been authorized for use by regulators either in the U.S. or abroad.



This includes

**196** active antivirals

**355** active treatments

**190** active vaccine candidates

**25 BIO members** are currently working on developing and testing vaccines, and **31** are working on therapeutics.

# BIOTECHNOLOGY: LEADING ON CLIMATE SOLUTIONS

## Background

The COVID-19 pandemic has exposed the vulnerabilities in our nation's capacity to respond to crisis, maintain supply chains, and withstand economic downturn. At the same time, this crisis has highlighted the breakthrough potential of science when it is unleashed. We can and must apply these learnings as we take bold and drastic action to address the next imminent threat to our society: climate change.

Advances in bio-based manufacturing, sustainable fuel production, and sustainable agricultural practices are already improving our environment and health, while also creating good paying jobs. They bring other proven benefits to society as well, in the form of reduced greenhouse gas emissions, reduced pesticide applications, and reduced water use. Biological advancements in this area also show tremendous potential to improve soil health, reduce food waste, and enhance nutrition and wellness for people and animals. BIO has worked closely with the federal government and key stakeholders to create favorable policies that promote sustainable bio-based manufacturing and agriculture, and we have seen tremendous progress over the past few years with executive orders, laws, and regulations advancing innovation. It will be critical to keep, and even build upon, this momentum as we build a resilient post-COVID economy.

The COVID-19 pandemic demonstrates the link between infectious diseases and climate change. Human encroachment into biodiverse areas and population shifts due to climate displacement will increase the risk of dangerous zoonotic diseases — those that jump between animals and people — like COVID-19. Additionally, too many minority communities and families in rural America find themselves trading clean air and water for a paycheck. Tackling air pollution remains a critical priority, especially since poor air quality increases the risk of COVID-19 complications. Using biotech innovations, we can enable green manufacturing and energy solutions that limit air pollution. The application of biotechnology will also insulate human populations from future infectious diseases and antimicrobial resistance (AMR) associated with climate change.

Finally, advancing bio-based manufacturing and renewable chemical development will be critical in achieving resiliency and greening our supply chains. Using renewable feedstocks such as plants, industrial and food waste, and agricultural residues, we can create renewable chemicals and bio-based products and processes that can revitalize domestic manufacturing and address the increasing rise in emissions in the petrochemical industry.

By adapting and accelerating innovation, we can be resilient, self-sustaining, and drive our economic recovery through a bioeconomy.

## Biotech Achievements

### BIOTECH CLIMATE SOLUTIONS INCLUDE:

- **Sustainable fuels** made from biomass and waste feedstocks can address air quality and reduce greenhouse gas emissions in ground transport, aviation, and marine engines. Biofuels have already removed 600 million metric tons (mmt) of $CO_2$, since the enactment of the renewable fuel standard (RFS).
- **Renewable chemicals and bio-based products** removed 12.7 mmt of $CO_2$ from the manufacturing sector in 2016 alone, and can continue to green our supply chains, reduce plastic pollution, and provide sustainable alternatives to fossil-based products.
- **Biotech crops,** such as those that require no-tilling, have saved 27.1 billion kg of carbon dioxide, equivalent to taking 16.7 million cars off the road.
- **Gene edited microbes** in the soil route more nutrients to plants. These microbes reduce the need for fertilizer, minimizing nitrogen runoff.

- **Synthetic biology** enables farmers to enhance soil health to grow more food on less land, manufacturers to create new food ingredients and alternative proteins, and industrial biotech companies to revolutionize manufacturing by optimizing processes for producing renewable chemicals, bio-based products, and biofuels.
- **Innovations in animal biotechnology** are making the production of meat, milk, and fish more sustainable, enhancing animal nutrition and well-being, increasing the accessibility to high-quality protein, and eliminating the need to import from other countries.

We can achieve our immediate goal of rebuilding our national economy and workforce by championing science and supporting biotechnology through sound public policy and predictable regulations that speed adoption of climate-friendly biotechnologies and build the public's trust in science. We can tackle decarbonization in our transportation systems, manufacturing processes, and agriculture in a forward-looking, self-sufficient, and sustainable manner that puts us on the path to a greener economy for the betterment of human and environmental health. To do so, we recommend the following policy approaches:

## Policy Recommendations

### GROW A CLIMATE SMART ECONOMY

#### *Decarbonizing Agriculture*

The agricultural sector has an outsized role to play in fighting climate change. Expanding the adoption of innovative technologies and practices will enable farmers to increase production while reducing greenhouse gas emissions. Doing so will be critical to combatting climate change while producing enough food, feed, fuel, and fiber for a growing world.

- **Incentivize Modern Agriculture Techniques:** Enable America's farmers, ranchers, and foresters to combat climate change by incentivizing the adoption of modern agricultural techniques and innovative technologies, including carbon sequestration, enhancing animal feed with enzymes, microbes to reduce emissions from livestock, precision plant breeding, biostimulants, and microbial inoculants, which boost production with fewer inputs and build up soil carbon.
- **Certify Sustainable Agriculture Practices:** Create a certification program at USDA to allow producers to participate in carbon credit markets and allow the manufacturers of bio-based fuels, chemicals, plastics, food, animal feed, and everyday materials to reliably demonstrate their true environmental benefit, from farm to consumer.

#### *Decarbonizing Manufacturing*

Bio-based manufacturing can revolutionize industry, creating a sustainable value chain that uses biological processes to convert renewable and waste feedstocks into everyday products. It can create new markets for agricultural crops, crop residues, and waste streams, as well as opportunities for innovation in producing consumer goods. These technologies represent novel, innovative ways to address plastic pollution, improve air quality, and tackle climate change.

- **Set a Performance-Based Standard:** Proposals to address pollution and waste in manufacturing should set a performance standard that recognizes reductions in emissions in the production of chemicals and plastics.
- **Expedite the Path to Market for Renewable Technologies:** Broad regulatory acceptance, and where applicable regulatory preference, should be given to innovative renewable chemicals and bio-based products and processes.
- **Promote Bioplastics:** Efforts to incentivize recyclability and reduce plastic waste should also seek to promote the use of bioplastics.
- **Ensure Federal Accountability for Bio-Based Procurement:** Enhance the USDA Biopreferred program to ensure that agencies are fulfilling their obligation to shop Biopreferred. While the program has been successful in certifying products over the years, procurement agencies have not been held accountable to buy Biopreferred options where available.

- **Accelerate Research and Development of New Tools:** Drive significant advances in foundational tool development and practical applications through supportive grants for research and development of new tool start-ups. Foster coordination across agencies to advance research and development in biomanufacturing, strengthening and broadening the U.S.' synthetic biology capabilities and developing the future bioeconomy workforce.
- **Expand Incentives for Carbon Capture, Utilization, and Sequestration:** Transform the manufacturing sector and reduce greenhouse gas emissions by turning carbon into value added products.
- **Incentivize Green Manufacturing Infrastructure:** Spur investment in development and scale-up of biorefineries through supportive grants and tax incentives.

***Decarbonizing Transportation***

Biofuels provide a strong and immediate solution to reducing emissions from all forms of transportation, the leading source of greenhouse gas emissions. Development of sustainable fuels will also enable agriculture to play a crucial role in addressing climate change. These are solutions that are available today, and do not require a mass turnover in vehicles.

- **Develop a Federal Low Carbon Fuel Standard (LCFS):** An LCFS that is technology and feedstock neutral and builds on the success of the Renewable Fuel Standard (RFS) to ensure agriculture and biofuels are part of the solution will significantly reduce emissions in transport.
- **Modernize the USDA's Biorefinery Assistance Program:** This will ensure all advanced biofuels, including sustainable aviation fuel, can qualify to spur investment and development of new biorefineries.
- **Incentivize Advanced and Cellulosic Fuel Development:** Ensuring the growth of the advanced and cellulosic biofuels industry will require long-term tax incentives to avoid creating uncertainty for investors and companies trying to raise capital. The development of a long-term sustainable aviation fuel specific blender's tax credit could attract significant investment and address existing structural and policy disincentives that have hampered aviation biofuels industry.

## BOOST ACCESS TO NUTRITIOUS FRUITS, VEGETABLES, GRAINS AND PROTEIN

- Grow public and private investment in high-value, transformative food and agricultural science and technologies.
- Promote access to healthful protein.
- Support the free flow of data that enables transformative and personalized food, farming, and medicine.
- Reduce the number of food deserts by supporting urban and indoor farming, and ensure federal programs accept biotechnology.
- Support anti-hunger and food security programs and ensure those programs accept biotechnology.

## ENSURE BIOTECHNOLOGY IS PART OF THE SOLUTION TO GLOBAL SUSTAINABILITY AND CLIMATE CHANGE REDUCTION CHALLENGES

The United States leads the world in biotechnology innovation and should lead efforts to build a global bioeconomy that advances sustainable, climate positive solutions for society. However, barriers to biotechnology innovation and access stifle the ability to apply the full promise of this technology globally, and populations most vulnerable to climate change do not have access to powerful biotechnology tools. The United States should position sustainability at the heart of U.S. trade policy objectives and lead the development of global norms and trade rules to spur the development of and access to innovative sustainable technologies.

## DRIVE A ONE HEALTH APPROACH TO PUBLIC HEALTH PREPAREDNESS

One Health represents a much-needed collaboration that would align human health, animal health, and environmental health strategies to create smarter, multi-faceted, and coordinated efforts, including to help enhance the ability of our planet to adapt to climate change. The thoughtful and bipartisan *Advancing Emergency Preparedness Through One Health Act (S. 1903/H.R. 3771)* directs HHS and USDA to coordinate with other agencies and state and local leaders to advance a national One Health framework to better prevent, prepare for, and respond to zoonotic disease outbreaks like COVID-19 and other challenges arising from increasing climate change.

## PROMOTE ANIMAL BIOTECHNOLOGY INNOVATIONS

Genetic innovation in animals can help prevent and respond to future infectious diseases. These technologies hold enormous potential to address numerous agricultural, environmental, humanitarian, and public health challenges associated with climate change by enabling animal agriculture to produce more protein with fewer animals and adapting livestock to a warming world. FDA and USDA should work to streamline oversight of animal biotechnology in order to create a clear, timely, and science-based regulatory approval process that provides a viable path to market for these critical new innovations.

# BIOTECHNOLOGY: INCREASING ACCESS TO HEALTHCARE & REDUCING HEALTH DISPARITIES

## Background

The COVID-19 pandemic has brought to the forefront a longstanding issue in this country: our healthcare system still fails many Americans. There is not one silver bullet to solve this problem; rather, a multifaceted approach that recognizes the unique challenges of diverse and underserved populations is necessary. We must foster an innovative ecosystem that pushes science forward, but also ensures that EVERYONE can benefit from these amazing advances.

America's healthcare system must heal the masses, not the few. At present, the system is not equipped to heal with 21st century medicines and therapeutics. In order to achieve greater access through a new age of therapeutics for both common and rare ailments, steps should be taken to further improve our healthcare system.

**BIO's diverse community of innovators is committed to creating solutions and working with the government on reforms to ensure that 21st century medicines and therapies are accessible and affordable to everyone who needs them.**

It is also critical to build research equity. BIO stands for inclusive science and diverse scientists in order to find new breakthroughs for and with all patients, regardless of race, creed, color, class, gender, or sexual orientation. Finally, we must insist on **always putting patients and consumers first.** Our innovation is based on a foundational belief that patients understand their illnesses and their needs. Our science is in service to both.

Recognizing that gains from transformative science are not always shared equally, BIO is challenging the industry, and its partners, to find solutions for inequitable healthcare delivery, disparate economic development, and nutritional and environmental disparities in the United States and around the globe.

## Biotech Achievements

The 2020 launch of the **BIOEquality Agenda** will mobilize the biotech industry in a social justice movement to address the disparities facing too many communities of color and enhance opportunities for these populations by improving health, nutritional, and environmental outcomes. This agenda revolves around three pillars of change that will invest in communities where health inequity persists, as outlined in the subsequent policy recommendations.

## Policy Recommendations

### PROMOTE HEALTH, NUTRITION, AND ENVIRONMENTAL EQUITY

- Enhance clinical trial diversity by partnering with Contract Research Organizations and minority-serving institutions.
- Promote access to vaccines and therapeutics for uninsured and underserved populations, especially related to COVID-19.
- Foster enhanced nutritional, environmental and mental wellness opportunities in economically disadvantaged communities.

### INVEST IN THE CURRENT AND NEXT GENERATION OF SCIENTISTS

- Identify and promote visibility of industry-sponsored minority training programs.
- Establish STEM training best practices for underrepresented populations.
- Create a network of scientists and engineers who represent people of color.

- Establish a partnership network the brings together industry-trained scientists, engineers, and other vendors who represent communities of color.
- Hire scientists, engineers, and other vendors who represent communities of color.

### EXPAND OPPORTUNITY FOR WOMEN AND OTHER UNDERREPRESENTED POPULATIONS

- Enhance use of minority- and women-owned small businesses in biotech supply chains, to promote economic development of marginalized communities and especially those most impacted by COVID-19.
- Promote diversity of NIH SBIR Grants.

## Biotechnology: The Economics of Cure & Building for the Future

As *The Economist* has noted, "Creating new drugs through biotechnology is at the risky end of a business in which superhuman stamina and bottomless pockets are minimum requirements." To understand the biopharmaceutical innovation ecosystem and its pricing dynamics, you have to understand the numbers.

### Key Data

70% of innovative **clinical programs are being led by small companies,** which rely heavily on venture capitalists, angel investors, or partnerships with larger pharmaceutical companies to provide the enormous amounts of private capital required to fund these challenging and incredibly risky endeavors.

90% of **clinical programs ultimately fail** to lead to an FDA approval; in fact, the success rate of clinical trials can be even less than that, particularly in areas like Alzheimer's and cancer.

92% of biopharmaceutical companies are **unprofitable** at any given time.

On average, it takes **10–15 Years** to secure FDA approval of a new medicine, from initial discovery of a potential new molecule or approach, through pre-clinical and clinical programs, and through the FDA regulatory and approval processes.

On average, it costs **$2.6 Billion** to develop and secure approval of a new medicine, taking into account all the trial and error and research failures along the way, and the cost of capital; this figure has skyrocketed in recent years, doubling since just 2003.

The biopharmaceutical industry ranks **36th** among domestic industries in terms of return on investment, despite the popular media narrative of excessive drug industry profits.

20.8% of the biopharmaceutical industry's sales went to R&D expenditures last year, more than any other major U.S. industry.

89% of all prescriptions in America are for lower-cost generic copies of once-branded pharmaceuticals.

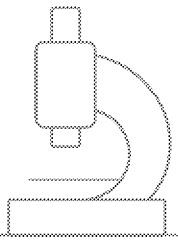
This critically important innovation ecosystem can continue to flourish only if it has the confidence and support of government and the American people. It is essential to maintain policies that encourage new and needed medicines get to patients.

## Biotechnology Innovation: **Driving the U.S. Economic Engine**

Now more than ever, **biotechnology is a critical component of the U.S. economy**, and efforts to incentivize growth in this sector domestically, while also protecting a global supply system, should be prioritized. The economics of innovative solutions transcend economic sectors and, if supported, will **enhance health, improve nutrition, mitigate climate change,** and **create jobs.**

### BIO Achievements by the Numbers — U.S. Bioscience Industry

- ✓ The nation's bioscience industry employs **1.87 million** across more than 101,000 U.S. business establishments.
- ✓ Since 2016, the industry has grown its employment base by **7.2 percent,** which is more than twice the growth rate for the overall private sector.
- ✓ Bioscience industry establishments and average wages grew as well; and the industry continues to stand out as a major job generator among knowledge — and **technology-driven sectors for the U.S. economy.**
- ✓ All five of the industry's major subsectors have **grown their employment** base since 2016.
- ✓ The bioscience industry's total economic impact on the U.S. economy totaled **$2.6 trillion dollars in 2018,** as measured by overall output.
- ✓ The associated economic output also supports **9.3 million jobs** throughout the entire U.S. economy, through both indirect and induced effects.



# APPENDIX

## BIO-INNOVATION: STATS BY STATE

A Legacy of Innovation in Key States

# NORTH CAROLINA

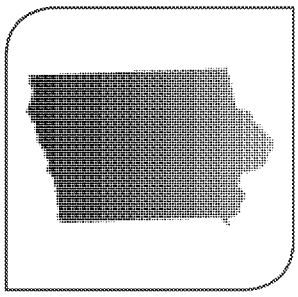
## STATE OVERVIEW

- North Carolina's bioscience industry is among the national leaders in its size, specialized employment concentration, and diverse strengths.
- Since 2016, the industry has increased its employment base by 10% to reach more than 83,000 jobs across 4,210 business establishments in 2018.
- North Carolina has specialized employment concentrations in three subsectors — drugs and pharmaceuticals; research, testing, and medical labs; and agricultural feedstock and industrial biosciences.
- The state is among the top tier in its bioscience-related university R&D activities, with $2.35 billion in expenditures in 2018.
- NIH funding to NC research institutions reached nearly $1.6 billion in 2019.
- The state has seen an increase in the volume of patents awarded in bioscience-related technology classes, which totaled 3,636 from 2016–2019.

## NORTH CAROLINA ACCOMPLISHMENTS IN BIO-INNOVATION

- In the 1980s, scientists in Research Triangle Park discovered that azidothymidine (AZT) could be used to treat AIDS.
  - ✓ This was the first drug to gain FDA approval for treating AIDS.
- Companies in North Carolina are leading the research, development, and manufacturing of gene therapy drugs.
- North Carolina is increasing plant yield by developing products for disease, insect, and weed control and drought tolerance.
  - ✓ These companies are innovating to help farmers, while also fighting climate change.
- A facility in Morrisville, NC, has been contracted to manufacture a COVID-19 vaccine candidate that is in a phase three clinical trial.
- An NC State University spin-out developed the world's first in ovo vaccination device.
  - ✓ These devices are used in the production of human influenza vaccine and many animal health vaccines due to their quality and reliability.

# IOWA



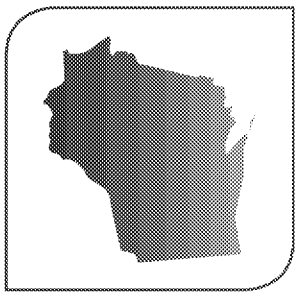
## STATE OVERVIEW

- Iowa's bioscience industry is sizable and among the most specialized in its concentration of industry employment.
- Since 2016, the industry has grown its industry employment base by 4% to reach 25,518 jobs in 2018 across more than 1,600 business establishments.
- The state has a specialized employment base in two of the five major subsectors — Iowa is a national leader in the agricultural feedstock and industrial biosciences subsector and is specialized in its concentration of jobs in bioscience-related distribution.
- The state's research universities conducted nearly $544 million in bioscience-related R&D in 2018.
- NIH funding contributes to academic R&D expenditures, and these awards have been steadily increasing in Iowa, exceeding $200 million in FY 2019.

## IOWA ACCOMPLISHMENTS IN BIO-INNOVATION

- Iowa is leading in the development and production of DNA and RNA strands.
  - ✓ These products can be used for academic research, agriculture, medical diagnostics, pharmaceutical development, and synthetic biology.
  - ✓ They are critical tools that help address global sustainability issues such as biodiversity, food security, bioremediation, and biofuels.
  - ✓ One gene therapy company developed one of the first approved test kits for COVID-19, and since then they have been shipping millions of tests around the country.
- One company in Ankeny, Iowa has developed technology to preserve and store pollen that can then be applied corn, rice, and wheat to increase yield.
  - ✓ For corn seed producers, this technology helps increase yield by more than 20 percent — an added value of $1,000/acre.
- One startup-style company in Iowa has developed technology to treat wastewater sustainably by extracting nutrients with algae, then recycling those nutrients through a fertilizer or bioplastic product.
  - ✓ They are creating solutions for cities that want to clean water without building a new water treatment plant.
  - ✓ The technology was developed at Iowa State University.
- Iowa is also leading foundations for cures of diseases such as cystic fibrosis.
  - ✓ One group develops genetically engineered swine models that exhibit a variety of human disease states.
  - ✓ These models allow researchers to study the efficacy of new medications and devices on platforms that more accurately represent humans.
- The University of Iowa is participating in a large-scale clinical trial of vaccines for COVID-19. The study is testing the RNA vaccine developed by BioNTech and Pfizer.
- The National Institute of Antimicrobial Resistance Research and Education at Iowa State University Research Park is working on national efforts to bolster discussion around antibiotic resistance and address knowledge gaps related to antimicrobial use.

# WISCONSIN



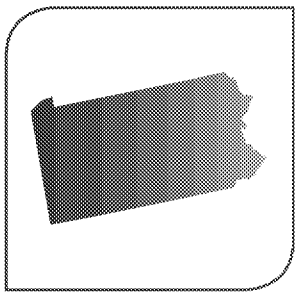
## STATE OVERVIEW

- Wisconsin's bioscience industry is sizable and has grown by 4.5% since 2016 to reach more than 36,000 jobs across 1,773 state business establishments.
- Wisconsin has a specialized employment concentration in two of its industry subsectors — medical device and equipment and agricultural feedstock and industrial biosciences.
- State research institutions have seen increases in NIH funding awards, which totaled $493 million in 2019.
- These federal awards represent a key funding source for the state's $1 billion in academic biosciences R&D expenditures.
- Wisconsin's universities have a strong concentration of biosciences research, accounting for 70% of all academic R&D activity, which is well above the national average.

## WISCONSIN ACCOMPLISHMENTS IN BIO-INNOVATION

- Discovered the first vitamin, paving the way for the discovery of all vitamins in food.
- Discovered how to enrich foods with vitamin D through irradiation, wiping out rickets and creating a commonly used technique.
- Created disease-resistant crops in the 1910s.
- Created a method to improve dairy cattle herds.
- Identified the mechanisms plants use to survive drought.
- Founded the Upper Midwestern Center of Excellence in Vector Borne Diseases, a research unit focused on stopping tick and mosquito-borne diseases.
- Founded the Wisconsin Crop Innovation Center a huge facility donated by Monsanto with a focus on improving commercially important crops.

# PENNSYLVANIA



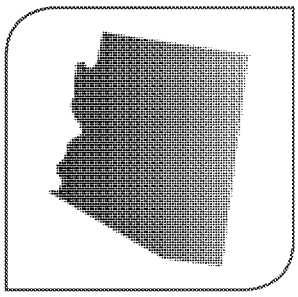
## STATE OVERVIEW

- State employers have grown the industry by 7% since 2016 to reach nearly 87,000 jobs that span 2,622 business establishments.
- All five subsectors contributed to the overall employment gains.
- The state has a specialized concentration in two subsectors — drugs and pharmaceuticals; and research, testing, and medical labs.
- Pennsylvania is among the top tier of states in academic R&D expenditures; NIH funding to its institutions; venture capital investments; and patents awarded to state inventors.
- Venture capital investments in bioscience companies have increased in recent years and totaled nearly $3.5 billion over the 2016–19 period.

## PENNSYLVANIA ACCOMPLISHMENTS IN BIO-INNOVATION

- Spark Therapeutics, headquartered in Philadelphia, is a gene therapy company that works to combat genetic diseases such as blindness, hemophilia, lysosomal storage disorders and neurodegenerative diseases.
  - ✓ The company was founded in 2013 after decades of research with the Children's Hospital of Philadelphia (CHOP).
  - ✓ In December 2017, Spark became the FDA approved first gene therapy for an inherited disease.
- Dr. Michael Sofia, a researcher based out of Doylestown, PA, invented a cure for Hepatitis C.
  - ✓ Sofia developed the drug in 2007 and received FDA approval in 2013.
  - ✓ He has since founded another company at the Pennsylvania Biotech Center to develop a cure for Hepatitis B.
- Dr. David Fajgenbaum, a researcher at the University of Pennsylvania, has pivoted his research on Castleman disease to address COVID-19.
  - ✓ Fajgenbaum has dedicated his life to finding a cure for Castleman disease, a rare condition that he has.
  - ✓ After noticing similarities between Castleman and COVID-19, however, his lab at Penn has been repurposing drugs to address the pandemic.
- The leading influenza vaccine producer is located in Pennsylvania, delivering nearly 200 million vaccines, 40% of all doses worldwide, each year.
  - ✓ The company produces their vaccines in Swiftwater, Pennsylvania.
  - ✓ The large majority of these vaccines are produced in eggs that come from Pennsylvania farmers.
  - ✓ In 2010, they were awarded a three-year contract for $56.94 million by the U.S. Department of Health and Human Services to maintain flocks to enable manufacturing pandemic influenza vaccine at full capacity on a year-round basis.

# ARIZONA



## STATE OVERVIEW

- Arizona's bioscience industry is growing rapidly and reached nearly 30,000 jobs spanning 2,160 business establishments in 2018.
- Industry employment has grown by 15% since 2016 — twice the growth rate of the nation — with each of the five major subsectors adding jobs during the period.
- Arizona's universities conducted nearly $580 million in R&D activities in bioscience-related fields in 2018.
- VC investments in Arizona bioscience companies increased in 2019, and totaled $349 million during the 2016–19 period.
- Arizona inventors have been awarded 2,178 bioscience-related patents since 2016, among the second quintile of states in patent activity.

## ARIZONA ACCOMPLISHMENTS IN BIO-INNOVATION

- Arizona is combining cloud computing and artificial intelligence with drug discovery to find new therapeutic opportunities for cancer.
  - ✓ One company is currently managing a growing pipeline of more than 10 innovative cancer therapeutic programs.
  - ✓ They also recently entered a commercial license agreement for an oral therapy for the treatment of resistant ER alpha positive breast cancer.
- The **University of Arizona** has been working with the US Department of Agriculture to study guayule, a desert plant that can replace synthetic or natural rubber.
  - ✓ The latex can be produced from the bark of this plant, and unlike other plant-based latex it is hypoallergenic.
- **Arizona State University** has been ranked the number one university for innovation six years in a row.
  - ✓ The Biodesign Institute at ASU was awarded a $40 million contract from BARDA in 2009 to create a diagnostic system for determining an individual's absorbed dose of radiation.
  - ✓ The Biodesign Institute also produced the Western United States' first FDA-approved saliva-based COVID-19 test, with test results delivered in 24–48 hours.
- One of the first trial sites for the Beau Biden research project was in Arizona, and state has the largest, very diverse population in the study.

# MICHIGAN

## STATE OVERVIEW

- Michigan's bioscience industry employed nearly 39,000 across 1,877 business establishments in 2018.
- Michigan is 6 percent more concentrated in its employment in medical device and equipment manufacturing compared with the national average.
- The state is among the top tier in university bioscience-related R&D activities, with more than $1.5 billion in expenditures in 2018.
- This university research is supported, in part, by federal funding.
- NIH awards to Michigan institutions have been steadily rising in recent years and reached nearly $827 million in 2019.
- VC investments in state bioscience firms have increased in recent years, and for the 2016–19 period totaled nearly $558 million.

## MICHIGAN ACCOMPLISHMENTS IN BIO-INNOVATION

- BIO-Innovation drives a larger sector of the economy than car manufacturing.
- Michigan bio-innovation includes medicines and therapeutics, medical devices, diagnostics, research tools, informatics, nutritional health, clinical research, industrial biotechnology, biofuels, and bio-agriculture.
- Conducting research and development of COVID-19 related therapies.
- Michigan State is the primary state university for discovery/IP that then goes for commercialization.
- One Michigan company, which is now building a facility in NC, came up with a bio pesticide derived from spider venom.
- Michigan is also home to the last US independent extract company.

# GEORGIA

## STATE OVERVIEW

- Georgia's bioscience industry has grown at a double-digit pace in recent years, reaching 35,602 jobs in 2018.
- All five of the major industry subsectors have grown their employment base since 2016.
- Georgia's research universities had bioscience-related R&D expenditures of more than $1.2 billion in 2018.
- The state has a growing base of NIH awards that reached $630 million in FY 2019.
- Venture capital investments in state bioscience companies rose in 2019 and totaled $726 million during the 2016–19 period.

## GEORGIA ACCOMPLISHMENTS IN BIO-INNOVATION

- Georgia Bio, founded in 1989, is a non-profit organization that promotes the interests and growth of the life sciences industry.
- It is the state's largest and most influential life sciences advocacy and business leadership organization, which works to improve access to innovative technologies and grow Georgia's life sciences economy.
- Members include companies, universities, research institutions, government groups, and other industry associations.

Message

**From**: Jennifer Schafer [jasca@cascadeassociates.net]
**Sent**: 1/26/2021 2:13:27 PM
**To**: 'Cliff Majersik' [cliff@imt.org]; jgoffman@law.harvard.edu; 'joe.goffman@jbrpt.org' [joe.goffman@jbrpt.org]; Goffman, Joseph [Goffman.Joseph@epa.gov]; 'joseph.goffman@jbrpt.org' [joseph.goffman@jbrpt.org]
**Subject**: RE: Meeting with EPA transition team re energy efficiency and existing admin authority?
**Attachments**: EESG Contacts .pdf

Congrats on your new position, Joe. We're all looking forward to working with you on energy efficiency as emissions reduction as we did back in 2014!

Attached is a list of the groups that will be in the meeting. Trying a couple other emails for you.

Thanks
Jennifer

Jennifer Schafer
Cascade Associates
202-297-6037

---

**From:** Cliff Majersik <cliff@imt.org>
**Sent:** Tuesday, January 26, 2021 8:00 AM
**To:** jgoffman@law.harvard.edu
**Cc:** Jennifer Schafer <jasca@cascadeassociates.net>
**Subject:** Re: Meeting with EPA transition team re energy efficiency and existing admin authority?

Joe,
I'm following up in case you didn't receive my note below. Jean Lupinacci suggested that we reach out to you in your EPA transition team capacity. Are you available to meet with us?

Warm regards,
Cliff

On Wed, Jan 13, 2021 at 8:00 AM Cliff Majersik <cliff@imt.org> wrote:

> Joe,
> Thank you for your role in the Biden EPA transition team!
>
> I write on behalf of the Energy Efficiency Strategy Group. The EESG coordinates Federal policy requests from the various energy efficiency community. Participants are: ACEEE, ASE, AEE, ASHRAE, BCSE, Building Performance Coalition, E2, E4theFuture, EESI, FPCC, ICC, IMT, NASEO, NAESCO, NRDC, NASCSP, Sierra Club, USGBC and WRI -- see attached contact list.
>
> We've met with the Biden DOE transition team and would like to schedule a meeting with the EPA team to discuss opportunities for EPA to utilize existing administrative authority to spur energy efficiency, fight climate change, create jobs, and protect public health -- see EESG's attached recommendations.
>
> Would you and the team like to suggest a few times in the next two weeks when you would be able to meet with us?
>
> Feel free to share plans or analyses that you'd like for us to review in advance of a meeting.
>
> Warm regards,

Cliff

--
Cliff Majersik
Institute for Market Transformation (IMT)
1707 L St. NW, Suite 1050
Washington, DC 20036
m (202) 297-0871

www.imt.org
@IMTCliff

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--
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Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/29/2021 2:18:20 AM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: Re: READING: Calendar & Materials January 29, 2021

Of course. My apologies. I thought Thierry and Delaney were doing this already. I will address it.

Ann (Campbell) Ferrio
Chief of Staff
Office of Air and Radiation
(202) 566-1370

On Jan 28, 2021, at 9:11 PM, Goffman, Joseph <Goffman.Joseph@epa.gov> wrote:

Deliverance! Thank you! Please serve this up every afternoon/evening. It will be immensely, immensely helpful if Tomas, Deputy AA #2, and I can count on receiving every day one, single email from you (or someone you designate) with all of the read-ahead materials in one place. It will be life-changing. Thanks, again.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** Campbell, Ann <Campbell.Ann@epa.gov>
**Sent:** Thursday, January 28, 2021 8:51 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** READING: Calendar & Materials January 29, 2021

Joe, attached are the materials I have received for tomorrow's meetings. Let me know if this helps. And let me know if you need anything else.

<image001.gif>

**Goffman, Joseph Calendar**
Goffman.Joseph@epa.gov
On Friday, January 29, 2021
Time zone: (UTC-05:00) Eastern Time (US & Canada)
(Adjusted for Daylight Saving Time)

<image002.gif>

**January 2021**

| Su | Mo | Tu | We | Th | Fr | Sa |
|---|---|---|---|---|---|---|
| | | | | | 1 | 2 |
| 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| 24 | 25 | 26 | 27 | 28 | 29 | 30 |

<image003.gif>

| | | | | | |
|---|---|---|---|---|---|
| <image004.gif> | Busy | <image005.gif> | Tentative | <image006.gif> | Free |
| <image007.gif> | Out of Office | <image008.gif> | Working Elsewhere | <image009.gif> | Outside of Working Hours |

**January 2021**

<image002.gif>

<image010.gif> **Fri, Jan 29**

| | | |
|---|---|---|
| <image009.gif> | **Before 8:00 AM** | **Free** |
| <image006.gif> | **8:00 AM – 8:30 AM** | **Free** |
| <image004.gif> | 8:30 AM – 9:00 AM | Check-In |
| <image004.gif> | 9:00 AM – 9:30 AM | Air Issues Meeting |
| <image004.gif> | 9:30 AM – 10:00 AM | Landfill CH4 |
| <image004.gif> | 10:00 AM – 10:30 AM | Management Round Table |
| <image004.gif> | 10:30 AM – 11:00 AM | OAR/ARLO Discussion |
| <image004.gif> | 11:00 AM – 11:45 AM | AIM Act – NODA (Materials attached) |
| <image006.gif> | **11:45 AM – 12:00 PM** | **Free** |
| <image004.gif> | 12:00 PM – 12:30 PM | One-on-One with Sarah Dunham |
| <image004.gif> | 12:30 PM – 1:00 PM | One-on-One with Jon Edwards |
| <image004.gif> | 1:00 PM – 2:00 PM | Overview of Key OAQPS Priority Topics (Materials attached) |
| <image006.gif> | 2:00 PM – 2:45 PM | Appointees IT Training (Option 1) |
| <image006.gif> | **2:45 PM – 3:00 PM** | **Free** |
| <image004.gif> | 3:00 PM – 4:00 PM | Briefing: PFAS Hot Issues (Materials attached) |
| <image004.gif> | 4:00 PM – 4:30 PM | Introductory Video-Call: Michael Regan and Joe Goffman (We provided your bio at Kathleen Lance's request) |
| <image004.gif> | 4:30 PM – 5:00 PM | To Discuss CRA |
| <image004.gif> | 5:00 PM – 5:30 PM | Check-In |
| <image004.gif> | 5:30 PM – 6:00 PM | Cars Working Group |
| <image009.gif> | **After 6:00 PM** | **Free** |

<image002.gif>

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Message

**From**: Murphy, Tina [Murphy.Tina@epa.gov]
**Sent**: 1/27/2021 4:47:04 PM
**To**: OAR Briefings [OAR_Briefings@epa.gov]
**CC**: Kocchi, Suzanne [Kocchi.Suzanne@epa.gov]; Harvey, Reid [Harvey.Reid@epa.gov]; Hooper, Daniel [hooper.daniel@epa.gov]
**Subject**: Briefing materials for tomorrow's OAR AA meeting - Revised CSAPR Update Rule: Options Selection -1/28: 11-11:45 a.m.
**Attachments**: Final_OAR AA Briefing_Revised CSAPR Update_Options Selection_01.28.21.docx

Dear OAR Leadership Team:

Please find attached briefing material for tomorrow's OAR AA meeting - Revised CSAPR Update Rule: Options Selection. Meeting taking place Thursday, January 28th: 11-11:45 a.m.

Thank you.

Message

**From**: Adams, Elizabeth [Adams.Elizabeth@epa.gov]
**Sent**: 1/26/2021 7:49:13 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: RE: Message from Joe Goffman, Acting Assistant Administrator for OAR

Welcome Back, Joe! We are so glad to have you at the helm and I'm looking forward to working with you.
I hope you are doing well.

All my best,
Elizabeth

Elizabeth J. Adams
Director, Air & Radiation Division
US EPA Region 9
Cell: 415-297-4308

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Tuesday, January 26, 2021 11:29 AM
**To:** Air Division Directors and Deputies <Air_Division_Directors_and_Deputies@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>; Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Shaw, Betsy <Shaw.Betsy@epa.gov>; Spenillo, Justin <Spenillo.Justin@epa.gov>
**Subject:** FW: Message from Joe Goffman, Acting Assistant Administrator for OAR

Dear Regional Air and Radiation Divisions Directors and Deputy Directors,

I wanted to share with and extend to you the greetings I sent to my colleagues in OAR this morning. I know for a fact that all of the characteristics of the OAR workforce I described below apply equally to you, our essential regional air program implementation partners. Tomas Carbonell, our new Deputy Assistant Administrator for Stationary Sources, and I are very much looking forward to working closely with all of you on the full range of essential Clean Air Act implementation activities and to engaging you in the exciting new challenges and opportunities ahead. Justin is working on scheduling us to join you for an upcoming ADD call in the near future. I look forward to seeing and interacting with each of you then.

Until then, stay safe and healthy,

Joe

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Goffman, Joseph
**Sent:** Tuesday, January 26, 2021 10:35 AM
**To:** OAR-WIDE-EVERYONE <OARWIDEEVERYONE@epa.gov>
**Subject:** Message from Joe Goffman, Acting Assistant Administrator for OAR

Dear OAR Colleagues –

No one will enjoy a greater honor or privilege than the honor and privilege I now enjoy of returning to your side as your colleague. As some of you may recall, from 2009-2017, I served as OAR's Associate Assistant Administrator for Climate and Senior Counsel, which was the best experience of my career. Happy as I am to occupy a new role, now as OAR's Principal Deputy Assistant Administrator and current Acting Assistant Administrator, simply being back here with you all is what makes this return such a pleasure.

First, I would like to thank you all – and by "all" I mean every single person who works in OAR – for your service to the public and for your ongoing dedication and commitment to the mission of the Office of Air and Radiation and of the Environmental Protection Agency. No matter what your job here is, you have earned, and will continue to earn, the unending gratitude of our fellow Americans for the energy and care you devote to protecting the air we breathe, our health, and our quality of life. Of course, you are not here in quest of "thanks" and I'm pretty sure that when you look in the mirror you don't see a hero, but you're entitled both to the "thanks" and to seeing yourselves that way. You are certainly my heroes – every single one of you.

That's not an exaggeration. This has been a difficult year for our country and the world. Since March, the pandemic has brought hard times, fear, and illness to our communities, friends and families. Many of you may have been touched in some way by the hardships and tragedies this year has brought and we are here as colleagues to support you however we can; virtually everyone has had to cope with challenges none of us imagined having to face a year ago.

From everything I've seen and heard, OAR employees' resilience, ingenuity and perseverance has shone through, and that's a tremendous source of comfort. Maintaining your characteristic commitment to our mission with the utmost professionalism while adapting to these tough times should give us all confidence that we can face the challenges, and harvest the opportunities, 2021 puts in our path and continue to deliver for the American people. After all, the OAR culture I knew when I was here last doubtless will propel us forward again: bringing out the best in each other and understanding that there is no success outside the success we all create and share in together.

In his note to all of us last week, EPA Chief of Staff Dan Utech introduced himself and members of the new leadership team who have arrived so far. He also called our attention to some of President Biden's executive orders. One in particular strikes to the core of our mission at OAR. The Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, says, "it is the policy of my Administration to listen to the science; to improve public health and protect our environment; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; to reduce greenhouse gas emissions; to bolster resilience to the impacts of climate change; … and to prioritize … environmental justice." It's as if President Biden were addressing EPA and OAR directly. Clearly, this is an amazing moment for us at OAR when our work will be even more vital and more highly valued in the coming months and years.

It is also my great pleasure to introduce Tomás Carbonell, who has joined the OAR leadership team as the Deputy Assistant Administrator for Stationary Sources. Tomás comes to EPA from the Environmental Defense Fund, where he was the Senior Counsel and Director of Regulatory Policy for that organization's clean air program. From 2008-2012, Tomás was an Associate at Van Ness Feldman, LLP, where he counseled diverse clients on federal legal and regulatory matters related to climate change, clean energy, and environmental and electricity regulation. He has a J.D. from Yale University, degrees in Environmental Change and Management and Development Economics from the University of Oxford, and bachelors' degrees in Chemical Engineering, Economics, and Multidisciplinary Studies from North Carolina State University. Please join me in welcoming Tomás, and please stay tuned for more introductions in the near future.

Very soon, via "Teams," we will have the chance to talk to and hear from each other directly as we get "all hands" meetings on the calendar with each of your offices. Please think about how you want to use that time to surface your concerns and share your suggestions for the best practices to continue or adopt in our work together going forward. A little later on we will also be engaging with the regions and states, the Office of General Counsel, the Office of Policy and other program offices as well as the public and our stakeholders.

Looking forward to connecting face-to-face

Thank you all very much for being here.

Stay safe and take care of yourselves and each other.

All best,
Joe

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Sent**: 1/23/2021 6:53:47 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: Fwd: general holding statement for press/public inquiries

# Ex. 5 Deliberative Process (DP)

Hope you're having a good weekend,

Tomás

Sent from my iPhone

Begin forwarded message:

> **From:** "Millett, John" <Millett.John@epa.gov>
> **Date:** January 22, 2021 at 11:28:17 AM EST
> **To:** "Goffman, Joseph" <Goffman.Joseph@epa.gov>, "Carbonell, Tomas" <Carbonell.Tomas@epa.gov>
> **Cc:** "DeLuca, Isabel" <DeLuca.Isabel@epa.gov>, "Campbell, Ann" <Campbell.Ann@epa.gov>, "Shaw, Betsy" <Shaw.Betsy@epa.gov>, "Shoaff, John" <Shoaff.John@epa.gov>
> **Subject: general holding statement for press/public inquiries**

# Ex. 5 Deliberative Process (DP)

Thanks –

John

~~~~~~~~~~~~~~~~

John Millett
Director, OAR Communications
Desk: 202-564-2903
Cell: 202-510-1822
~~~~~~~~~~~~~~~~

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/25/2021 2:41:29 PM
**To**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: RE: List of Actions Not Published

Tomas, the 4 rules sent back to us from OMB are below. I can provide you with the briefing papers that accompanied these packages through the process if it would be helpful.

Biogenic CO2 (Proposed Rule)
2021 RFS Rule (Proposed Rule)
Guidance for Ozone and Fine Particulate Matter Permit Modeling
Add 1-BP to HAP List (Advanced Notice of Proposed Rulemaking)

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

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**From:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Sent:** Monday, January 25, 2021 8:55 AM
**To:** Campbell, Ann <Campbell.Ann@epa.gov>; Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** RE: List of Actions Not Published

Thank you Ann! Do you happen to have more information about the packages that came back from OMB?

---

**From:** Campbell, Ann <Campbell.Ann@epa.gov>
**Sent:** Friday, January 22, 2021 5:28 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Subject:** List of Actions Not Published

**Ex. 5 Deliberative Process (DP)**

# Ex. 5 Deliberative Process (DP)

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Message

**From:** POLITICO Pro [alert@email.politicopro.com]
**Sent:** 1/29/2021 10:13:10 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** A $30B fund sitting inside USDA tees up a tug-of-war

## A $30B fund sitting inside USDA tees up a tug-of-war

By Liz Crampton

01/29/2021 05:12 PM EST

The Trump administration used it to bail out farmers suffering from its trade wars. Now the Biden administration wants to deploy a $30 billion pot of money in the Agriculture Department to tackle climate change, support restaurants and kickstart other programs without waiting for Congress.

Long hidden in obscurity as a Depression-era financial institution, the Commodity Credit Corp. is shaping up as one of the first focal points for how the Biden administration is quickly revamping flexible programs left behind by former President Donald Trump.

Before the Trump era, the CCC was used in narrow ways to support farm income and prices, like helping cotton growers with ginning costs and purchasing cheese to boost dairy farmers. It's also used to fund certain conservation programs, foreign market development, export credit and commodity purchases.

It became a signature tool in the last administration, which used it to dole out billions in aid to farmers suffering from Trump's trade wars and tariffs. It was also dipped into to provide financial relief to farmers hit by the pandemic.

Trump's Agriculture secretary, Sonny Perdue, "certainly took the training wheels off," said Scott Faber, senior vice president of government affairs for the Environmental Working Group, a human health and environment nonprofit.

Perdue dusted off the little-known fund and leveraged its authority to help out producers financially hurt by retaliatory tariffs through a combination of direct payments and commodity purchases that eventually ballooned farmers' bottom lines. The billions paid out to farmers far eclipsed the massive 2008 auto bailout, and accounted for 40 percent of farm income in 2020.

That aggressive approach could now leave Biden's USDA nominee, Tom Vilsack, wide leeway to pursue his own priorities.

Biden officials have their own ideas about how the money should be spent, setting up a tug-of-war over its limited resources. The trick will be convincing Congress that the USDA has the authority to use funds from the so-called Commodity Credit Corp. to create a "carbon bank" to pay producers for using sustainable farming practices to capture carbon in soil.

"Secretary Sonny sure made a strong play for the CCC and it certainly seems like Secretary Vilsack ought to have that kind of influence on how it's spent," an agriculture lobbyist told POLITICO who was granted anonymity in order to speak freely.

But Vilsack could run into some problems before the USDA can start writing checks. His intentions with the CCC are expected to be a line of questioning during his Senate confirmation hearing, which is scheduled for Tuesday. The fund, which borrows from the U.S. Treasury, must be replenished through the congressional appropriation process.

Vilsack already indicated in an interview with the Storm Lake Times that he believes he will have significant executive authority through the corporation and he will "create demonstration projects that can be incorporated as full programs into the next farm bill in two years."

New purposes for the CCC may extend to many different needs. In his stimulus plan, Biden identified the fund as a potential source of economic relief for restaurants as many have shuttered or scaled back operations during the pandemic.

The Agriculture Department declined to comment.

Senate Agriculture Chairwoman Debbie Stabenow told reporters Thursday that she believes Vilsack, when confirmed, will have the leeway to use the funds to create a carbon bank, making congressional action to expand its charter unnecessary.

"We're looking closely at that," she said. "My initial look is that he does have the authority but we will certainly be following that further. We will take a deep dive on that but my initial look is that the secretary would have the ability to do that."

During the Trump administration, the Agriculture Department's allocation of trade aid payments, which went largely to the nation's biggest row-crop farming operations, ran into criticism from Democrats on Capitol Hill. But Congress never attached any terms to how the money was spent, and continued to replenish the bank's annual $30 billion borrowing limit.

"You could argue that Congress didn't authorize anything related to MFP [Market Facilitation Program] so why would they speak out now?'" said Ferd Hoefer, founder of Farm, Food, Environment Policy Consulting. "That will work itself out politically."

Yet additional trade payments may not be completely off the table. While some signs indicate that parts of the farm economy have rebounded from their slump in 2020, such as rising corn prices, unsettled trade relationships could throw net farm income for a loop. And there will be a continued need to use the CCC to help producers and other parts of the food supply chain weather the pandemic.

"I don't think we have a full sense of what's ahead of us," said John Newton, the American Farm Bureau Federation's chief economist.

Therefore if the Biden administration moves forward with the carbon bank idea, agriculture lobbying groups are anticipated to push Congress to add more money to the fund.

Newton said that "serious consideration" should be given to expanding the fund's borrowing capacity, potentially up to $60 billion. "Somewhere in that neighborhood would increase the ability to provide financial and technical support for increased adoption of climate smart practices," he said.

"Figuring out a way to revisit their borrowing capacity will allow us to do some very creative things with the CCC," Newton said.

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**Subject**: Accepted: Climate Change Website
**Location**: Microsoft Teams Meeting

**Start**: 1/27/2021 4:30:00 PM
**End**: 1/27/2021 5:00:00 PM

**Recurrence**: (none)

# United States Court of Appeals

**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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Argued September 22, 2020 Decided January 29, 2021

No. 15-1465

SIERRA CLUB, ET AL.,
PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY AND ANDREW WHEELER, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENTS

STATE OF TEXAS AND TEXAS COMMISSION ON ENVIRONMENTAL QUALITY,
INTERVENORS

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Consolidated with 19-1024

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On Petitions for Review of Administrative Action
of the United States Environmental Protection Agency

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*Seth L. Johnson* argued the cause and filed the briefs for petitioners.

*David O'Brien Frederick* and *Amy Catherine Dinn* were on the brief for *amicus curiae* Caring for Pasadena Communities in support of petitioners.

*Perry M. Rosen*, Senior Attorney, United States Department of Justice, argued the cause for the respondents. With him on the brief were *Jeffrey Bossert Clark*, Assistant Attorney General, and *Jonathan D. Brightbill*, Principal Deputy Assistant Attorney General.

*Ken Paxton*, Attorney General, Office of the Attorney General for the State of Texas, *Jeffrey C. Mateer*, First Assistant Attorney General, *Priscilla M. Hubenak*, Chief, Environmental Protection Division, and *Linda B. Secord*, Assistant Attorney General, were on the brief for intervenor-respondents the State of Texas and the Texas Commission on Environmental Quality.

*Bayron T. Gilchrist*, *Barbara Baird*, and *Megan E. Lorenz Angarita* were on the brief for *amicus curiae* South Coast Air Quality Management District in support of respondents.

*Aaron M. Flynn*, *Lucinda Minton Langworthy*, *Daryl L. Joseffer*, *Michael B. Schon*, and *Peter Tolsdorf* were on the brief for *amicus curiae* American Chemistry Council, et al. in support of respondents.

Before: TATEL and KATSAS, *Circuit Judges*, and EDWARDS, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* TATEL.

TATEL, *Circuit Judge*: In these consolidated cases, we consider challenges to four provisions of the Environmental Protection Agency's 2015 and 2018 rules implementing the National Ambient Air Quality Standards for ozone. For the reasons set forth below, we vacate two provisions—the interprecursor trading program and the interpretation of the

Clean Air Act's contingency measures requirements—because they contravene the statute's unambiguous language. We vacate another provision—the implementation of the milestone compliance demonstration requirement—because it rests on an unreasonable interpretation of the statute. Lastly, we deny the petition for review with respect to the alternative baseline years provision.

## I.

Under the Clean Air Act, the Environmental Protection Agency (EPA) must publish a list of air pollutants that "may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. § 7408(a)(1)(A). For each air pollutant, EPA must set primary and secondary National Ambient Air Quality Standards (NAAQS), specifying the levels of air quality "based on such criteria and allowing an adequate margin of safety" that are "requisite to protect the public health" for primary NAAQS, *id.* § 7409(b)(1), and specifying levels that are "requisite to protect the public welfare" for secondary NAAQS, *id.* § 7409(b)(2).

"Once EPA establishes NAAQS for a particular pollutant," those NAAQS become "the centerpiece of a complex statutory regime aimed at reducing the pollutant's atmospheric concentration." *Natural Resources Defense Council v. EPA* (*NRDC I*), 777 F.3d 456, 458 (D.C. Cir. 2014) (internal quotation marks omitted). After setting NAAQS, EPA establishes air quality control regions, 42 U.S.C. § 7407, and areas within those regions are designated as "nonattainment" when they do not meet the NAAQS for a specific pollutant, "attainment" when they do meet them, or "unclassifiable" when it cannot be determined "on the basis of available information" whether they meet the NAAQS, *id.* § 7407(d)(1)(A). States have "the primary responsibility for assuring air quality," *id.* § 7407(a), and they must submit state

implementation plans (SIPs) that "provide[] for implementation, maintenance, and enforcement of" the NAAQS. *Id.* § 7410(a)(1).

This case concerns the implementation of the NAAQS for ozone, "an essential presence in the atmosphere's stratospheric layer" that is "dangerous at ground level." *South Coast Air Quality Management District v. EPA* (*South Coast I*), 472 F.3d 882, 887 (D.C. Cir. 2006). Not directly emitted through human activity, ozone "forms when other atmospheric pollutants—ozone 'precursors'—react in the presence of sunlight." *American Trucking Associations, Inc. v. EPA*, 283 F.3d 355, 359 (D.C. Cir. 2002). These precursors include volatile organic compounds (VOCs) and oxides of nitrogen ($NO_X$). *South Coast I*, 472 F.3d at 887.

In 1990, Congress amended the Clean Air Act, finding that the statute had failed to produce the anticipated reductions of ozone and certain other pollutants. Accordingly, it "abandoned the discretion-filled approach of two decades prior in favor of more comprehensive regulation of six pollutants," including ozone, "that Congress found to be particularly injurious to public health." *South Coast I*, 472 F.3d at 887. Congress first redesignated the existing approach as Subpart 1, and that approach "continued to apply as a default matter to pollutants not specifically addressed in the amended portions of the Act." *NRDC I*, 777 F.3d at 460. Congress then added Subpart 2, which focuses on ozone and its precursors. *See* 42 U.S.C. §§ 7511–7511f. Subpart 2 directs that each ozone nonattainment area shall be classified as "marginal," "moderate," "serious," "severe," or "extreme" based on how much the ozone level in that area exceeds the NAAQS. *Id.* §§ 7511(a)–(b). Nonattainment areas must achieve the primary NAAQS "as expeditiously as practicable," *id.* § 7511(a)(1), although "[a]n area that exceeds the NAAQS by a greater

margin is given more time to meet the standard but is subjected to progressively more stringent emissions controls for ozone precursors," chiefly, VOCs and $NO_X$. *South Coast Air Quality Management District v. EPA* (*South Coast II*), 882 F.3d 1138, 1143 (D.C. Cir. 2018) (internal quotation marks omitted).

Setting the stage for this case, EPA promulgated a new NAAQS for ozone in 2008. National Ambient Air Quality Standards for Ozone, 73 Fed. Reg. 16,436 (Mar. 27, 2008). Seven years later, in 2015, it promulgated a rule implementing the 2008 NAAQS. Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements (2015 Implementation Rule), 80 Fed. Reg. 12,264 (Mar. 6, 2015). Several petitioners in this case challenged various provisions of that 2015 Implementation Rule, and our court resolved all but one of those challenges in *South Coast Air Quality Management District v. EPA*, or *South Coast II*, 882 F.3d 1138. That remaining challenge related to a provision called the "interprecursor trading program." While *South Coast II* was pending, EPA granted an administrative petition to reconsider that program, so the *South Coast II* panel severed the challenge, leaving it unresolved. Order, *South Coast Air Quality Management District v. EPA*, No. 15-1115 (D.C. Cir. Dec. 18, 2015).

Three years later, EPA included the interprecursor trading program in a rule implementing new ozone NAAQS that it had issued in 2015. *See* National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. 65,292 (Oct. 26, 2015); Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements (2018 Implementation Rule), 83 Fed. Reg. 62,998 (Dec. 6, 2018). That 2018 Implementation Rule is the focus of this case.

Petitioners Sierra Club, Conservation Law Foundation, Downwinders at Risk, Physicians for Social Responsibility – Los Angeles, and National Parks Conservation Association challenge four features of the 2018 Rule: (1) the interprecursor trading program, as well as provisions (2) allowing states to demonstrate compliance with the Act's reasonable further progress milestone requirements through an implementation-based method, (3) allowing states to choose between two options for the reasonable further progress baseline year, and (4) allowing nonattainment areas to use already-implemented measures to satisfy the Act's contingency measures requirements. Petitioners argue that these four provisions are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 7607(d)(9)(A). We have jurisdiction to consider their challenges under 42 U.S.C. § 7607(b)(1), "which gives this court exclusive jurisdiction over challenges to final EPA actions." *Natural Resources Defense Council v. EPA*, 643 F.3d 311, 317 (D.C. Cir. 2011).

## II.

Because Petitioners challenge all four provisions on the ground that they violate the Clean Air Act, we apply the familiar two-step framework of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *See NRDC I*, 777 F.3d at 463 ("review[ing] EPA's interpretation of the Clean Air Act pursuant to the two-step *Chevron* framework"). We first ask whether Congress has "directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. But if "the statute is silent or ambiguous with respect to the specific issue," we defer to EPA's interpretation of the Act as long as it is "based on a permissible construction of the statute." *Id.* at 843.

**A.**

We start with Petitioners' challenge to the interprecursor trading program for permitting offsets. Under the Act's Nonattainment New Source Review program, SIPs must require permits for the modification or construction of major stationary sources "to assure" that the relevant NAAQS "are achieved." 42 U.S.C. § 7410(a)(2)(C); *see South Coast II*, 882 F.3d at 1144. The goal is "to ensure that new or modified sources will not exacerbate the pollution problem in the nonattainment area." *South Coast II*, 882 F.3d at 1144. EPA may issue permits for a source if the agency determines that sufficient offsets, or emissions reductions, have been obtained from other sources in the area, "such that total allowable emissions from existing sources in the region, from new or modified sources which are not major emitting facilities, and from the proposed source will be sufficiently less than total emissions from existing sources" by the time construction or modification begins. 42 U.S.C. § 7503(a)(1)(A). Generally, sources can comply with offset requirements "for increased emissions of any air pollutant only by obtaining emission reductions of such air pollutant from the same source or other sources in the same nonattainment area." *Id.* § 7503(c)(1). These emissions reductions "shall assure that the total tonnage of increased emissions of the air pollutant from the new or modified source shall be offset by an equal or greater reduction . . . in the actual emissions of such air pollutant from the same or other sources in the area." *Id.*

Subpart 2 extends the permit requirements to ozone and its precursors. *See id.* § 7511a(a)(2)(C) (requiring permit program in SIPs for marginal areas); *id.* § 7511a(b) (moderate areas); *id.* § 7511a(c) (serious areas); *id.* § 7511a(d) (severe areas); *id.* § 7511a(e) (extreme areas). As for VOC offsets, Subpart 2 provides that "[f]or purposes of satisfying the emission offset requirements of this part, the ratio of total emission reductions

of volatile organic compounds to total increased emissions of such air pollutant shall be at least" various default ratios, depending on the level of nonattainment: 1.1 to 1 for marginal areas, *id.* § 7511a(a)(4), 1.15 to 1 for moderate areas, *id.* § 7511a(b)(5), 1.2 to 1 for serious areas, *id.* § 7511a(c)(10), 1.3 to 1 for severe areas, *id.* § 7511a(d)(2) (subject to exception), and 1.5 to 1 for extreme areas, *id.* § 7511a(e)(1) (subject to exception). Subpart 2 extends these provisions to $NO_X$, although it excludes certain circumstances, such as when EPA determines that, for specific sources, "net air quality benefits are greater in the absence of reductions of oxides of nitrogen from the sources concerned." *Id.* § 7511a(f)(1).

The 2018 Implementation Rule interprets these provisions to allow interprecursor trading programs for offsets. Under these programs, which states may choose to establish, when ozone-related offsets are required for permits under the Act's Nonattainment New Source Review program, the offset requirement can be satisfied by "trading" reductions in emissions of ozone *precursors*, i.e., VOCs and $NO_X$. 2018 Implementation Rule, 83 Fed. Reg. at 63,016–21. Put differently, the 2018 Rule interprets the statute as requiring offsets of *ozone* for these permits, and accordingly allows offsets—emissions reductions—of one ozone precursor (VOCs or $NO_X$) to stand in for the other ($NO_X$ or VOCs, respectively) in most circumstances. *Id.* Because reductions in one precursor's emissions are not always equivalent, in terms of their impact on ozone levels, to reductions in the other precursor's emissions, the 2018 Implementation Rule requires that, to mediate between the two precursors, states would have to use (1) default ratios, (2) case-specific ratios, or (3) a combination of the two. *Id.* at 63,017. States may implement interprecursor trading ratios without EPA approval, but those ratios not in SIPs would be subject to public comment when used in individual permits. *Id.* at 63,017–18. These ratios, the

2018 Rule explains, must "provide an equivalent or greater ozone air quality benefit in the applicable ozone nonattainment area" than would exist absent interprecursor trading. *Id.* at 63,017.

An example in the 2018 Implementation Rule helps to clarify what this arrangement might look like in practice. *See id.* at 63,016 n.39. Suppose that a major source subject to Nonattainment New Source Review in a moderate area seeks to offset an increase in $NO_X$ emissions of 200 tons per year with reductions in VOC emissions. *Id.* Under the 2018 Rule, that 200 tons per year increase is first subject to the moderate area offset ratio of 1.15 to 1 set by the Act, *see* 42 U.S.C. § 7511a(b)(5), and the result of that calculation is then subject to the relevant interprecursor trading ratio, which the Rule assumes is 5 here. 2018 Implementation Rule, 83 Fed. Reg. at 63,016 n.39. At the first step, 200 tons per year is multiplied by 1.15, yielding 230 tons per year. At the second step, those 230 tons per year are multiplied by 5, yielding 1,150 tons per year. So the increase in $NO_X$ emissions of 200 tons per year could be offset by a reduction in VOC emissions of 1,150 tons per year.

Petitioners urge us to vacate the interprecursor trading program, arguing that (1) the Clean Air Act unambiguously prohibits interprecursor trading, (2) EPA has provided no rational basis for authorizing the program, and (3) interprecursor trading violates the Act's anti-backsliding provision. Petitioners also contend that the program impermissibly allows required emissions reductions for one precursor to be offset with "banked allowances" of emissions reductions of the other precursor. Because we agree with Petitioners that the interprecursor trading program violates the statute's plain text, we have no need to address their other arguments.

Recall that Subpart 2's offset provisions related to ozone and its precursors specify that "the ratio of total emission reductions of volatile organic compounds to total increased emissions of *such* air pollutant shall be" the various ratios previously laid out. 42 U.S.C. §§ 7511a(a)(4), (b)(5), (c)(10), (d)(2), (e)(1) (emphasis added). The statute generally extends these offset ratios to $NO_X$. *See* 42 U.S.C. § 7511a(f)(1).

As Petitioners argue, the phrase "such air pollutant" in these subsections unambiguously refers back to VOCs. In general, "the adjective 'such' means 'of the kind or degree already described or implied.'" *Culbertson v. Berryhill*, 139 S. Ct. 517, 522 (2019) (quoting H. Fowler & F. Fowler, Concise Oxford Dictionary of Current English 1289 (5th ed. 1964)). The closest potential "air pollutant" preceding the "such air pollutant" language is "volatile organic compounds," which appears in the very same sentence just five words earlier. *See* 42 U.S.C. §§ 7511a(a)(4), (b)(5), (c)(10), (d)(2), (e)(1). By contrast, the word "ozone," which EPA interprets "such air pollutant" to mean, last appears five subsections above the first precursor offset provision and 334 words before the phrase "such air pollutant." *See id.* § 7511a(1)(C). The phrase "such air pollutant" thus "quite obviously refers back to" volatile organic compounds, and the same reasoning applies to $NO_X$ under the provision extending these offset requirements to $NO_X$. *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (per curiam). In this context, then, the statute treats VOCs and $NO_X$ as the relevant air pollutants. Had Congress intended to allow interprecursor trading for offsets, it would have used the phrase "ozone precursors" instead of "such air pollutant," as it does elsewhere in the contemporaneously enacted provisions of Subpart 2. *See, e.g.*, 42 U.S.C. §§ 7511d(e), 7511f. The plain language of the statute thus requires that increased VOC emissions be offset with

reductions in VOC emissions, and the same is true for $NO_X$ emissions under most circumstances.

Seeking to avoid the definitional and grammatical consequences of "such," EPA focuses on the statute's general offset provision in Subpart 1, 42 U.S.C. § 7503(c)(1), and its definition of air pollutant, which "includes any precursors to the formation of any air pollutant, to the extent [EPA] has identified such precursor or precursors for the particular purpose for which the term 'air pollutant' is used," *id.* § 7602(g). These provisions, EPA argues, give it broad discretion to define "air pollutant" for the purpose of offsets, and it has determined that it is ozone, not VOCs and $NO_X$, that is the "air pollutant" here. Consequently, "a source may satisfy *any* offset requirement . . . by obtaining commensurate reductions of the 'air pollutant' associated with the newly constructed or modified source, in this case ozone." EPA Br. 16.

In addition to ignoring the word "such," EPA's argument runs afoul of the "'basic principle of statutory construction that a specific statute . . . controls over a general provision . . . particularly when the two are interrelated and closely positioned.'" *Adirondack Medical Center v. Sebelius*, 740 F.3d 692, 698 (D.C. Cir. 2014) (alterations in original) (quoting *HCSC–Laundry v. United States*, 450 U.S. 1, 6 (1981)). It is true that section 7602(g) gives EPA general authority to define "air pollutant," but section 7511a(a)(4) and its counterparts expressly recognize that VOCs and $NO_X$ are precursors for the purpose of offsets, precluding EPA from determining otherwise. It is especially clear that whatever discretion section 7602(g) affords EPA cannot trump the precursor-specific provisions given that, as the Supreme Court has made clear, "[t]he principal distinction between Subpart 1 and Subpart 2 is that the latter eliminates regulatory discretion that the former

allowed." *Whitman v. American Trucking Associations, Inc.*, 531 U.S. 457, 484 (2001).

Moreover, EPA's interpretation of "such air pollutant" as referring to ozone conflicts with the plain text of the general offset provision and the ozone-specific offset provisions. Those provisions all relate to "emissions" of "such air pollutant," *see id.* §§ 7503(c)(1), 7511a(a)(4), but, as EPA recognizes, "ozone is not emitted directly into air," *Maryland v. EPA*, 958 F.3d 1185, 1190 (D.C. Cir. 2020); *see* National Ambient Air Quality Standards for Ozone, 80 Fed. Reg. at 65,299 ("Ozone is formed near the earth's surface due to chemical interactions involving solar radiation and precursor pollutants including volatile organic compounds (VOCs) and NOx."). Given that there are no emissions of ozone in the same way that there are emissions of VOCs or NOx, it makes no sense to read those provisions as referring to ozone. EPA's interpretation also conflicts with the general offset provision's tonnage requirements. Although that provision requires that the tonnage to be reduced be "greater or equal" to the increased tonnage of an air pollutant, *see* 42 U.S.C. § 7503(c)(1), if emissions reductions of VOCs and NOx were traded, the increased tonnage of emissions of one air pollutant—either VOCs or $NO_X$—could be less than the tonnage of the reduced emissions of the same pollutant.

EPA attempts to distinguish section 7511a(a)(4) and its counterparts from other provisions of Subpart 2 that specifically refer to one or both precursors instead of using the phrase "such air pollutant." According to EPA, Congress's use of the phrase "such air pollutant" in section 7511a(a)(4) when it could have specified VOC emissions reductions demonstrates an intent to allow the agency to define what "such air pollutant" is. This argument overlooks the word "such" and ignores the differing contexts of section 7511a(a)(4) and the

provision that EPA relies on, section 7511a(b)(1)(A)(i). The latter addresses "volatile organic compound emission reductions" before addressing both "reductions in emissions of volatile organic compounds and oxides of nitrogen." 42 U.S.C. § 7511a(b)(1)(A)(i). In that context, when both precursors are discussed together in the same section, use of the phrase "such air pollutant" at any point would only confuse the reader. It would, in other words, be unclear which precursor "such" referred to. But section 7511a(a)(4) and its counterparts risk no such confusion since the only possible air pollutant referenced in the same section is VOCs. *See* 42 U.S.C. §§ 7511(a)(4), (b)(5), (c)(10), (d)(2), (e)(1). Section 7511a(b)(1)(A)(i)'s language thus yields no insight as to the meaning of section 7511a(a)(4) and its parallel provisions.

Next, EPA relies on section 7511a(c)(2)(C), which it claims allows interprecursor trading in the context of the second progress requirement. *See* 42 U.S.C. § 7511a(c)(2)(C). That section provides that, for the relevant reasonable further progress demonstration, a SIP may contain "a demonstration to the satisfaction of [EPA] that the applicable implementation plan . . . provides for reductions of emissions of VOC[s] and oxides of nitrogen . . . that would result in a reduction in ozone concentrations at least equivalent to that which would result from the amount of VOC emission reductions required." *Id.* According to EPA, this section indicates that Congress intended to permit interprecursor trading more broadly. The provision, however, proves just the opposite. "[W]e 'generally presum[e] that Congress acts intentionally and purposely when it includes particular language in one section of a statute but omits it in another.'" *Intel Corp. Investment Policy Committee v. Sulyma*, 140 S. Ct. 768, 777 (2020) (second alteration in original) (quoting *BFP v. Resolution Trust Corp.*, 511 U.S. 531 (1994)). That Congress permitted limited interprecursor trading in the context of the second reasonable

further progress requirement in Subpart 2, but not in the general or precursor-specific offset provisions, demonstrates that it did not intend to allow such trading outside this narrow context. *See South Coast I*, 472 F.3d at 894 (finding that the lack of certain provisions in Subpart 2, when they had been included in Subpart 1, demonstrated that Congress did not intend them to apply to Subpart 2).

EPA's remaining argument, that its interpretation better aligns with section 7511a(f)(1)'s exception for when the precursor-specific offset provisions extend to $NO_X$, is "post hoc," as it appears nowhere in the 2018 Rule. *NRDC I*, 755 F.3d at 1020. Accordingly, we cannot sustain the interprecursor trading program on that basis. *See Motor Vehicle Manufacturers Ass'n of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 50 (1983) ("It is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself."). In any event, EPA's argument conflicts with the plain meaning of the directly controlling provisions, as we have explained above.

**B.**

Petitioners next challenge EPA's interpretation of the statutory provisions governing how states are to demonstrate that they have achieved reasonable further progress milestones. Specifically, SIPs for nonattainment areas must "require reasonable further progress," 42 U.S.C. § 7502(c)(2), defined as "such annual incremental reductions in emissions of the relevant air pollutant as are required by this part or may reasonably be required by [EPA] for the purpose of ensuring attainment of the applicable national ambient air quality standard by the applicable date," *id.* § 7501(1). And under Subpart 2, SIPs for ozone nonattainment areas classified as moderate or above must provide for reductions of VOC emissions by "at least 15 percent from baseline emissions." *Id.*

§ 7511a(b)(1)(A). "Baseline emissions" are defined as "the total amount of actual VOC or $NO_X$ emissions from all anthropogenic sources in the area during the" baseline year, originally 1990, excluding certain emissions not at issue here. *Id.* § 7511a(b)(1)(B). For serious and above ozone nonattainment areas, reductions in VOC emissions must average at least three percent per year over each consecutive three-year period until attainment. *Id.* § 7511a(c)(2)(B). States are further required to submit "a comprehensive, accurate, current inventory of actual emissions from all sources" every three years. *Id.* §§ 7511a(a)(1), (3).

Beginning six years after the baseline year, and every three years thereafter, states must determine whether each serious or above ozone nonattainment area "has achieved a reduction in emissions during the preceding intervals equivalent to the total emission reductions required to be achieved by the end of such interval" by the reasonable further progress provisions. *Id.* § 7511a(g)(1). This reduction in emissions is called a "milestone." *Id.* Within ninety days of achieving a milestone, each state in which the relevant nonattainment area is located must "submit to the Administrator a demonstration that the milestone has been met." *Id.* § 7511a(g)(2). That demonstration "shall be submitted in such form and manner, and shall contain such information and analysis, as [EPA] shall require, by rule." *Id.* Within ninety days of receiving the demonstration, EPA determines whether that demonstration is adequate. *Id.*

The 2018 Rule allows states to demonstrate milestone compliance in one of two ways: either with "actual emissions reductions, as demonstrated with periodic emissions inventory data," or "[c]ompliance with control measures requirements in" the relevant reasonable further progress plan. 2018 Implementation Rule, 83 Fed. Reg. at 63,011. Petitioners

challenge the implementation-based method, which allows states to demonstrate that they have met a milestone by showing "percent implementation," that is, that the area has implemented measures from the relevant plan projected to meet that milestone, rather than by presenting actual emissions data. *Id.* at 63,011–12. Petitioners argue that EPA's interpretation is unlawful and unreasonable, and that the agency failed to respond adequately to comments raising concerns with its approach.

As for the former argument, it is true, as EPA points out, that the statute provides that the milestone compliance demonstration "shall be submitted in such form and manner, and shall contain such information and analysis, as the [EPA] shall require, by rule." 42 U.S.C. § 7511a(g)(1). Given the discretion that this provision allows, Congress has not "unambiguously foreclosed the agency's statutory interpretation." *Catawba County, North Carolina v. EPA*, 571 F.3d 20, 35 (D.C. Cir. 2009). Since Congress has not spoken directly to this precise issue, our inquiry is governed by *Chevron* step two. We ask whether EPA, in interpreting this ambiguous provision, "'has acted reasonably and thus has stayed within the bounds of its statutory authority.'" *Maryland*, 958 F.3d at 1198 (quoting *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 315 (2014)).

Two closely related statutory provisions are particularly relevant here. First, the "baseline emissions" from which milestone compliance is to be measured are defined in terms of "*actual* VOC or $NO_X$ emissions." 42 U.S.C. § 7511a(b)(1)(B) (emphasis added). Second, the provisions for reasonable further progress make clear that "emissions reductions are creditable toward the" required "15 percent" reduction only "to the extent they have *actually* occurred." *Id.* § 7511a(b)(1)(C) (emphasis added). The statute later references and incorporates

this subsection into the milestone requirements. *See id.* § 7511a(g)(1). Significantly for our purposes, both provisions are unquestionably quantitative and grounded in actual emissions data. The second requires a quantitatively measurable 15 percent reduction in actually occurring emissions, *id.* § 7511a(b)(1)(B), and the first indicates that the baseline from which milestone compliance is measured is actual emissions, *id.* § 7511a(b)(1)(C). Notwithstanding EPA's focus on section 7511a(g)(1), sections 7511a(b)(1)(B) and (C) demonstrate that milestones can be achieved only through reductions in actual emissions, and that milestone compliance can be demonstrated only through some form of actual emissions data. *See National Treasury Employees Union v. Chertoff*, 452 F.3d 839, 861 (D.C. Cir. 2006) (explaining that an agency may not focus on one provision in such a way that it "elevate[s] one provision of the [Act] over" other provisions).

Highlighting the unreasonableness of EPA's position, a 2004 Evaluation Report by the Office of the Inspector General details how emissions may outpace projections and how a SIP's control measures may be less effective than anticipated. *Evaluation Report: EPA and States Not Making Sufficient Progress in Reducing Ozone Precursor Emissions in Some Major Metropolitan Areas*, Office of the Inspector General (Sept. 29, 2004), Joint Appendix (J.A.) 244–46. According to the Evaluation Report's executive summary, review of data from the 1990s revealed that "States may have used inaccurate data, assumptions, and projections of emission growth, resulting in fewer reductions planned than appropriate." *Id.* at ii, J.A. 246. For example, it points to the Atlanta metropolitan area, where the relevant ozone reduction plan "assumed a [population] growth rate that was about half of the population growth rate" that the area actually experienced during the relevant period. *See id.*, J.A. 246. Indeed, the Report devotes an entire section to explaining how emissions reductions were

"underestimated due to inaccurate growth projections and other factors." *See id.* at 22–25, J.A. 249–52. The Report also explains how implementation plans may be less effective than anticipated, pointing out that Georgia's program had projected that its VOC emissions reductions plan would be 100% effective but was ultimately only 81% effective. *Id.* at 20, J.A. 247. These problems, the Report finds, were compounded by "[l]imited EPA oversight of the development and implementation of emission control plans." *Id.* at ii, J.A. 246. Such record evidence demonstrates that EPA's implementation-based approach will fall far short of the actual emissions data that the statute contemplates.

EPA has failed to address these shortfalls. When Petitioners raised them during the rulemaking, EPA "encourage[d] air agencies to work with their EPA Regional office to develop a [milestone compliance demonstration] suitable for the specific facts and circumstances of the attainment plan," which it claimed would "address[], as appropriate, the potential emissions growth." Response to Comments on Implementation of the 2015 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements, EPA (Oct. 31, 2018), J.A. 518. Yet, as Petitioners point out, EPA never explained how that suggestion would address the referenced shortfalls of the implementation-based approach. Nor has EPA suggested that the problems identified in the 2004 Evaluation Report are somehow inapplicable or outdated today. Given such problems, EPA has failed to show how its implementation-based approach can be squared with the quantitative statute. That failure is all the more glaring in light of the fact that the 1990 Amendments were "purposefully crafted to limit EPA discretion" and to ensure that actual emissions reductions were made. *South Coast I*, 472 F.3d at 887, 894–95; *see* H.R. Rep. No. 101-490, pt. 1, at 229 (1990) ("The objective is to achieve the standard as early

as possible with effective and enforceable measures and without gaming by the States, industry, and others.").

According to EPA, it "makes sense" for baseline emissions to be actual emissions "because those emissions are historic, as a baseline should be." EPA Br. 41. Consequently, it insists, the provision's reference to actual emissions says nothing about "how States or EPA are to assess compliance with a milestone." *Id.*; *see* 42 U.S.C. § 7511a(b)(1)(B). This argument falls flat. Given sections 7511a(b)(1)(B) and (C)'s focus on actual, quantitative reductions in emissions, "[t]he interpretation advanced by EPA cannot be squared with Congress's desire to limit EPA discretion" or with the statutory structure. *South Coast I*, 472 F.3d at 894.

EPA argues that the flexibility afforded by the implementation-based approach is required by time schedules established in other regulations. Specifically, although the statute directs states to demonstrate milestone compliance within ninety days of that milestone being met, 42 U.S.C. § 7511a(g)(1), "EPA regulations allow States twelve months to report their inventory" due to "the complexities associated with generating and verifying the data." EPA Br. 42. For this reason, EPA tells us, it would be difficult, if not impossible, for states to comply with the ninety-day deadline if actual emissions data were required. Perhaps so, but the *statute* requires quantitative and actual emissions data, and "EPA may not construe the statute in a way that completely nullifies textually applicable provisions meant to limit its discretion." *Whitman*, 531 U.S. at 485. EPA's arguments miss the mark for an additional reason, as they fail to explain how reductions from *actual* baseline emissions numbers can be measured, or how emissions reductions that *actually* occurred can be credited toward an area's progress, without *actual* emissions data. *See* 42 U.S.C. §§ 7511a(b)(1)(B), (C).

EPA makes two final arguments: that actual emissions data is just as fallible as the modeling underlying the implementation-based method, and that its review, together with the contingency measures, will ensure that actual reductions occur. But EPA made neither of these arguments in the rulemaking, and as indicated above, "we cannot accept appellate counsel's *post hoc* rationalizations for agency action." *National Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1138 (D.C. Cir. 2013) (internal quotation marks omitted).

Given that the implementation-based approach is "[un]reasonable in light of the Act's text, legislative history, and purpose," we cannot defer to it. *Southern California Edison Co. v. FERC*, 116 F.3d 507, 511 (D.C. Cir. 1997). We thus have no need to reach Petitioners' other arguments.

**C.**

Petitioners' next challenge also relates to the 2018 Implementation Rule's interpretation of the reasonable further progress requirements. Specifically, they challenge the provision allowing states to choose between two alternative baseline years.

As explained above, the Act measures reasonable further progress from a starting baseline year. *See South Coast II*, 882 F.3d at 1152. Although the statute establishes a baseline year of 1990, it does not define baseline years for any future NAAQS. 42 U.S.C. §§ 7511a(b)(1)(A)–(B); *see South Coast II*, 882 F.3d at 1152. The 2018 Rule defines the default baseline year as "the calendar year for the most recent triennial emissions inventory preceding the year of the area's effective date of nonattainment designation." 2018 Implementation Rule, 83 Fed. Reg. at 63,005. If an area were designated nonattainment in 2018, for example, the reasonable further

progress baseline year would be 2017, which "would be the year of the most recent triennial emissions inventory." *Id.* The Rule also allows states to use an alternative reasonable further progress baseline year that "corresponds with the year of the effective date of an area's designation." *Id.*

In *South Coast II*, we considered a challenge to a similar provision in EPA's 2015 Implementation Rule. That provision allowed states to select an alternative baseline year between 2008 and 2012 if they provided appropriate justification. *South Coast II*, 882 F.3d at 1152. We found that the 2015 Rule's default year—2011, the year for the most recently available triennial emissions inventory preceding nonattainment designation—was reasonable because it was "tied to the three-year statutory cycle for emissions inventories." *Id.* But because "EPA ha[d] failed to provide a statutory justification" when it came to the choice of an alternative baseline year, we vacated the alternative baseline year portion of the 2015 Rule. *Id.* at 1152–53.

Unlike in *South Coast II*, here EPA has "ground[ed] its reasons for" both baseline year alternatives "in the statute, rather than on reasoning divorced from the statutory text." *Id.* at 1152 (internal quotation marks omitted). The default year definition in the 2018 Implementation Rule is the same one that we sustained in *South Coast II* as grounded in the statute. *See id.* at 1152–53. And the alternative year—"the year of the effective date of an area's designation," 2018 Implementation Rule, 83 Fed. Reg. at 63,005—is also rooted in the statute, as 1990 was the year when nonattainment designations first took effect, *see NRDC I*, 777 F.3d at 464. Either option, then, represents a reasonable interpretation of the ambiguous baseline year provision.

Although Petitioners concede as much, *see* Oral Arg. Rec. 15:10–15:30, 18:18–18:30, they nonetheless take issue with EPA allowing states to choose between the two years. They argue that this choice has no grounding in the statute. But it does. As we pointed out in *South Coast II*, the Act contains a gap with respect to the baseline year for future reasonable progress requirements. 882 F.3d at 1152. The original year was 1990, which happened to be both the year that began the triennial emissions inventory cycle and the year in which the designations took effect. *See* 42 U.S.C. §§ 7511a(b)(1)(A)–(B); *South Coast II*, 882 F.3d at 1152; *NRDC I*, 777 F.3d at 464. But now that an area may be designated in any year, and now that the three-year statutory cycle for emissions inventories is underway, not every post-1990 year will satisfy both conditions for a particular area. As the Rule itself points out, this is precisely what happened with the 2015 ozone NAAQS: "for future promulgations and revisions of NAAQS, the year of designations and the year of the most recent triennial emissions inventory may not coincide[,] and for the 2015 ozone NAAQS, they do not." 2018 Implementation Rule, 83 Fed. Reg. at 63,005. Because no single year can serve as a perfect stand-in for 1990, EPA acted reasonably when it allowed states to choose between two baseline year options, each of which is "ground[ed] in the statute." *NRDC I*, 777 F.3d at 468.

**D.**

Lastly, Petitioners dispute EPA's approach to the contingency measure requirements. SIPs must include contingency measures, or "specific measures to be undertaken if the area fails to make reasonable further progress, or to attain the national primary ambient air quality standard by the [applicable] attainment date." 42 U.S.C. § 7502(c)(9). These "measures shall be included in the plan revision as contingency measures to take effect in any such case without further action by the State or the Administrator." *Id.* In addition, SIPs must

"provide for the implementation of specific measures to be undertaken if the area fails to meet any applicable milestone" under Subpart 2's ozone provisions. *Id.* § 7511a(c)(9). Like the general measures, these "shall be included in the plan revision as contingency measures to take effect without further action by the State or the Administrator upon a failure by the State to meet the applicable milestone." *Id.*

Petitioners challenge the 2018 Rule's provision "allow[ing] approval of already implemented measures as contingency measures, so long as" those measures meet other relevant parameters and the state does not rely on them for reasonable further progress or attainment demonstrations. 2018 Implementation Rule, 83 Fed. Reg. at 63,026. The Rule explains that this policy applies only outside of the Ninth Circuit, which has "rejected" EPA's interpretation "that allowed states to rely on control measures that are already in effect as a valid means to meet the contingency measure requirement." *Id.*; *see Bahr v. EPA*, 836 F.3d 1218, 1235–36 (9th Cir. 2016). Instead, the Rule invokes a Fifth Circuit decision "upholding" EPA's interpretation as applied to a particular SIP. 2018 Implementation Rule, 83 Fed. Reg. at 63,026; *see Louisiana Environmental Action Network v. EPA*, 382 F.3d 575, 582–84 (5th Cir. 2004).

We agree with Petitioners and the Ninth Circuit that Congress has "directly spoken to the precise question at issue"—that is, that previously implemented measures cannot qualify as contingency measures. *Chevron*, 467 U.S. at 842–43. The Act's plain text expressly provides that valid contingency measures become operative only when the triggering conditions set forth in the statute occur, and not any earlier.

Using conditional and prospective language, both provisions require SIPs to include measures "to be undertaken if" certain conditions are not achieved, and both require that the measures be included as "contingency measures" "to take effect . . . upon" failure to meet the requirements. *See* 42 U.S.C. §§ 7502(c)(9), 7511a(c)(9). A measure "to be undertaken if" certain standards are not met is, by definition, a measure not yet implemented. *See State Farm Fire & Casualty Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436, 443 (2016) (explaining that "if" and "unless" are "clear[] conditional words"); *Dodd v. United States*, 545 U.S. 353, 358 (2005) (explaining that the word "if" "impose[d] a condition on the applicability of [a] subsection" and citing the dictionary definition of the word, which was "in the event that" or "on condition that" (internal quotation marks omitted)). "[C]ontingency measures" that are "to take effect . . . upon" failure to satisfy standards are likewise not measures that have been implemented before such failure occurs. *See Contingent*, The Merriam-Webster Collegiate Dictionary 270 (11th ed. 2009) (including as a definition of the adjective "contingent" "dependent on or conditioned by something else"); *Delaware Department of Natural Resources & Environmental Control v. EPA*, 895 F.3d 90, 98 (D.C. Cir. 2018) (explaining that the word "upon" denotes "a conditional context" in relation to another provision of Subpart 2 of the Act). And measures that are already implemented are not measures "to take effect" or "to be undertaken" if the area fails to satisfy the applicable requirements. *See, e.g.*, *Take effect*, The Merriam-Webster Collegiate Dictionary 1273 (defining "to take effect" as "to become operative"); *To undertake*, The Merriam-Webster Collegiate Dictionary 1365 (defining "to undertake" as "to take upon oneself; set about," "to put oneself under obligation to perform," "to accept as a charge or responsibility," and "to guarantee" or "promise"). They are simply measures that have failed. *See Bahr*, 836 F.3d at 1235 (finding that the contingency

measures are "control measures that will be implemented in the future").

EPA argues that "Congress was silent as to whether already-implemented measures could serve as contingency measures." EPA Br. 53. As our court has explained, however, "[t]o suggest . . . that *Chevron* step two is implicated any time a statute does not expressly *negate* the existence of a claimed administrative power (*i.e.* when the statute is not written in 'thou shalt not' terms), is both flatly unfaithful to the principles of administrative law . . . and refuted by precedent." *Railway Labor Executives' Ass'n v. National Mediation Board*, 29 F.3d 655, 671 (D.C. Cir. 1994) (en banc). Nor, contrary to EPA's argument, does it make any difference that four judges in other circuits—three in the Fifth and one in the Ninth—have found the statute ambiguous. *See, e.g.*, *Adams Fruit Co. v. Barrett*, 494 U.S. 638 (1990) (finding a provision unambiguous on an issue about which circuits had disagreed). Although we are always interested in knowing how our sister circuits have approached the same question in other cases, it is *this* court that is interpreting the statute here, and *this* court has concluded that the statute is unambiguous. That ends the matter. *See Chevron*, 467 U.S. at 842–43. EPA "cannot rely on its gap-filling authority to supplement the Clean Air Act's provisions when," as here, "Congress has not left the agency a gap to fill." *Natural Resources Defense Council v. EPA*, 749 F.3d 1055, 1064 (D.C. Cir. 2014).

## III.

For the foregoing reasons, we grant in part and deny in part the petitions for review in these consolidated cases. Specifically, we vacate the provisions of the rule allowing (1) interprecursor trading, *see* 2018 Implementation Rule, 83 Fed. Reg. at 63,016–21; (2) use of the implementation-based option for milestone compliance demonstrations, *see id.* at 63,010–12;

and (3) use of already implemented measures as contingency measures, *see id.* at 63,026–27. We deny the petition for review as to the provision allowing states to choose between two alternative baseline years.

*So ordered.*

Message

**From**: Millett, John [Millett.John@epa.gov]
**Sent**: 3/12/2021 9:57:15 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]; Shoaff, John [Shoaff.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]; DeLuca, Isabel [DeLuca.Isabel@epa.gov]; Stevens, Katherine [stevens.katherine@epa.gov]
**Subject**: CSAPR Comms materials - PR, comms plan, and call list/tick-tock
**Attachments**: CSAPR draft pr_31121.docx; OAR Communications Plan_Final Revised CSAPR Update DRAFT 3.11.21v2.docx; Detailed Comms Plan for Final RCU March 12.docx

Hi All – this is the latest of everything – the press release is close to final, but OPA still needs to review and approve the administrator quote. CAMD, the regions, OCIR and Rosemary are handling the notifications and follow up, so there are no calls (at this point) for the OAR/IO's time for notifications. Talking points are in the "OAR Communications Plan" .doc, and the call list and tick-tock are in the "Detailed comms plan."

Folks are as prepared as they can be for whenever the rule is signed.

Thanks --

John

~~~~~~~~~~~~~~~~

John Millett
Director, OAR Communications
Desk: 202-564-2903
Cell: 202-510-1822
~~~~~~~~~~~~~~~~

Message

**From**: Millett, John [Millett.John@epa.gov]
**Sent**: 1/26/2021 1:21:04 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]; Shaw, Betsy [Shaw.Betsy@epa.gov]
**Subject**: RE: Greeting to OAR Staff -- near final draft
**Attachments**: OAR arrival note 1-26 jg CLEAN.docx

Thanks, Joe Betsy and Ann – all cleaned up and ready to go. The message is attached and in text, just below the sending instructions.

Sorry one of us can't be in your office to walk you through this!

**Ex. 5 Deliberative Process (DP)**

Check everything again . . . then click "send"

Please call me at 202-510-1822 if anything weird happens!

~~~~~~~~~~~~~~~~~

Subject: Message from Joe Goffman, Acting Assistant Administrator for OAR

**Ex. 5 Deliberative Process (DP)**
~~~~~~~~~~~~~~~~~

# Ex. 5 Deliberative Process (DP)

Looking forward to connecting face-to-face

Thank you all very much for being here.

Stay safe and take care of yourselves and each other.

All best,
Joe

Appointment

**From**: Microsoft Outlook [MicrosoftExchange329e71ec88ae4615bbc36ab6ce41109e@usepa.onmicrosoft.com]
**Sent**: 1/27/2021 4:28:09 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]

**Subject**: Meeting Forward Notification: Climate Change Website
**Location**: Microsoft Teams Meeting

**Start**: 1/27/2021 4:30:00 PM
**End**: 1/27/2021 5:00:00 PM

**Recurrence**: (none)

## Your meeting was forwarded

Widener, Charles (Chuck) has forwarded your meeting request to additional recipients.

**Meeting**

Climate Change Website

**Meeting Time**

Wednesday, 27 January 2021 11:30-12:00.

**Recipients**

Shogren, Angela

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Sent by Microsoft Exchange Server

Message

**From**: Shaw, Betsy [Shaw.Betsy@epa.gov]
**Sent**: 1/22/2021 1:49:21 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**CC**: Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: FW: EPA request to DOJ for abeyances and stays of proceedings in rule defensive cases, consistent with new Executive Order
**Attachments**: Draft GC Abeyance Letter to DOJ 01-21-20docx.pdf

FYI in case you haven't already seen this through other channels.

---

**From:** Payne, James (Jim) <payne.james@epa.gov>
**Sent:** Thursday, January 21, 2021 7:16 PM
**To:** Career Deputy Assistant Administrators <Career_Deputy_Assistant_Administrators@epa.gov>; Leadership_Deputy_Regional_Administrators <Leadership_Deputy_Regional_Administrators@epa.gov>
**Subject:** EPA request to DOJ for abeyances and stays of proceedings in rule defensive cases, consistent with new Executive Order

FYI.

Jim

Ex. 6 Personal Privacy (PP) cell

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/26/2021 7:39:36 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: FW: ACTION: Regulatory Freeze memo and process for reviewing FR notices
**Attachments**: Instructions for Resubmittal of Previously Signed FRNs.docx

FYA, please let me know if you have any additional feedback or revisions to the direction I provided to the programs below.

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

**From:** Campbell, Ann
**Sent:** Tuesday, January 26, 2021 2:36 PM
**To:** Iglesias, Amber <Iglesias.Amber@epa.gov>; Culligan, Kevin <culligan.kevin@epa.gov>; Chang, Alice <Chang.Alice@epa.gov>; Burch, Julia <Burch.Julia@epa.gov>; Jessica Mroz (mroz.jessica@epa.gov) <mroz.jessica@epa.gov>; Herbolsheimer, Courtney <herbolsheimer.courtney@epa.gov>; Clarke, Deirdre <clarke.deirdre@epa.gov>; Lee, Raymond <Lee.Raymond@epa.gov>
**Cc:** Shoaff, John <Shoaff.John@epa.gov>; Lubetsky, Jonathan <Lubetsky.Jonathan@epa.gov>; Mcquilkin, Wendy <Mcquilkin.Wendy@epa.gov>; Sandfoss, Kristina <Sandfoss.Kristina@epa.gov>
**Subject:** ACTION: Regulatory Freeze memo and process for reviewing FR notices

**Ex. 5 Deliberative Process (DP)**

# Ex. 5 Deliberative Process (DP)

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/29/2021 9:58:07 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: READING: Briefing Materials for Monday, February 1, 2021
**Attachments**: Goffman Joseph Calendar.ics; 2021-January OTAQ All Hands themes and talking points.docx; OTAQ All Hands - Detailed Agenda.docx; otaqioorgchart-01-2021.pdf; otaqorchart-01-2021.pdf; Hearing Prep_Questions.docx; Final_Administrator Briefing_Revised CSAPR Update_Options Selection_02.01.21.docx; SCC Briefing for Joe Goffman - 012921.pptx; Climate web page mock-up; EO lookback.xlsx; OAR Overview Presentation February 2021.pptx; Jobs Package_OAR.docx

Joe, as discussed, attached are your briefing materials for Monday, February 1, 2021. Copying Tomás here as your calendars are nearly a mirror image.

I've also attached for your review, the climate website materials, the EO Lookback, and a ROUGH framework of the presentation we are putting together for Tuesday's Overview briefing.

And last but not least, I've attached the jobs ideas doc so you have it at the ready as discussion continues through the weekend.

**Goffman, Joseph Calendar**
Goffman.Joseph@epa.gov
On Monday, February 1, 2021
Time zone: (UTC-05:00) Eastern Time (US & Canada)
(Adjusted for Daylight Saving Time)

**February 2021**

| Su | Mo | Tu | We | Th | Fr | Sa |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | | | | | | |

Busy
Out of Office
Tentative
Working Elsewhere
Free
Outside of Working Hours

**February 2021**

**Mon, Feb 1**

**Before 8:00 AM** **Free**

| | | |
|---|---|---|
| ☐ | **8:00 AM – 8:30 AM** | **Free** |
| ■ | 8:30 AM – 9:00 AM | Check-In |
| ■ | 9:00 AM – 9:30 AM | Management Roundtable |
| ■ | 9:15 AM – 10:30 AM | OTAQ All Hands Meeting (Materials attached, 4) |
| ■ | 10:30 AM – 11:30 AM | Moot Prep (Hearing Qs reattached) |
| ■ | 11:30 AM – 12:30 PM | Briefing: Options Selection - Revised CSAPR Update Rule (Materials attached) |
| ■ | 12:30 PM – 1:00 PM | Air Issues Meeting |
| ■ | 1:00 PM – 1:45 PM | Social Cost of Carbon - HFC's (Materials attached) |
| ☐ | **1:45 PM – 2:00 PM** | **Free** |
| ■ | 2:00 PM – 3:00 PM | Senior Staff Meeting |
| ■ | 3:00 PM – 3:45 PM | OAQPS Weekly |
| ■ | 3:45 PM – 4:30 PM | ACE Litigation meeting |
| ☐ | **4:30 PM – 5:00 PM** | **Free** |
| ☐ | 5:00 PM – 5:30 PM | Management Time |
| ☐ | **5:30 PM – 6:00 PM** | **Free** |
| ■ | 6:00 PM – 7:00 PM | The Climate Agenda Interagency Panel |
| ☐ | **After 7:00 PM** | **Free** |

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Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

| | |
|---|---|
| **Subject:** | The Climate Agenda Interagency Panel |
| **Start Time:** | 2021-02-01T18:00:00-05:00 |
| **End Time:** | 2021-02-01T19:00:00-05:00 |

# Office of Transportation and Air Quality

January 2021

**Sarah Dunham, *Office Director***
Benjamin Hengst, *Deputy Office Director*
Julie Henning, Acting *Associate Office Director*
Erica Watkins, *Planning and Budget Office*
Erica Watkins, *Business Operations & Resources Center*
Ruth Schenk, *Safety, Quality, & Facilities Management Center*
Pamela Christian, *Human Resources Officer*

## Assessment and Standards Division
Bill Charmley, *Director*
Kathryn Sargeant, *DD*
Ines Storhok, *AD*

- **Air Quality and Modeling Center** – David Choi
- **Data and Testing Center** – Angela Cullen
- **Fuels Center** – Paul Machiele
- **Health Effects, Benefits and Toxics Center** – Marion Hoyer
- **Heavy-Duty Onroad and Nonroad Center** – Brian Nelson
- **Large Marine and Aviation Center** – Mike Samulski
- **Light-Duty Vehicles and Small Engines Center** – Mike Olechiw

## Compliance Division
Byron Bunker, *Director*
Mary Manners, *DD*
Janet Cohen, *AD*
Sara Zaremski, *AD*

- **Data Analysis and Information Center** – Ching-Shih Yang
- **Diesel Engine Compliance Center** – Allen Duncan
- **Fuels Compliance Center - IT** – John Weihrauch
- **Gasoline Engine Compliance Center** – Cleophas Jackson
- **Light-Duty Vehicle Center** – Linc Wehrly
- **Fuels Compliance Center - Policy** – Kurt Gustafson

## Testing and Advanced Technology Division
David Haugen, *Director*
Matt Brusstar, *DD*
Cay Yanca, *AD*

- **Advanced Testing Center** – Maria Peralta
- **Engine Testing Center** – Sterling Imfeld
- **Fuels/Chemistry Center** – Bruce Kolowich
- **Information Management Center** – Fidel Galano
- **National Center for Advanced Technology** – Dan Barba
- **Testing Services Center** – Kirk Hildreth
- **Vehicle Testing Center** – John Spieth

## Transportation and Climate Division
Karl Simon, *Director*
Michael Moltzen, *DD*
Ken Yale, Acting *AD*

- **Climate Analysis and Strategies Center** – Lisa Snapp
- **Climate Economics and Modeling Center** – Sharyn Lie
- **Legacy Fleet Incentives and Assessment Center** – Christine Koester
- **SmartWay and Supply Chain Programs Center** – Cheryl Bynum
- **State Measures and Transportation Planning Center** – Meg Patulski
- **Technology Assessment Center** – Dennis Johnson

**DD = Deputy Division Director** **AD = Associate Division Director**

Message

**From**: Shaw, Betsy [Shaw.Betsy@epa.gov]
**Sent**: 1/25/2021 1:36:48 PM
**To**: Campbell, Ann [Campbell.Ann@epa.gov]; Millett, John [Millett.John@epa.gov]; Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: RE: draft all-staff note

I concur with your suggestion Ann. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

---

**From:** Campbell, Ann <Campbell.Ann@epa.gov>
**Sent:** Monday, January 25, 2021 8:22 AM
**To:** Millett, John <Millett.John@epa.gov>; Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Shaw, Betsy <Shaw.Betsy@epa.gov>
**Subject:** RE: draft all-staff note

Ex. 5 Deliberative Process (DP)

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

---

**From:** Millett, John <Millett.John@epa.gov>
**Sent:** Monday, January 25, 2021 8:18 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Shaw, Betsy <Shaw.Betsy@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** Re: draft all-staff note

Haha. No worries and thanks. I'll just combine both sets of edits and re-send a clean draft for one more look.

On Jan 24, 2021, at 9:27 PM, Goffman, Joseph <Goffman.Joseph@epa.gov> wrote:

Ex. 5 Deliberative Process (DP)

Thanks.

---

**From:** Shaw, Betsy <Shaw.Betsy@epa.gov>
**Sent:** Sunday, January 24, 2021 9:23 PM
**To:** Millett, John <Millett.John@epa.gov>; Goffman, Joseph <Goffman.Joseph@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** RE: draft all-staff note

Great draft John! Just a couple of minor ideas in red below you can take or leave Joe.

BTW, I need to learn how to add the accent to Tomas' name.

Thanks,

Betsy

---

**From:** Millett, John <Millett.John@epa.gov>
**Sent:** Friday, January 22, 2021 4:39 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Shaw, Betsy <Shaw.Betsy@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** draft all-staff note

Hi Joe, Betsy and Ann – below and attached is the draft note from to OAR staff. Thoughts and edits welcome!

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Dear OAR Colleagues –

**Ex. 5 Deliberative Process (DP)**
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# Ex. 5 Deliberative Process (DP)

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John Millett
Director, OAR Communications
Desk: 202-564-2903
Cell: 202-510-1822
~~~~~~~~~~~~~~~~~~

Message

**From:** POLITICO Pro [alert@email.politicopro.com]
**Sent:** 1/26/2021 10:06:55 AM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** Ethanol sector pivots as Biden takes the wheel

**Ethanol sector pivots as Biden takes the wheel**

By Eric Wolff

01/26/2021 05:01 AM EST

President Joe Biden's goal to rapidly expand the nation's electric vehicle charging infrastructure and speed adoption of the vehicles that run on electrons rather than liquid fuels will hasten the decline of gasoline consumption, leaving a shrinking market for the oil refiners and corn ethanol makers to fight over.

That's got ethanol advocates pushing hard for boosting the portion of each gallon of gasoline that comes from corn. The Trump administration approved the year-round sale of 15 percent gasoline ethanol blends in 2019, but nearly all the fuel burned in cars in and light trucks in the U.S. is still the 10 percent E10 blend that has been the standard for over a decade.

"It's all about an increasing share of a shrinking tank," said Emily Skor, CEO of Growth Energy, an ethanol trade association. "In the short term, it's moving from E10 to E15 blend. That's 2 billion gallons in demand. That would turn us around right there."

Sales of E15 fuel reached 500 million gallons in 2019 after Trump's move, reaching a new record, according to the biofuels trade group Renewable Fuels Association. But that's still a tiny percentage of the 142 billion gallons of finished motor fuels the Energy Information Administration says U.S. drivers consumed.

Despite expanding the market for E15, the Trump administration failed to win over ethanol makers because of EPA's liberal use of waivers that allowed dozens of refineries to avoid blending the fuel, which biofuels groups say effectively slashed their mandate under the Renewable Fuel Standard by 4.3 billion gallons between 2016 and 2018. Owners of the small refineries that can seek those waivers argue that without them, many plants will go out of business trying to carry the extra costs.

A court ruling last year sharply limited those waivers, and while a pending legal case on several waivers issued in the waning days of the Trump administration may curb their use even further, the Supreme Court has taken up the 2020 court decision, leaving everyone uncertain about the future of the program.

Both the refining industry and ethanol makers have suffered as demand for fuel slumped during the pandemic. Last year, oil refiners announced they would shut down over 1 million barrels per day of capacity in the U.S., while the ethanol producers idled dozens of plants and reduced operations at many others. Tom Kloza, the head of global analytics for the oil price tracking service OPIS, believes U.S. gasoline consumption will never return to pre-Covid peaks, and a long-term analysis from energy giant BP shows liquid fuel consumption crashing over the next several decades.

U.S. biofuels producers know that they'll have to shift strategies. Trade groups see their best near-term opportunity for recovery after the pandemic slammed all transportation fuels by pushing for wider adoption of

15 percent ethanol fuel, as well as lobbying the Biden administration officials to promote high fuel-efficient engines that would boost demand for ethanol to increase gasoline octane levels.

Biden's EPA is expected to tighten the rules on vehicle greenhouse gas emissions, and it must also rewrite biofuel blending mandates when the rules Congress set under the George W. Bush administration expire in 2022. Both of those actions will have a major impact on biofuels demand and involve several incoming cabinet members, including Jennifer Granholm, the former Michigan governor picked to run the Energy Department, North Carolina environmental regulator Michael Regan, who was tapped for EPA, as well as former Iowa governor and Obama Agriculture Secretary Tom Vilsack, who will take up the job again, and former South Bend, Ind., Mayor Pete Buttigieg, who will take the helm at the Transportation Department.

At EPA, Regan will have to make immediate decisions on some small refinery exemptions, as well as writing a rule setting blending mandates for 2021 after the Trump EPA failed to produce even a proposed rule by last year's deadline.

Regan appeared to show his support for the industry by making one of his first calls after receiving the nomination to the National Corn Growers Association, a trade group for corn farmers. He told NCGA CEO John Doggett he understood how important the RFS is to corn country, according to a NCGA spokesperson.

Biofuels advocates are hoping Regan breaks from the Trump EPA practice of giving out waivers to small refiners that make them exempt from ethanol blending mandates, a practice that has been curtailed by a court, even though former Administrator Andrew Wheeler continued to issue them even in the final days at EPA.

Biofuels leaders plan to hold Biden to campaign promises he made backing renewable fuels.

“Doubling down on biofuels was part of President Biden’s commitment in his Rural Plan," Growth Energy's Skor is expected to tell an event in Iowa on Tuesday. "He delivered repeated, pointed comments on the importance of biofuels and a strong Renewable Fuel Standard. And he was harsh in his admonishment of the previous EPA’s abuse of small refinery exemptions. We look forward to working with this White House to ensure they keep those promises, and restore strength to the rural economy, while addressing our country’s climate goals.”

Ethanol producers who found powerful allies in Sens. Chuck Grassley (R-Iowa) and Joni Ernst (R-Iowa) under a Republican administration appear to have had success in garnering support from the other side of the aisle now. Illinois Sen. Tammy Duckworth and five other Democratic lawmakers, including Majority Whip Dick Durbin (Ill.) and former presidential candidate Sen. Amy Klobuchar (Minn.), sent a letter to Biden earlier this month pressing the case for biofuels.

"It is critical that the integrity of this policy be restored, and that biofuels be part of your efforts to combat climate change and reduce greenhouse gas emissions from the Nation’s largest emitting sector," they wrote.

While the small refinery exemptions remain a sore spot, biofuels groups see the upcoming emissions rules for cars and light trucks as just as important for their future. The new rules are expected to be more stringent than the Trump administration's version, and while they're likely to promote adoption of electric vehicles, biofuel makers could benefit if they call for increasing the efficiency of internal combustion vehicle engines. That could open up a path to gasoline blends containing as much as 30 percent ethanol to boost octane levels.

"We're hoping and assuming the next iteration of fuel economy standards includes some role for improvements in the fuel," said Geoff Cooper, CEO of the Renewable Fuels Association, another ethanol producers trade association. "Unfortunately, previous standards regimes, they've been 100% focused on the vehicle and have not been designed in a way that compels improvements in the fuels that go into these vehicles."

Ethanol proponents will, of course, have to square off against the oil industry, which has not to this point focused much on efficiency rules, but also against some of the biggest environmental groups that have largely stayed out of the RFS battles of the last four years. The green groups put their weight behind zero-emission electric vehicles and see little purpose in continuing to use internal combustion engines. They point to a recent study from Bloomberg New Energy Finance that indicates falling battery costs could lead to parity between EVs and gas cars in the mid-2020s.

"We need to move as quickly as possible to zero emission vehicles," said Katherine Garcia, deputy director for the Sierra Club's Clean Transportation for All campaign. "We need to be reducing oil production and then this idea of the biofuels — we do not need a bridge fuel."

The auto industry may have already gotten the hint. The Alliance for Automotive Innovation, a trade association for automakers, released in December its "Innovation Agenda," which focuses almost exclusively on advancing electric vehicle penetration. The document highlights the industry's $250 billion investment into electric vehicles, and it lays out how improved charging infrastructure can close what it calls "the convenience gap" holding back consumers from buying the zero-emission technology.

"The problem is the auto industry as a whole has decided to embrace the electric vehicles future," said an oil industry source. "It's where they're going to aim their technology dollars and their marketing dollars."

But more broadly, oil refiners see room for everyone in the marketplace over the next several decades.

"Liquid fuels, both traditional and biofuels, are going to be part of the future of transportation, along with EVs. We don't believe EVs work for every consumer, which is why we oppose bans, mandates, and subsidies that effectively eliminate real consumer choice," said Geoff Moody, head of government relations for the American Fuel and Petrochemicals Manufacturers, a refiners trade group. "And we have a lot of common cause here with the biofuels industry."

*To view online*:
https://subscriber.politicopro.com/energy/article/2021/01/ethanol-sector-pivots-as-biden-takes-the-wheel-2026161

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This email was sent to goffman.joseph@epa.gov by:
POLITICO, LLC
1000 Wilson Blvd.
Arlington, VA 22209

USA

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 1/29/2021 1:51:07 AM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: READING: Calendar & Materials January 29, 2021
**Attachments**: Goffman Joseph Calendar.ics; HFC Baseline NODA 1-28-2021 summary rev1.docx; Overview of Key OAQPS Priority Topics for OAR revised.docx; PFAS background for Acting Admin. Briefing Friday @ 3:00

Joe, attached are the materials I have received for tomorrow's meetings. Let me know if this helps. And let me know if you need anything else.

**Goffman, Joseph Calendar**
Goffman.Joseph@epa.gov
On Friday, January 29, 2021
Time zone: (UTC-05:00) Eastern Time (US & Canada)
(Adjusted for Daylight Saving Time)

**January 2021**

| Su | Mo | Tu | We | Th | Fr | Sa |
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| 31 | | | | | | |

Busy
Out of Office
Tentative
Working Elsewhere
Free
Outside of Working Hours

**January 2021**

**Fri, Jan 29**

| | | |
|---|---|---|
| | **Before 8:00 AM** | **Free** |
| | **8:00 AM – 8:30 AM** | **Free** |
| | 8:30 AM – 9:00 AM | Check-In |
| | 9:00 AM – 9:30 AM | Air Issues Meeting |
| | 9:30 AM – 10:00 AM | Landfill CH4 |
| | 10:00 AM – 10:30 AM | Management Round Table |
| | 10:30 AM – 11:00 AM | OAR/ARLO Discussion |
| | 11:00 AM – 11:45 AM | AIM Act – NODA (Materials attached) |
| | **11:45 AM – 12:00 PM** | **Free** |

| | | |
|---|---|---|
| ■ | 12:00 PM – 12:30 PM | One-on-One with Sarah Dunham |
| ■ | 12:30 PM – 1:00 PM | One-on-One with Jon Edwards |
| ■ | 1:00 PM – 2:00 PM | Overview of Key OAQPS Priority Topics (Materials attached) |
| □ | 2:00 PM – 2:45 PM | Appointees IT Training (Option 1) |
| □ | **2:45 PM – 3:00 PM** | **Free** |
| ■ | 3:00 PM – 4:00 PM | Briefing: PFAS Hot Issues (Materials attached) |
| ■ | 4:00 PM – 4:30 PM | Introductory Video-Call: Michael Regan and Joe Goffman (We provided your bio at Kathleen Lance's request) |
| ■ | 4:30 PM – 5:00 PM | To Discuss CRA |
| ■ | 5:00 PM – 5:30 PM | Check-In |
| ■ | 5:30 PM – 6:00 PM | Cars Working Group |
| □ | **After 6:00 PM** | **Free** |

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Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

| | |
|---|---|
| **Subject:** | To Discuss CRA |
| **Start Time:** | 2021-01-29T16:30:00-05:00 |
| **End Time:** | 2021-01-29T17:00:00-05:00 |

**Adjustment of Civil Penalties**

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,[2] which requires agencies to adjust civil monetary penalties for inflation and to publish the adjustments in the **Federal Register**. An initial adjustment was required to be made by interim final rule published by July 1, 2016, and effective by August 1, 2016. Subsequent adjustments must be published by January 15 each year after 2016.

On December 23, 2020, the Office of Management and Budget issued memorandum M–21–10 on implementation of the 2021 annual inflation adjustment pursuant to the 2015 Act.[3] The memorandum provides agencies with the cost-of-living adjustment multiplier for 2021, which is based on the Consumer Price Index (CPI–U) for the month of October 2020, not seasonally adjusted. The multiplier for 2021 is 1.01182. The adjusted maximum amounts are $2,259 for section 4071 penalties and $301 for section 4302 penalties.

**Compliance With Regulatory Requirements**

The Office of Management and Budget has determined that this rule is not a "significant regulatory action" under Executive Order 12866 and therefore not subject to its review. As this is not a significant regulatory action under E.O. 12866, it is not considered an E.O. 13771 regulatory action.

The Office of Management and Budget also has determined that notice and public comment on this final rule are unnecessary because the adjustment of civil penalties implemented in the rule is required by law. See 5 U.S.C. 553(b).

Because no general notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

**List of Subjects**

*29 CFR Part 4071*

Penalties.

*29 CFR Part 4302*

Penalties.

In consideration of the foregoing, PBGC amends 29 CFR parts 4071 and 4302 as follows:

[2] Sec. 701, Public Law 114–74, 129 Stat. 599–601 (Bipartisan Budget Act of 2015).

[3] See M–21–10, Implementation of Penalty Inflation Adjustments for 2021, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, *https://www.whitehouse.gov/wp-content/uploads/2020/12/M-21-10.pdf.*

## PART 4071—PENALTIES FOR FAILURE TO PROVIDE CERTAIN NOTICES OR OTHER MATERIAL INFORMATION

■ 1. The authority citation for part 4071 continues to read as follows:

**Authority:** 28 U.S.C. 2461 note, as amended by sec. 701, Pub. L. 114–74, 129 Stat. 599–601; 29 U.S.C. 1302(b)(3), 1371.

**§ 4071.3 [Amended]**

■ 2. In § 4071.3, the figures "$2,233" are removed and the figures "$2,259" are added in their place.

## PART 4302—PENALTIES FOR FAILURE TO PROVIDE CERTAIN MULTIEMPLOYER PLAN NOTICES

■ 3. The authority citation for part 4302 continues to read as follows:

**Authority:** 28 U.S.C. 2461 note, as amended by sec. 701, Pub. L. 114–74, 129 Stat. 599–601; 29 U.S.C. 1302(b)(3), 1452.

**§ 4302.3 [Amended]**

■ 4. In § 4302.3, the figures "$297" are removed and the figures "$301" are added in their place.

Issued in Washington, DC, by:

**Gordon Hartogensis,**

*Director, Pension Benefit Guaranty Corporation.*

[FR Doc. 2021–00297 Filed 1–12–21; 8:45 am]

BILLING CODE 7709–02–P

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## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

### 37 CFR Part 1

**[Docket No. PTO–P–2019–0009]**

**RIN 0651–AD33**

### Small Entity Government Use License Exception

**Correction**

In rule document 2020–27049 appearing on pages 82917–82923 in the issue of Monday, December 21, 2020, make the following correction:

On page 82917, in the third column, in the **DATES** section, change "January 20, 2021" to read "January 21, 2021."

[FR Doc. C1–2020–27049 Filed 1–12–21; 8:45 am]

BILLING CODE 1301–00–D

## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

### 37 CFR Part 42

**[Docket No. PTO–P–2019–0011]**

**RIN 0651–AD34**

### Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board

**Correction**

In rule document 2020–28159 appearing on pages 82923–82936 in the issue of Monday, December 21, 2020, make the following correction:

(1) On page 82924, in the first column, in the **DATES** section, in the second line under the heading, change "January 20, 2021" to read "January 21, 2021."

(2) On page 82924, in the first column, in the **DATES** section, in the sixth line under the heading, change "January 20, 2021" to read "January 21, 2021."

[FR Doc. C1–2020–28159 Filed 1–12–21; 8:45 am]

BILLING CODE 1301–00–D

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 60

**[EPA–HQ–OAR–2013–0495; FRL–10019–30–OAR]**

**RIN 2060–AT56**

### Pollutant-Specific Significant Contribution Finding for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units, and Process for Determining Significance of Other New Source Performance Standards Source Categories

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** In this final action, the U.S. Environmental Protection Agency (EPA) is finalizing a significant contribution finding (SCF) for purposes of regulating source categories for greenhouse gas (GHG) emissions, under section 111(b) of the Clean Air Act (CAA) for electric generating units (EGUs), and in doing so, reaffirming that EGUs remain a listed source category. The EPA has reached that conclusion by articulating a framework under which source categories are considered to contribute

significantly to dangerous air pollution due to their GHG emissions if the amount of those emissions exceeds 3 percent of total U.S. GHG emissions. The EPA is applying the 3-percent threshold to the EGU source category to demonstrate that GHG emissions from the EGU source category would contribute significantly to dangerous air pollution. While EGU GHG emissions exceed this threshold by a sufficient magnitude to warrant an SCF without more ado, the EPA has also, for completeness, analyzed EGU emissions under a secondary criteria framework, which also demonstrates the propriety of the SCF.

**DATES:** The final rule is effective on March 15, 2021.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2013–0495. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. With the exception of such material, publicly available docket materials are available electronically through *https://www.regulations.gov/.* Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:** For questions about this final action, contact Mr. Christopher Werner, Sector Policies and Programs Division (D243–01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5133; fax number: (919) 541–4991; and email address: *werner.christopher@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

*Preamble acronyms and abbreviations.* The EPA uses multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

AEO Annual Energy Outlook
BSER best system of emission reduction
°C degrees Celsius
CAA Clean Air Act
CFR Code of Federal Regulations
$CH_4$ methane
CO carbon monoxide
$CO_2$ carbon dioxide
D.C. Cir. United States Court of Appeals for the District of Columbia Circuit
DOE Department of Energy
EGU electric utility generating unit
EIA U.S. Energy Information Administration
EPA Environmental Protection Agency
°F degrees Fahrenheit
GHG greenhouse gas
HAP hazardous air pollutant(s)
HFC hydrofluorocarbon
km kilometers
M million
$N_2O$ nitrous oxide
NAICS North American Industry Classification System
NGCC natural gas combined cycle
$NO_X$ nitrogen oxides
NSPS new source performance standards
OMB Office of Management and Budget
PC pulverized coal
PFC perfluorocarbon
PM particulate matter
$SF_6$ sulfur hexafluoride
$SO_2$ sulfur dioxide
U.S. United States
U.S.C. United States Code

*Organization of this document.* The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
C. Judicial Review
II. Executive Summary
A. What is the purpose of this regulatory action?
B. What is the summary of the major provisions in this action?
C. What are the costs and benefits?
III. Summary of Previous Rulemaking Actions
IV. Pollutant-Specific Significant Contribution Finding (SCF)
A. Background
B. What is a Significant Contribution Finding (SCF)?
C. Primary Criteria for Determining Significance
D. Secondary Criteria for Determining Significance
E. Significant Contribution Finding for EGUs
V. Summary of Cost, Environmental, and Economic Impacts
A. What are the affected facilities?
B. What are the air quality impacts?
C. What are the energy impacts?
D. What are the cost impacts?
E. What are the economic impacts?
F. What are the benefits?
VI. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs
C. Paperwork Reduction Act (PRA)
D. Regulatory Flexibility Act (RFA)
E. Unfunded Mandates Reform Act (UMRA)
F. Executive Order 13132: Federalism
G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act (NTTAA)
K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
L. Congressional Review Act (CRA)

## I. General Information

### *A. Does this action apply to me?*

Categories and entities potentially impacted by this rule include sources subject to new source performance standards (NSPS) requirements under section 111 of the CAA. While this rule informs all NSPS source categories, the EPA is finalizing a SCF specific to electric generating units regulated under 40 CFR part 60, subpart TTTT. The North American Industry Classification System (NAICS) code for the industrial, federal government, and state/local government electric generating units is 221112. The NAICS code for tribal government electric generating units is 921150.

### *B. Where can I get a copy of this document and other related information?*

In addition to being available in the docket, an electronic copy of this final action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at *https://www.epa.gov/stationary-sources-air-pollution/nsps-ghg-emissions-new-modified-and-reconstructed-electric-utility.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the final rule and key technical documents at this same website.

### *C. Judicial Review*

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the D.C. Circuit) by March 15, 2021. Moreover, under

section 307(b)(2) of the CAA, the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce these requirements. The Administrator has determined that this action is subject to section 307(d) of the CAA (42 U.S.C. 7607(d)(1)(V)). Section 307(d)(7)(B) of the CAA further provides that "[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review." This section also provides a mechanism for the EPA to convene a proceeding for reconsideration "[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment, (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule." Any person seeking to make such a demonstration to us should submit a Petition for Reconsideration to the Office of the Administrator, U.S. Environmental Protection Agency, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

## II. Executive Summary

### *A. What is the purpose of this regulatory action?*

In Executive Order 13783 (Promoting Energy Independence and Economic Growth), all executive departments and agencies, including the EPA, were directed to "immediately review existing regulations that potentially burden the development or use of domestically produced energy resources and appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources beyond the degree necessary to protect the public interest or otherwise comply with the law." [1] Moreover, the Executive Order directed the EPA to undertake this process of review with regard to the "Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units," 80 FR 64510 (October 23, 2015) (2015 Rule).

In a document signed the same day as Executive Order 13783 and published in the **Federal Register** at 82 FR 16330 (April 4, 2017), the EPA announced that, consistent with the Executive Order, it was initiating a review of the 2015 Rule and providing notice of a forthcoming proposed rulemaking consistent with the Executive Order. After due deliberation, the EPA issued a proposed rulemaking, "Review of Standards of Performance for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units—Proposed Rule," 83 FR 65424 (December 20, 2018) (2018 Proposal). Here the EPA is finalizing a rulemaking with respect to whether GHG emissions from EGUs contribute significantly to dangerous air pollution, in reliance on a methodology articulated herein for determining whether GHG emissions from other NSPS source categories contribute significantly to dangerous air pollution. Any action regarding the proposal to revise the standards of performance, including the underlying determinations of the BSER, for new, reconstructed, and modified coal-fired EGUs, including certain technical issues, is beyond the scope of this final rule and comments received on the 2018 Proposal will be addressed in a separate future action.

### *B. What is the summary of the major provisions in this action?*

The EPA is finalizing a pollutant-specific SCF for GHG emissions from EGUs. That finding is based on an emissions threshold framework for determining significance, as well as secondary criteria to be applied in certain circumstances, for other NSPS source categories.

### *C. What are the costs and benefits?*

In 2015, the EPA promulgated "Standards of Performance for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units," 80 FR 64510 (October 23, 2015) (2015 Rule). When the EPA promulgated the 2015 Rule, it took note of both utility announcements and U.S. Energy Information Administration (EIA) modeling and, based on that information, concluded that even in the absence of this rule, (1) existing and anticipated economic conditions are such that few, if any, coal-fired EGUs will be built in the foreseeable future, and that (2) utilities and project developers are expected to choose new generation technologies (primarily natural gas combined cycle (NGCC)) that would meet the final standards and also renewable generating sources that are not affected by these final standards. *See* 80 FR 64515 (October 23, 2015). The EPA, therefore, projected that the 2015 Rule would "result in negligible $CO_2$ emission changes, quantified benefits, and costs by 2022 as a result of the performance standards for newly constructed EGUs." *Id.* The Agency went on to say that it had been "notified of few power sector new source performance standards (NSPS) modifications or reconstructions." Based on that additional information, the EPA said it "expects that few EGUs will trigger either the modification or the reconstruction provisions" of the 2015 Rule. *Id.* at 64516.

The EPA has concluded that the projections described in the 2015 Rule remain generally correct.[2] In the period of analysis,[3] the EPA expects there to be few, if any, newly constructed, reconstructed, or modified sources that will trigger the provisions the EPA is promulgating in this action. Consequently, the EPA projects that there will be no significant changes in carbon dioxide ($CO_2$) emissions or in compliance costs as a result of this final rule.

## III. Summary of Previous Rulemaking Actions

On December 20, 2018, the EPA published a proposal to revise certain parts of the 2015 Rule; "Review of Standards of Performance for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units." 83 FR 65424 (2018 Proposal). The majority of that proposal was dedicated to the issue of the best system of emission reduction (BSER) for newly constructed, modified, and reconstructed coal-fired EGUs. Comments received on that issue are not being addressed in this rule and will be addressed in any future EPA action. In that proposal, the EPA solicited comment on whether to make a pollutant-specific significant contribution determination for GHG emissions from EGUs, 83 FR 65432 n. 25, which is the subject of this action.

[1] Executive Order 13783, Section 1(c), 82 FR 16093, March 31, 2017.

[2] In the reference case for the most recent Annual Energy Outlook (AEO2020), the EIA projected no additions of new planned or unplanned coal capacity through 2050 (*www.eia.gov/aeo2020;* Table 9. Electricity Generating Capacity).

[3] Standards developed under the NSPS program must, by statutory requirement, be reviewed, at least, every 8 years.

## IV. Pollutant-Specific Significant Contribution Finding (SCF)

### *A. Background*

CAA section 111(b)(1)(A) states that "[The Administrator] shall include a category of sources in such list if in his judgment it causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare."

In the 2015 Rule, the EPA promulgated standards for GHG (measured $CO_2$ emissions) from fossil fuel-fired steam generating EGUs and combustion turbines, a pollutant that the Administrator had not considered when he listed the categories of those sources—fossil fuel-fired steam generators [4] and stationary gas turbines.[5] *See* 80 FR 64510. Similarly, in 2016, the EPA promulgated an NSPS for GHG (measured by methane ($CH_4$) emissions) from oil and gas sources, a pollutant that the Administrator had not considered when he listed the category for those sources—the Crude Oil and Natural Gas Production source category.[6] *See* 81 FR 35824 (June 3, 2016) (2016 Oil & Gas Rule).

In each rule, the EPA interpreted CAA section 111(b) to require that an SCF and endangerment finding be made only with respect to the source category, at the time the EPA lists the category, and to authorize the EPA to promulgate NSPS for GHG, as long as the EPA provides a rational basis for doing so. However, in each rule, the EPA acknowledged that some stakeholders had argued that the EPA first needed to make a pollutant-specific SCF, that is, a finding that GHG from the source category contributes significantly to dangerous air pollution. In each rule, the EPA stated that it disagreed with those stakeholders, but nevertheless, in the alternative, did make a pollutant-specific SCF for GHG, supported by the same reasons that the EPA had used to determine that it had a rational basis to regulate GHG. *See* 80 FR 64529 through 64531 (2015 EGU Rule); 81 FR 35840 through 35843 (2016 Oil & Gas Rule).

In the 2018 Proposal, in which the EPA proposed to revise the 2015 Rule, the EPA solicited comment on whether to adopt the interpretation that it was required to make an SCF for GHG from the EGU source category before it could promulgate an NSPS for $CO_2$. Some commenters stated that the EPA must make pollutant-specific findings of endangerment and significant contribution in order to establish an NSPS for that pollutant. These commenters explained that in their view, CAA section 111(b)(1)(A) requires the EPA to make two specific findings: (1) The specific "air pollution" to be regulated is "reasonably . . . anticipated to endanger public health or welfare;" and (2) the specific source category "causes or contributes significantly to" that air pollution. Commenters asserted that CAA section 111(b)(1)(A) is not ambiguous in this respect, and, therefore, the Agency's interpretation in the 2015 Rule directly contradicts the plain language of that section.

Other commenters stated that the EPA's approach in the 2015 Rule, that it needs to determine only that it has a rational basis to regulate GHGs emitted by this source category as a prerequisite to regulation, is sound. They said in the context of CAA section 111, the SCF and endangerment finding are made with respect to the source category, and not as to specific pollutants. These commenters supported the conclusion in the 2015 Rule that the EPA possesses authority to regulate GHG emissions from fossil fuel-fired EGUs under CAA section 111 because there was no new evidence calling into question its determination that GHG air pollution may reasonably be anticipated to endanger public health and welfare and fossil fuel-fired EGUs have a high level of GHG emissions. The commenters stated that these considerations hew closely to the statutory factors that inform the decision whether to list a source category in the first place—namely, whether the category "causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare," under CAA section 111(b)(1)(A). The commenters added that this approach, which closely parallels the listing analysis but does not require a formal endangerment finding or SCF, is legally sound. They also added that the statute is clear that a formal endangerment finding is required to initially list a sector to be regulated under CAA section 111; but it is also clear that such a finding is not required before regulating additional harmful pollutants from a previously-listed sector.[7]

Similarly, in a 2019 proposal to revise the 2016 Oil & Gas Rule, the EPA solicited comment on whether to adopt the interpretation that it was required to make an SCF for GHG from the Oil and Gas source category before it could promulgate a $CH_4$ NSPS. Recently, the EPA completed the final rule to revise the 2016 Oil & Gas Rule, "Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review: Final Rule," 85 FR 57018 (September 14, 2020) (2020 Oil & Gas Rule). There, the EPA determined that a pollutant-specific SCF is required. In addition, the EPA further determined that the pollutant-specific SCF in the 2016 Oil & Gas Rule was invalid on grounds, in part, that the EPA had not established a threshold or criteria by which to determine whether an amount of emissions contributes significantly to dangerous air pollution, and to distinguish from an amount of emissions that simply contributes to dangerous air pollution. The EPA stated

[4] *See* "List of Categories of Stationary Sources," 36 FR 5931 (March 31, 1971) (listing source category); "Standards of Performance for New Stationary Sources," 36 FR 24376 (December 31, 1971) (promulgating NSPS for source category).

[5] *See* "Standards of Performance for New Stationary Sources; Gas Turbines," 44 FR 52792 (September 10, 1979) (listing and promulgating NSPS for source category).

[6] *See* "Priority List and Additions to the List of Categories of Stationary Sources," 49 FR 49222 (August 21, 1979) (listing source category); "Standards of Performance for New Stationary Sources; Equipment Leaks of VOC From Onshore Natural Gas Processing Plants," 50 FR 26124 (June 23, 1985), and "Standards of Performance for New Stationary Sources; Onshore Natural Gas Processing $SO_2$ Emissions," 50 FR 40160 (October 1, 1985) (promulgating standards of performance).

[7] Some commenters on the 2018 Proposal also said that, in the 2009 Endangerment Finding, the EPA specifically defined air pollution, as referred to in section 202(a) of the CAA, to be the mix of six well-mixed, long-lived, and directly emitted GHGs: $CO_2$, $CH_4$, $N_2O$, HFCs, PFCs, and $SF_6$. 74 FR 66497. They commented that the EPA needs to make, but has never made, a separate finding that $CO_2$ alone is reasonably anticipated to endanger the public health or welfare. The Agency disagrees with commenters. The air pollutant that the 2015 Rule regulates is GHG, and that air pollutant contributes to the same GHG air pollution that was addressed by the Endangerment Finding. The standards of performance adopted in the 2015 Rule take the form of an emission limitation on only one constituent gas of this air pollutant, $CO_2$. *See* 40 CFR 60.5515(a) ("The pollutants regulated by this subpart are greenhouse gases. The greenhouse gas standard in this subpart is in the form of a limitation on emission of carbon dioxide."). This is reasonable, given that $CO_2$ is the constituent gas emitted in the largest volume by the source category and for which there are available controls that are technically feasible and cost effective. There is no requirement that standards of performance address each component of an air pollutant. CAA section 111(b)(1)(B) requires the EPA to establish "standards of performance" for listed source categories, and the definition of "standard of performance" in CAA section 111(a)(1) does not specify which air pollutants must be controlled. Moreover, as the EPA noted in the 2015 Rule, the information considered in the 2009 Endangerment Finding and its supporting record, together with additional discussion of GHG impacts in the 2015 Rule, makes clear that GHG air pollution may reasonably be anticipated to endanger public health or welfare. *See* 80 FR 64517, 64530 and 31. Because the 2015 Rule followed the same approach as in the 2009 findings and regulated the same pollutant as contributing to the same air pollution (to reiterate, both the air pollutant and the air pollution are GHG as the group of six well-mixed gases, including $CO_2$), it was not necessary to evaluate $CO_2$ separately. The EPA took the same position in the 2016 Oil & Gas Rule in response to a similar comment concerning $CH_4$. *See* 81 FR 35843.

that section 111(b) of the CAA requires, or at least authorizes, a pollutant-specific SCF, and such an SCF must be based on defined criteria or thresholds. *Id.* at 57033–40.

*B. What is a Significant Contribution Finding (SCF)?*

1. Significant Contribution Finding and Key Comments Received

CAA section 111 directs the EPA to regulate, through a multi-step process, air pollutants from categories of stationary sources. CAA section 111(b)(1)(A) requires the initial action, which is that the Administrator must "publish . . . a list of categories of stationary sources. He shall include a category of sources in such list if in his judgment it causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare." Therefore, the first action that the EPA must take, specified in CAA section 111(b)(1)(A), is to list a source category for regulation on the basis of a determination that the category contributes significantly to dangerous air pollution. This provision makes clear that although Congress designed CAA section 111 to apply broadly to source categories of all types wherever located, Congress also imposed a constraint: The EPA is authorized to regulate only sources that it finds cause or contribute significantly to air pollution that the EPA finds to be dangerous. Because CAA section 111(b)(1)(A) refers to air *pollution,* the EPA's determination that a source category should be listed for regulation can be based on all pollutants emitted by the category (*i.e.,* collective contribution), or for a specific pollutant.

After the EPA lists a source category, CAA section 111(b)(1)(B) then directs the EPA to propose regulations "establishing Federal standards of performance" for new sources within the source category, to allow public comment, and to "promulgate . . . such standards with such modifications as he deems appropriate." CAA section 111(a)(1) defines the term "standard of performance" as "a standard for emissions of air pollutants which [the Administrator is required to determine through a specified methodology]." These provisions read together make clear that the standards of performance that CAA section 111(b)(1)(A) directs the Administrator to promulgate must concern air pollutants emitted from the sources in the source category. However, industrial sources of the type subject to CAA section 111(b)(1)(A) invariably emit more than one air pollutant, and neither CAA section 111(b)(1)(B) nor CAA section 111(a)(1), by their terms, specifies for which of those air pollutants the EPA must promulgate standards of performance.

In the past, the EPA has interpreted CAA section 111(b)(1)(B) to authorize it to promulgate standards of performance for any air pollutant that the EPA identified in listing the source category and any additional air pollutant for which the EPA has identified a rational basis for regulation. 81 FR 35843 (2016 Oil & Gas Rule); 80 FR 64510 (2015 Rule). Inherent in this approach is the recognition that CAA section 111(b)(1)(A) does not, by its terms, necessarily require the EPA to promulgate standards of performance for all air pollutants emitting from the source category. The EPA could list a source category on grounds that it emits numerous air pollutants that, taken together, significantly contribute to air pollution that may reasonably be anticipated to endanger public health or welfare, and proceed to regulate each of those pollutants, without ever finding that each (or any) of those air pollutants by itself causes or contributes significantly to—or, in terms of the text of other provisions, causes or contributes to—air pollution that may reasonably be anticipated to endanger public health or welfare.

As described in the 2020 Oil and Gas Policy Rule, CAA section 111(b)(1)(A) does not provide or suggest any criteria to define the rational basis approach, the EPA has not articulated any criteria in its previous applications in the EGU $CO_2$ NSPS and the 2016 40 CFR part 60, subpart OOOOa rules, and in instances before those rules in which the EPA has relied on the "rational basis" approach, the EPA has done so to justify not setting a standard for a given pollutant, rather than to justify setting such a standard. 85 FR 77037, December 1, 2020. Thus, the rational basis test allows the EPA virtually unfettered discretion in determining which air pollutants to regulate. As a result, the rational basis standard creates the possibility that the EPA could seek to promulgate NSPS for pollutants that may be emitted in relatively minor amounts.

In contrast, CAA section 111(b)(1)(A) is clear that the EPA may list a source category for regulation only if the EPA determines that the source category "causes or contributes *significantly*" (emphasis added) to dangerous air pollution. As described in the 2020 Oil and Gas Policy Rule, in light of the stringency of this statutory requirement for listing a source category, it would be unreasonable to interpret CAA section 111(b)(1)(B) to allow the Agency to regulate air pollutants from the source category merely by making an administrative determination under the open-ended and undefined rational basis test. The EPA, therefore, determined it is logical to interpret CAA section 111(b)(1)(B) to require that the Agency apply the same degree of rigor in determining which air pollutants to regulate as it does in determining which source categories to list for regulation, and, therefore, must make a pollutant-specific SCF. *Id.*

Requiring a pollutant-specific SCF necessitates the establishment of a clearer framework for assessing which air pollutants merit regulatory attention that will require sources to bear control costs. The establishment of such a framework or criteria promotes regulatory certainty for stakeholders and consistency in the EPA's identification of which air pollutants to regulate and reduces the risk that air pollutants that do not merit regulation will nevertheless become subject to regulation due to an unduly vague standard.

As previously described, CAA section 111(b)(1)(B) requires the EPA to establish an NSPS for a source category listed under CAA section 111(b)(1)(A). For a source category previously listed under CAA section 111(b)(1)(A), in order to subsequently promulgate an NSPS for a pollutant that the EPA did not evaluate the source category for at the time of listing, the EPA must make a pollutant-specific SCF for the reasons described above. As part of making an SCF, the EPA concluded in the 2020 Oil and Gas Policy Rule that, "a standard or an established set of a criteria, or perhaps both, are necessary to identify what is significant and what is not." 85 FR 57039. The EPA did not finalize or take a position in the 2020 Oil and Gas Policy Rule on potential criteria, stating that it was deferring the identification of such criteria to a future rulemaking. *Id.* CAA section 111(b) itself does not specify what the criteria for a pollutant-specific SCF.

The "contributes significantly" provision in CAA section 111(b)(1)(A) is ambiguous as to what level of contribution is considered to be significant. *See* 84 FR 50267 and 50268, September 24, 2019 (citing *EPA* v. *EME Homer City Generation, L.P.,* 572 U.S. 489 (2014) (holding that a similar provision in CAA section 110(a)(2)(D)(i), often termed the "good neighbor" provision, is ambiguous)). Accordingly, the EPA has authority to interpret that provision. *Id.* at 50268. As noted above, the EPA reads CAA section 111(b)(1)(B) in light of CAA sections 111(b)(1)(A) and 111(a)(1) to incorporate the "contributes significantly" standard in

connection with promulgating NSPS for particular air pollutants. The EPA has concluded that to allow the EPA to distinguish between a *contribution* and a *significant contribution* to dangerous pollution, some type of (reasonably explained and intelligible) standard and/or established set of criteria that can be consistently applied is necessary.

A supporting basis for this conclusion can be found by looking at the EPA's interpretation of the similarly worded "contribute significantly" provisions of CAA section 189(e), concerning major stationary sources of particulate matter with a diameter of 10 micrometers or less ($PM_{10}$). This provision requires that the control requirements applicable to major stationary sources of $PM_{10}$ also apply to major stationary sources of $PM_{10}$ precursors "except where the Administrator determines that such sources [of precursors] do not contribute significantly to $PM_{10}$ levels which exceed the standard in the area." As the EPA noted in the 2019 Oil and Gas Policy Rule proposal, in CAA section 189(e), Congress intended that, in order to be subject to regulation, the emissions must have a greater impact than a simple contribution not characterized as a significant contribution. However, Congress did not quantify how much greater. Therefore, the EPA developed criteria for identifying whether the impact of a particular precursor would "contribute significantly" to a NAAQS exceedance. 84 FR 50268. These criteria included numerical thresholds. *Id.* The EPA concluded similarly that, under CAA section 111(b), a standard or an established set of a criteria, or perhaps both, are necessary to identify what is significant and what is not.

These criteria help ensure that the EPA's decision-making is well-reasoned and consistent. The EPA considers it particularly important to develop a set of criteria and/or a standard in order to determine when a *significant* contribution occurs, in order, as noted above, to distinguish it from a simple contribution. A contribution can be greater or lesser and remain a contribution, but a significant contribution determination necessarily involves a judgment about the degree of the contribution that rises to the level of significance. For such a judgment to be meaningful (and, of critical importance, to be understood by regulated parties and by the public), the Agency must identify the criteria it will use to determine significance.

2. Other Comments Received on the EPA's Basis for Regulating GHG Emissions from EGUs

*Comment:* Commenters stated that the EPA must make the specific pollutant findings of endangerment and significant contribution that are required in listing a source category in order to establish a NSPS for that pollutant. Commenters stated they are not arguing that the EPA could not or should not make these findings. Rather, that the Clean Air Act (CAA) requires the EPA to make two specific findings: (i) The specific "air pollution" to be regulated is "reasonably . . . anticipated to endanger public health or welfare"; and (ii) the specific source category "causes or contributes significantly to" that endangering air pollution. CAA section 111(b)(1)(A). The commenters said section 111(b)(1)A) is not ambiguous at all in this respect, and therefore the Agency's interpretation in the 2015 Rule directly contradicts the plain language of this section. Additionally, they said that in the 2009 Endangerment Finding, the EPA specifically defined air pollution, as referred to in section 202(a) of the CAA, to be the mix of six long-lived and directly emitted GHGs: $CO_2$, $CH_4$, $N_2O$, HFCs, PFCs, and $SF_6$ (74 FR 66497, December 15, 2009). They commented that the EPA did not make a separate finding then, or now, that $CO_2$ alone is a danger to the public health or welfare and the EPA has argued that because $CO_2$ is the "dominant anthropogenic GHG," it is not required to "make an endangerment finding with respect to a particular pollutant." (*Id*). They argued that this view does not satisfy the statutory standard and said the GHG endangerment determination in section 111(b)(1)(A) is fundamentally different than that in section 202(a) and other CAA sections, in part because it: (i) Is source-category based; and (ii) requires a finding of significance.

These commenters stated that in the 2015 Rule, the EPA made three arguments as to why it believed it had met its statutory obligations. The commenters stated that none of these arguments are correct as a legal matter for the following primary reasons: (1) The EPA was wrong in claiming that new $CO_2$-specific findings were unnecessary, as the 2015 Rule was for a new category of electric utility generating unit (EGUs) emitting $CO_2$—a specific pollutant for which an endangerment finding had not been made. EPA's prior listings of "steam generators" and "stationary gas turbines" covered only emissions of $NO_X$, $SO_2$, and particulate matter. Because EPA's findings in earlier listings addressed different pollutants, those listings triggered and authorized only regulation of $NO_X$, $SO_2$, and particulate matter. *Cf. Nat'l Asphalt Pavement Ass'n* v. *Train,* 539 F.2d 775 (D.C. Cir. 1976). EPA has asserted the authority to regulate under section 111 any pollutant for which EPA believes it has a "rational basis" to regulate (see 83 FR 65432; 80 FR 64530). But this "rational basis" standard is not the one authorized by section 111; the endangerment and significant contribution standard governs section 111 regulation. EPA cannot rewrite the statute to circumvent the endangerment and significant contribution standard that Congress prescribed for section 111 regulation.; (2) the EPA cannot rely on its 2009 finding regarding GHG emissions from automobiles which determined that "six well-mixed GHGs" in the "aggregate" endanger public health or welfare, as this "combined mix" is different air pollutant than the single pollutant controlled here ($CO_2$ alone). EPA has never found that $CO_2$ alone endangers public health or welfare, much less that $CO_2$ from fossil fuel-fired steam generating units (as opposed to motor vehicles) has that effect; and (3) the EPA's attempt to rely on "information and conclusions" contained in the 2015 Rule does not satisfy the CAA. Simply identifying the evidence that might support a finding is not the same as completing the administrative process of distilling and analyzing that data in the context of the Agency's statutory obligations and its failure to make the requisite findings of endangerment and significant contribution in the 2015 Rule violated the CAA. They said the CAA grants the EPA narrowly bounded authority to regulate stationary sources that emit pollutants that may reasonably be anticipated to endanger public health or welfare *for those pollutants* which led to the endangerment finding and to which the source category significantly contributes. The CAA does not grant the Agency unlimited authority to regulate any pollutant emitted by that source. Accordingly, before the EPA finalizes the 2018 Proposal, it must make a specific and supportable finding that $CO_2$ emissions from fossil fuel-fired EGUs pose a danger to public health and welfare. They said the EPA should reject its ill-founded "rational basis test" for imposing performance standards without endangerment and contribution findings. The Agency's rational basis test is not in the CAA. They argued that section 111 never uses the term and the case law on which the EPA relied for

this test addresses agency authority under a different statute, the Administrative Procedure Act (APA). The APA does not define the scope of the EPA's authority to undertake this rulemaking.

Commenters added that as a textual matter, the endangerment requirement modifies, and relates back to, "air pollution," not "sources": The provision requires the EPA to determine whether a source causes or contributes significantly to "air pollution which may reasonably be anticipated to endanger public health or welfare." 42 United States Code (U.S.C.) section 7411(b)(1)(A). Only after the EPA determines that a pollutant poses a threat to "public health or welfare" must it inquire whether the particular category of sources "contributes significantly" to that pollution. *Id.* The idea that an endangerment finding is "one and done" on a source level also cannot be squared with the surrounding statutory requirements. Section 111(b)(1)(B) provides that the EPA may issue performance standards after a source category is listed pursuant to section 111(b)(1)(A). *Id.* section 7411(b)(1)(B). Yet by definition, a "standard of performance" is tied to specific pollutants for which an endangerment finding has been made. *Id.* section 7411 (a)(1) (defining a "standard of performance" as "a standard for emissions of air pollutants). Commenters said that as such, the approach in the 2015 Rule would give the EPA unfettered authority to regulate any air pollutant emitted by a source regardless of whether it endangers health or welfare and the 2015 Rule's approach of mixing and matching elements of endangerment findings would allow the EPA to impose stringent regulations on sources that do not "contribute significantly" to emissions of a pollutant. In summary, the commenters argued that if the EPA "retain[s]" the "statutory interpretation" of section 111 as set out in the 2015 Rule, 83 FR 65432 n. 25, it will once again be setting standards beyond the scope of its authority and it may be that the EPA can make the findings section 111(b)(1)(A) requires for $CO_2$ emissions from fossil-fuel-fired electricity generating units, but unless and until the EPA makes those determinations under the proper legal standard, the Proposed Rule will rest on a flawed foundation.

Commenters stated that the previous endangerment findings the EPA listed in the 2015 Rule did not relate to "fossil fuel-fired electricity generating units." (80 FR 64527 nn.86 & 87). Rather, one related to "steam generators," (36 FR 5931, March 31, 1971,—cited at 80 FR 64527 n.86), and the other to "stationary gas turbines," (42 FR 53657. October 3, 1977,—cited at 80 FR 64527 n.87). The commenters stated that this failing should prevent the EPA's ability to move forward with proposed regulation because the Agency has not issued the required endangerment finding for the specific source category, it becomes irrelevant whether it may rely on that (nonexistent) finding to justify setting standards of performance for different emissions from sources in the category.

Commenters stated that in the 2016 subpart OOOOa rulemaking, the EPA established NSPS for $CH_4$ without making an endangerment finding for $CH_4$ emissions from oil and gas sources. Commenters and other industry groups filed comments pointing out the EPA's omission in failing to make a section 111(b) endangerment finding for the new pollutant subject to regulation under NSPS. By imposing NSPS requirements for a new pollutant without first establishing that that pollutant "may reasonably be anticipated to endanger public health or welfare" *(i.e.,* making an endangerment finding), commenters urged the EPA to reject and withdraw the interpretation that the EPA may skip the endangerment finding step in this context. The commenters further urged the EPA to clarify that a statutory prerequisite for regulation of a new pollutant under the NSPS program is an endangerment finding for that particular pollutant. Finally, and as a separate matter, the commenters urged the EPA to revisit the legal underpinnings for the subpart OOOOa standards as the commenters asserted the EPA did not follow the statutory prerequisites for the adoption of such standards. According to the commenters, those standards are illegal as being outside of the agency's authority, and as such should now be withdrawn.

Other commenters stated that the EPA's previous approach in the 2015 Rule to determining that it has a rational basis to regulate GHGs emitted by this source category is sound. The Agency has correctly not reopened this approach, nor has it proposed any alternatives to it. They said in the context of section 111, the endangerment finding is made with respect to the source category, and not as to specific pollutants (80 FR 64530). It would be unlawful for the Agency to finalize any alternative approach. In 2015, the EPA concluded that it possesses authority to regulate GHG emissions from fossil fuel-fired EGUs under section 111 for two reasons: (1) There was no new evidence calling into question its determination that "GHG air pollution may reasonably be anticipated to endanger public health and welfare"; and (2) fossil fuel-fired EGUs have a "high level of GHG emissions." These considerations hew closely to the statutory factors that inform the decision whether to list a source category in the first place—namely, whether the category "causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare." In fact, in 2015 the Agency confirmed that, even if it were required to issue endangerment and significant contribution findings under this provision in order to regulate GHGs emitted by EGUs, the same information that underpinned its rational basis conclusion would support such findings (80 FR 64530). This approach, which closely parallels the listing analysis but does not require formal endangerment or cause-or-contribute findings, is legally sound. The statute is clear that a formal endangerment finding is required to initially list a sector to be regulated under section 111—and is also clear that such a finding is not required before regulating additional harmful pollutants from a previously-listed sector. Because Congress did not provide specific criteria for regulating additional pollutants from a source category that is already listed under section 111, it is reasonable to look to the statutory factors that trigger regulation initially when deciding whether to require reductions of other pollutants. They said the statutory factors for listing a source category—the endangerment and cause-or-contribute findings—provide a floor for when EPA *must* regulate an additional pollutant from a listed source category under the rational basis inquiry. It would be irrational to fail to regulate an additional pollutant simply because a source category was already listed, if the same evidence regarding that pollutant would have triggered a formal listing of that source category had the source category not previously been listed. Thus, it would be arbitrary for the agency to decline to regulate a pollutant on the basis of considerations wholly unrelated to the harms that pollutant poses or the quantities in which it is emitted from a particular source category.

Other commenters also stated that any effort to reverse the EPA's decision to regulate $CO_2$ from power plants would require, among other things, that the EPA fully contend with each step of the statutory and legal analysis of section 111 it undertook in the 2015 Rule, and

explain why each of them has become invalid. They said promulgating a final rule contrary to the 2015 Rule without the requisite record-based, factual analysis and reasoned explanation would yield "an unexplained inconsistency in agency policy" that is arbitrary, capricious, and unlawful. Commenters stated that that while the most comprehensive approach to sensible GHG regulation remains through congressional action, and while the CAA is far from the perfect tool for regulating GHGs, it is preferable to protracted legal battles and to the potential patchwork of judicial and regulatory outcomes. As a result, the Agency should retain the existing endangerment finding. They said that if the EPA fails to regulate GHG emissions from new coal-fired EGUs it would be wholly unreasonable and contrary to the endangerment finding.

*Response:* The EPA addressed the substance of these comments in a lengthy discussion in "Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review: Final Rule," 85 FR 57018, 57033–40, 57052–58 (September 14, 2020). That discussion is incorporated by reference here. That discussion further elaborates the rationale for EPA's determination that a pollutant-specific significant contribution determination is appropriate, and EPA's related determinations. That discussion also responds in full to the comments on the present rule.

It should be noted that in the 2015 Rule, EPA combined the steam generating source category and combustion turbine source category into a single source category for purposes of GHG emission regulation, 80 FR 64510, 64521–32 (October 23, 2015), and determined, in the alternative, that GHG emissions from the combined source category contribute significantly to dangerous air pollution. *Id.* at 64531. In today's rulemaking, the EPA is not revising the source category determination in the 2015 Rule and, by the same token, the significant contribution finding that EPA is making in the present rulemaking for GHG emissions concerns emissions from the same, combined source category.

*Comment:* Commenters stated that if the Endangerment Finding is overturned, the electric power sector could be broadly exposed to tort and nuisance suits brought by citizens and states—as was the case prior to the EPA regulation of GHGs (*e.g., American Electric Power Co.* v. *Connecticut,* 564 U.S. 610 (2011)). Accordingly, these efforts would create more uncertainty about the future of GHG regulations applicable to new EGUs—uncertainty that likely would not be resolved for years and could undermine any potential for generation owners and operators to consider new coal-based generation as a viable option. They said as a result, the Agency should retain the existing endangerment finding.

*Response:* The Agency has not proposed to overturn the existing Endangerment Finding and is not overturning it in this final rule.

*Comment:* Commenters stated that to the extent that emissions of $CO_2$ from new, modified, or reconstructed electric utility generating units are to be subjected by the EPA to regulation under the CAA, the proper path would be to regulate such emissions as part of a broader effort to regulate $CO_2$ emissions from "numerous or diverse" sources under sections 108–110 of the CAA. Alternatively, if the EPA is adamant in engaging in regulating such emissions under section 111(b), at the very least the EPA must complete a specific endangerment finding for $CO_2$ emissions from such facilities under the applicable criteria set forth in section 111(b), which the EPA has failed to do to date. Either way, commenters stated that the proposed rule amendment is beyond the legal authority of the CAA.

*Response:* EPA is making a pollutant-specific significant contribution finding in this action.

*Comment:* Commenters quoted the NSPS proposal as stating that "the Agency will consider comments on the correctness of the EPA's interpretations and determinations, and whether there are alternative interpretations that may be permissible, either as a general matter or specifically as applied to GHG emissions" (83 FR 65242, 65432 n.25). Commenters then stated that they filed a petition in 2017 contending that the EPA should commence a new rulemaking on the subject of the Agency's 2009 endangerment finding. They provided the following arguments of the 2017 petition: (1) There had been no statistically significant atmospheric warming despite a continued increase in atmospheric $CO_2$ levels; (2) changes in global temperatures in recent decades were far from unusual; (3) new balloon and satellite data showed that the atmosphere was far less sensitive to $CO_2$ forcing than the climate models had predicted; and (4) there was mounting evidence that the EPA's GHG rules would have no discernible climate impact. For these reasons, they said there was a need to reexamine both the three lines of evidence for the EPA's endangerment finding as well as its underlying rationale. Regarding the proposal, the commenters stated that in addition to their still pending petition, they are providing new evidence for why the Agency should proceed with this petition and with similar petitions pending before it. They submitted references (titles, weblinks, and synopses) to nine research papers published since filing their initial petition which they argue add additional support. They stated that given the points and data outlined in this newer research, in addition to those set forth in their 2017 petition, the EPA should commence a new proceeding to reexamine its 2009 endangerment finding.

*Response:* The Agency is retaining the existing endangerment finding. The submitted material is out of scope for this rulemaking. With regards to the claim that EPA was soliciting comments on this subject, the footnote quoted by the commenters goes on to specifically outline examples of the kind of comments referred to: This further elaboration made clear that EPA was not soliciting comments on the science of climate change but rather regarding interpretation of statutory language and legal opinion as to whether the Agency would need to make an endangerment finding for previously listed source categories ("For example, the Agency will consider comments on the issue of whether it is correct to interpret the "endangerment finding" as a finding that is only made once for each source category at the time that the EPA lists the source category or whether the EPA must make a new endangerment finding each time the Agency regulates an additional pollutant by an already-listed source category. Further, the EPA will consider comments on the issue of whether GHG emissions are different in salient respects from traditional emissions such that it would be appropriate to conduct a new "endangerment finding" with respect to GHG emissions from a previously listed source category. In addition, the EPA solicits comment on whether the Agency does have a rational basis for regulating $CO_2$ emissions from new coal-fired electric utility steam generating units and whether it would have a rational basis for declining to do so at this time" 83 FR 65242, 65432 n.25).

*Comment:* Commenters also said that the Agency suggestion in footnote 25 of the Proposal is unreasonable in that the Agency seems to presume that it might not be appropriate to regulate GHGs from new coal-fired power plants because the Agency projects that few such plants will be built in coming years. They said this approach asks the

wrong question. The question should be whether there is a rational basis to regulate GHGs from power plants—not just new coal-fired plants. This is because, once new sources are regulated under section 111(b), the obligation to regulate existing sources under section 111(d) is triggered. If new sources in a source category could not be regulated under section 111(b), no sources in the category could be regulated. Commenters further stated that the EPA cannot reverse its position merely by asking for comments on whether it should adopt a new position diametrically opposed to both current law and the position it maintains in the Proposed Rule.

Commenters stated that using footnote 25 as a means of requesting public comment is misleading and violates administrative procedures. They said that it appears that the EPA is seeking rationale or justification to under the legal basis for this rule while claiming that is retaining its legal basis. The EPA cannot have it both ways: either EPA is using its legal basis, or it is looking for alternatives. If it is looking for alternatives, then EPA has not met its responsibilities under the Administrative Procedures Act for fair notice of the nature and scope of this rulemaking.

Commenters stated that in the endangerment finding footnote of the 2018 Proposal (83 FR 65432 n 25), the EPA suggests that it may consider whether it would have a rational basis to decline to regulate given that "no more than a few new coal-fired EGUs can be expected to be built." The commenters said this suggestion is not legally or factually sound and does not provides a valid reason not to regulate GHGs from fossil fuel-fired EGUs under section 111. They said the statute is unambiguous: The EPA must consider pollution from both new and existing sources when deciding whether to regulate a pollutant within a source category. To the extent that the statute contains any ambiguity, a decision not to regulate based solely on projected levels of emissions from new sources would be disallowed as an impermissible construction. They argued that section 111(b) unambiguously expresses Congress's concern with pollution emitted from a source category as a whole, not just new sources and 111(b) directs the Administrator to base decisions about whether to list a source category on an analysis of the entire category, including existing sources. Section 111(b)(1)(A) does not distinguish between "new" and "existing" sources but rather conveys Congress's directive to address pollution across the source category.

The commenters also stated that Footnote 25 of the proposal raises the prospect that, on the question of regulating a pollutant from a listed source category, Congress inexplicably intended for the EPA to consider pollution from new sources only, irrespective of the harm caused by pollution from existing sources—and even though Congress directed the EPA to consider the air pollution from the sector as a whole, that plain language should be ignored. They said the Agency presents no support for this theory, which is contrary to both the clear terms and the evident objective of the statute. The commenters argued that Footnote 25's suggested interpretation disregards statutory language in other ways as well. For example, section 111(b)(1) provides that the Administrator "shall include a category of sources in such list if in his judgment it *causes, or contributes significantly to,* air pollution which may reasonably be anticipated to endanger public health or welfare." (42 U.S.C. 7411(b)(1)(A)). Yet as of the date of when the EPA determines to list a source category, there are no "new" sources in existence. Section 111(a)(2) provides: "The term "new source" means any stationary source, the construction or modification of which is commenced *after the publication of regulations (or, if earlier, proposed regulations) prescribing a standard of performance under this section* which will be applicable to such source." (*Id.* section 7411(a)(2)). They said under section 111, listing *precedes* promulgation of standards. So, when the EPA decides whether to list a category, by definition it has not yet *proposed* section 111 standards for that category and because it has not proposed such standards, no sources qualify as "new" sources under section 111(a)(2). Basing a decision not to list (and therefore not to regulate) a source category solely on the absence of emissions from as yet nonexistent "new" sources—while ignoring sources that already exist and are emitting pollutants that threaten harm to public health and welfare—is not a tenable reading of the statutory language.

*Response:* In this rule, EPA takes the position that GHG emissions from new and existing EGUs contribute significantly to dangerous air pollution. While EPA proposed to retain the position that it stated in the 2015 Rule that a pollutant-specific significant contribution finding is not required, it solicited comment on whether such a finding is required, and that comment solicitation provided adequate notice.

*Comment:* Commenters stated that though the EPA notes that it is not proposing to revisit its 2009 endangerment finding for greenhouse gases, the proposed NSPS revisions request comment on whether recent and projected power sector trends present a rational basis to decline to regulate $CO_2$ emissions from the power sector. The suggested comment area, presented in footnote 25, cites power sector trend projections from the Energy Information Administration's (EIA's) 2018 Annual Energy Outlook and findings from the EPA's proposed Affordable Clean Energy (ACE) rule as potential support for this position. Commenters also stated that the EIA's 2018 Annual Energy Outlook does not indicate that power sector $CO_2$ emissions will decline significantly in the future. Instead, the estimates referenced by the EPA in the proposal project that $CO_2$ emissions from the power sector will remain the single largest sector-based source of $CO_2$ emissions over the long term, totaling 1.72 billion tons in 2020, 1.71 billion tons in 2030, and 1.78 billion tons in 2050. Commenters said though the EPA found that the transportation sector overtook the power sector as the largest sector-based source of GHG emissions in 2017, the 2018 Annual Energy Outlook projects that power sector emissions will regain the top ranking in 2026 and maintain a lead over the transportation sector by growing modestly through 2050. Commenters stated while newer EIA projections that were unavailable at the time of the EPA's proposal indicate slightly lower power sector $CO_2$ emissions, EIA still projects significant and sustained power sector GHG emissions through 2050, not a steady decline. Commenters said a report from the Rhodium Group based on preliminary EIA data for 2018 and released a few weeks after the EPA's proposal estimates that power sector-related GHG emissions increased 3.4 percent in 2018, breaking a three-year trend of decreases. Commenters added still more recent EPA data reveals the same pattern. Commenters stated preliminary 2018 emissions data compiled by EPA's Clean Air Markets Division (CAMD), also released after the proposed NSPS revisions were published in the **Federal Register**, show power sector $CO_2$ emissions rising from 1.92 billion tons in 2017 to 1.93 billion tons in 2018. Commenters said prior to the 2018 release, EPA's CAMD data had shown flat or declining $CO_2$ emissions for every year since 2013.

Commenters stated it would be unlawful and arbitrary for the EPA to use declining power sector emissions as

reason for not regulating. They argued that even if power sector emissions are declining—which is not at all clear—they are far higher than levels necessary to keep $CO_2$ concentrations from rising further, let alone to achieve the necessary net-zero balance. $CO_2$ pollution accumulates in the atmosphere, where it lingers for centuries, such that a year-to-year decline in emissions does not prevent atmospheric concentrations from continuing to rise, exacerbating the impacts of climate change. "[T]he urgency of reducing emissions now," (80 FR 64520) which the EPA acknowledged in the 2015 Rule, has only increased in recent years. Commenters said reliance on recent emission trends is even more unfounded because U.S. climate pollution significantly increased in 2018, including a 1.9 percent increase in power sector carbon pollution. Even before the 2018 data were available, U.S. Energy Information Administration (EIA) had recognized long-term market and economic uncertainty, which could potentially drive some shift back to coal generation. EIA projections now show that the general trend toward declining carbon pollution from the power sector is likely to flatten out in the early 2020s. Commenters stated standards that even if pollution levels were declining more steadily, that would not authorize the EPA to ignore its obligation to protect the public from what will continue to be a major threat to public health and the environment. The CAA is not concerned merely with whether pollution levels are currently below their historic peak. To the contrary, the Agency must ensure that pollution is controlled to the degree the statute requires—*i.e.,* in accordance with a standard of performance that reflects the best system of emission reduction (BSER) (42 U.S.C. 7411(a)(1)).

The commenters also said that there may be other reasons why a developer would be willing to pay a premium to build a new coal-fired plant that the models do not consider (80 FR 64559–64562). Thus, it is unreasonable not to establish standards of performance on the assumption that coal-fired power plants will never again be built (or modified). They said that the Agency does not even consider the fact that the source category includes not only new sources but also existing sources that undergo certain "modifications," and that such modified sources have significant $CO_2$ emissions.

Commenters said that by asking whether the Agency has a rational basis for regulating $CO_2$ emissions from new coal-fired EGUs "in light of" the projections cited in footnote 25, the EPA is setting itself up to conduct continual market evaluations for all the EPA regulations for which regulation is premised on a similar type of prerequisite determination. An interpretation of section 111 that leads to that result is unreasonable and impractical. They said that there is no indication in the CAA that Congress intended the Agency to undertake a continual market assessment of this nature.

Commenters stated that the endangerment finding footnote of the 2018 Proposal (83 FR 65432 footnote 25) contains a fatal factual deficiency in that it suggests that the rational basis finding might be reversed because "no more than a few new coal-fired EGUs can be expected to be built, which raises questions about whether new coal-fired EGUs contribute significantly to atmospheric $CO_2$ levels." The commenters said that not only does this suggestion disregard the EPA's 2015 acknowledgment that "the $CO_2$ emissions from even a single new coal-fired power plant may amount to millions of tons each year," but it entirely ignores natural gas-fired power plants, which are also included in the source category. In making the 2015 determination, the EPA specifically observed that "the $CO_2$ emissions from even a single natural gas combined cycle (NGCC) unit may amount to one million or more tons per year." They said natural gas-fired power plants continue to be built at a steady clip as evidenced by the first ten months of 2018 in which 14.9 gigawatts (GW) of natural gas-fired EGU capacity was added to the grid. New gas plants must be accounted for and by failing to do so, the Agency would forfeit any "rational connection between the facts found and the choice made," and would fail to provide "a reasoned explanation . . . for disregarding facts and circumstances that underlay . . . the prior policy." Each of those flaws would render the decision arbitrary and capricious. Commenters said that even if the EPA legally could regulate $CO_2$ emissions from new natural gas plants without regulating $CO_2$ emissions from new coal-fired power plants, the EPA should not do so because such partial regulation would provide an inadvertent subsidy to new coal-fired plants.

*Response:* In this rule, the EPA is determining that GHG emissions from EGUs contribute significantly to dangerous air pollution and is promulgating revised standards of performance for EGU GHG emissions. To the extent it is useful or necessary in this rulemaking for the EPA to further address whether long-term emission trends, or related considerations, are relevant for a significant contribution determination, the EPA does so elsewhere in this document.

### *C. Primary Criteria for Determining Significance*

In this section, the EPA describes criteria for determining when GHG emissions from a source category contribute significantly to dangerous air pollution in response to comments submitted on this rule. The EPA indicated in the 2020 Oil and Gas Policy Rule that it would finalize these criteria in a separate rulemaking. 85 FR 57039.

#### 1. GHG Emissions

The criteria discussed herein only apply to GHG in the context of the EPA's SCF under CAA section 111(b)(1)(B). This action does not discuss criteria for pollutants other than GHGs. Under this framework, the EPA is determining that the quantity of GHG emissions from a source category is the primary criterion in determining significance for purposes of regulation of GHGs from a source category under CAA section 111(b). Gross GHG emissions are important for this set of pollutants because GHGs are global long-lived pollutants and do not have the local, near-term ramifications found with other pollutants (*e.g.,* criteria pollutants). Unlike other pollutants where both the location and quantity of pollution emissions are factors in determining the impact of the emissions, GHGs' impact (*i.e.,* climate change) is based on a cumulative global loading and the location of emissions is not nearly as important a factor as it is for assessing local, near-term impacts associated with criteria pollutants. It is for this reason that, when the EPA is assessing GHGs impact in contributing significantly to air pollution which may reasonably be anticipated to endanger public health and welfare, the quantity of emissions should be the primary criterion that the EPA should evaluate.

The GHG emissions are the best, but not necessarily only, indicator of significance because the quantity of emissions emitted from a source category correlates directly with impacts. Calculations using the Model for the Assessment of Greenhouse Gas Induced Climate Change (MAGICC model) to investigate the impact of including or eliminating a single sector's emissions from 2020 through 2100 have shown that the magnitude of emissions from that single sector is very close to being linearly related to the projected temperature change in 2100 resulting from eliminating that sector's emissions. This is consistent with the

results of a number of peer reviewed publications in the past decade: *e.g.,* Matthews *et al.* found that the temperature change is roughly proportional to the total quantity of $CO_2$ emissions over a wide range of potential scenarios.[8]

A threshold of GHG emissions from the source category compared to the rest of the U.S. GHG emissions (*i.e.,* the percent of total U.S. GHG emissions) can be used to demonstrate significance. Emissions can be large enough from a source category that the evaluation of GHG emissions in isolation is sufficient for making a finding of significance for the source category. Conversely, the EPA believes that some source categories are sufficiently small in GHG emissions that a finding of insignificance can be made by only evaluating the GHG emissions from the source category. For many source categories, the evaluation of GHG emissions alone will be sufficient for determining whether there is significant contribution.

It should be noted that under section 111(b)(1)(A), the EPA is required to make a significance finding on a category-by-category basis. That provision requires the Administrator to list "*a* category of sources" for regulation if he determines that "*it* causes or contributes significantly to" dangerous air pollution. Section 111(b)(1)(A) (emphasis. added). As a result, the text of 111(b)(1)(A) compels or is at least best read to require the EPA to make the significance determination for a particular source category on the basis of the emissions (or other relevant attributes) of that particular source category. In contrast, the EPA may not combine source categories that individually would not meet the significance criteria and determine that, when combined, the source categories do meet the significance criteria.[9]

2. Using a Threshold in Significance Determination

Under this framework, the EPA is determining a threshold for the evaluation of significance of GHG emissions from source categories. The use of a clear threshold provides certainty regarding the EPA's process and allows the regulated entities to have insight into how the EPA will make determinations on significance for their respective source category. The threshold introduced in this rulemaking is a reflection of the EPA's best understanding of the landscape of the U.S. GHG emissions from stationary sources. The EPA is introducing a methodology to evaluate significance with respect to the U.S. GHG emissions that can be applied for any source category, and that application of the methodology is only being directly applied to the EGU source category in this action as further introduction of this approach. It is important to note that a significance determination for the U.S. GHG emissions will be needed before the EPA may regulate any other source category under CAA section 111(b) for GHG emissions.

As Table 1, below, makes clear, there are at least two natural breakpoints between groups of emitting source categories. The first natural breakpoint is between EGUs and all other source categories. EGUs stand out as by far the largest stationary source of the U.S. GHG emissions, emitting over 25 percent of all the U.S. GHG emissions. Based on available data, the next largest source category, Oil and Natural Gas, emits just under 3 percent of U.S. GHG emissions. Two other source categories, Boilers and Petroleum Refineries, also fall between 2.5 percent and 3.0 percent of U.S. emissions. Between 1.5 percent and 2.5 percent of U.S. GHG emissions there is another natural breakpoint and all of the remaining source categories fall below 1.5 percent of the U.S. GHG emissions. Note that source category emissions in Table 1 are an estimate of what the Agency currently understands about the emissions from CAA section 111 source categories. If the EPA were to do a rulemaking and a significance determination for a specific source category, the EPA would do a thorough analysis of the available and attributable GHG emissions data to ensure appropriate determinations and assessments.

TABLE 1—EXAMINATION OF GHG EMISSIONS FROM LARGE STATIONARY SOURCES OF GHG EMISSIONS

| % of total U.S. GHG emissions | Emissions in that range (MMT $CO_2e$) * | Source categories affected at different thresholds | Percent of U.S. GHG emissions from stationary sources covered at given threshold (%) |
|---|---|---|---|
| Above 25% | >1670 MMT | EGUs (1778 MMT/27% of total US GHG Emissions, 3.6% of Global emissions). | 43 |
| 3% to 25% | 200 MMT–1670 MMT | No categories identified | 43 |
| 2.5% to 3.0% | 167–200 MMT | Oil/Gas Production and Processing; ^ Refineries; Boilers | 56 |
| 2.0% to 2.5% | 134–167 MMT | No categories identified | 56 |
| 1.5% to 2.0% | 100–134 MMT | No categories identified | 56 |
| 1.0% to 1.5% | 67–100 MMT | Landfills; ‡ Iron and Steel | 60 |

* MMT $CO_2e$ = Million metric tons of carbon dioxide equivalent

^ Note that the oil and gas production and processing GHG emissions are very close to the 3% value and thus there is a possibility that this source category may be above the threshold in the near term.

‡ Note that the Landfills source category has already been regulated under CAA section 111 and the level of the emissions in Table 1. reflects reductions in GHG emissions as a result of that regulation as a co-benefit.

The EPA is introducing a threshold of 3 percent of U.S. GHG emissions to evaluate a source category's emissions to determine significance for purposes of CAA section 111(b). The EPA is also determining that source categories that

[8] H. Damon Matthews, Nathan P. Gillett, Peter A. Stott & Kirsten Zickfeld, The Proportionality of Global Warming to Cumulative Carbon Emissions. Nature 459, 829–832 (2009), available at *https://www.nature.com/articles/nature08047.*

[9] By the same token, as the EPA explained in the 2020 Oil & Gas Rule, there are limits to the EPA's ability to expand a source category to include other sources. As the EPA stated in that rule, "the authority to revise the scope of a source category must be exercised within reasonable boundaries and cannot be employed in a way that results in an unreasonable expansion of an existing source category. . . . [T]he EPA is not authorized to expand the scope of a listed source category to cover a new set of sources that are not sufficiently related to the sources in the pre-existing category. . . " 85 FR 57027.

are less than this value (*i.e.,* 3 percent or less) are necessarily insignificant without consideration of any other factors. The reasoning for choosing this threshold is presented later in this document.

The EPA acknowledges that, when interpreting other CAA provisions, the EPA has used different thresholds to define "significant contribution," but it is appropriate to select a threshold based on the nature of the problem being addressed. For example, to address the problem of interstate transport under CAA section 111(a)(2)(D)(i)(I)—which concerns criteria pollutants, *i.e.,* pollutants that affect the NAAQS—the EPA selected a threshold of 1 percent based on analysis of air quality modeling specific to the criteria pollutant at issue. 76 FR 48208, 48236 (August 8, 2011) (Cross-State Air Pollution Rule (CSAPR)). For criteria pollutants, both the location and quantity of emissions are factors in determining their impact. In contrast, the impact of GHGs (*e.g.,* climate change) is based on a cumulative global loading, and the location of emissions is not nearly as important a factor as it is for assessing local impacts associated with criteria pollutants. Because GHGs do not have the local near-term impacts that criteria pollutants tend to have, a larger value is appropriate to use in determining significance as it still addresses the health and welfare impacts of GHG emissions without specifically evaluating local near-term impacts, which is analytically unreasonable to do given the global nature of GHGs. While the 3 percent threshold will be applied against domestic emissions, source categories exceeding that threshold represent a much smaller fraction of global GHG emissions.[10]

By determining a threshold, the EPA is setting a clear indication of how source categories will be evaluated for significance based on GHG emissions. For those source categories that are below the 3 percent threshold, the EPA would make a determination (through future rulemaking) of insignificance. This means that if a source category collectively emits 3 percent or less of the total U.S. GHG emissions, it will be considered to be insignificant. For those source categories that are above the threshold, a more detailed evaluation of other criteria can be used to make a determination of significance. This is described in section IV.D below. It is important for the EPA to make this clear indication as it allows source categories and the general public a level of transparency as to how the EPA will be evaluating source categories for significance. The threshold in this action will provide a degree of certainty regarding whether a source category will later be found significant or insignificant based on the threshold.[11]

After evaluating the two natural break points in GHG emissions, the EPA determined that 3 percent of the U.S. GHG emissions was the best threshold for determining significance. As noted above, there is currently only one source category above this threshold, EGUs, and the evaluation of significance for the EGU source category has been a topic explored and discussed by the Agency in great detail over the course of the last decade.[12] Just below the 3 percent threshold are three source categories: Oil and Natural Gas, Petroleum Refineries, and Industrial-Commercial-Institutional Steam Generating Units (*i.e.,* "Boilers"). There are no other source categories with GHG emissions between 1.5 percent and the 3 percent. By using a threshold of 3 percent of the U.S. GHG emissions (*i.e.,* only including EGUs above the threshold), the EPA will effectively be covering 43 percent of the U.S. stationary source GHG emissions via regulation of a single source category. If the EPA were to instead set a threshold between the other identified breakpoint—between 1.5 percent and 2.5 percent of U.S. GHG emissions—the EPA observes that this threshold would lead to a relatively modest increase in the stationary source U.S. GHG emissions that would be regulated of an additional 13 percent (for a total of 56 percent of U.S. stationary source GHG emissions).[13] In addition, regulation of the additional source categories that comprise 13 percent of U.S. emissions would eliminate only a portion of those emissions. With an even lower threshold of significance set at 1.0 percent of U.S. GHG emissions, there would be significantly more source categories covered (about 10 based on the EPA estimates) above the threshold but likely would include an even more modest increase in stationary source GHGs that would cover 60 percent of U.S. stationary source GHGs. Under this framework, the EPA is basing a decision to apply a threshold of 3 percent on the relative contribution of regulating source categories that contribute significantly to the overall impact of climate change. To that end, the temperature impact associated with the hypothetical elimination of all source categories above a 3 percent threshold corresponds to a hypothetical global mean temperature reduction of 0.049 degrees Celsius (°C) (approximately 0.1 degree Fahrenheit, the calculated effect in 2100 of removing 1,780 million metric tons (MMT) of $CO_2$ emissions each year from 2020 through 2100) from source categories above that threshold (*i.e.,* just EGUs). Eliminating the next largest source category (*i.e.,* Oil and Gas Processing and Production) would only generate an additional hypothetical global mean temperature reduction of less than 0.01°C and even smaller source categories correspondingly contribute less to global temperature. The EPA is making the decision that the threshold for a significance determination for U.S. GHG emissions to be in the form of a percentage. A percentage is a metric that measures the relative contribution to the whole and, in this action, the EPA believes that it is appropriate to measure and evaluate significant contribution of U.S. GHG emissions as a relative contribution to the whole of GHG emissions in the U.S. The EPA is determining that a threshold in the form of a percentage is both reasonable and more appropriate for making the significance determination in this rule based on a percent's relative nature. This is important because the trajectory of U.S. GHG emissions is trending down. As overall emissions decrease over the course of time, a source category's relative contribution to GHGs may not have changed or may have even increased based on GHG reductions in other source categories and sectors. A relative percentage threshold recognizes that the EPA may later determine a source category is significant based on these circumstances, because a source category's emissions may eventually exceed the threshold even though it is currently below the threshold.

[10] The EPA recognizes that in the 2016 Oil & Gas Rule, it determined that GHG emissions from the oil and natural gas source category contribute significantly to dangerous air pollution, in part, on the grounds that those emissions exceeded the total amount of emissions from various foreign countries. 81 FR 35824, 35840 (June 3, 2016). The EPA believes that its current approach of identifying a threshold for significance based on a percentage of U.S. emissions is better reasoned than the 2016 Oil & Gas Rule's approach of drawing comparisons to the absolute emissions of other countries.

[11] The EPA does not currently have a comprehensive inventory of the U.S. GHG emissions for all of the NSPS source categories. For the EPA to make determinations of significance for a source category, a more comprehensive emissions profile of a source category should be used. The EPA will make determinations of significance for other source categories in the future.

[12] *See* 79 FR 34960 and 80 FR 64510.

[13] Note that one of those "next three largest" source categories is oil and natural gas. In the recently finalized policy package, the EPA found that regulation of GHGs from this source category is unnecessary as it is currently being controlled by regulation of volatile organic compounds. See 85 FR 57018, 57030 (September 14, 2020).

Accordingly, a percentage threshold allows the EPA, over time, to always focus on the source categories with the potential to have the greatest impact. The framework on which EPA bases its decision today is, therefore, amenable to future use, which augurs in favor of the framework's use to make today's finding.

The EPA is introducing in this action that a threshold in the form of a percentage is both reasonable and more appropriate for making a significance determination for GHGs based on a percent's relative nature. A tonnage threshold is a static metric that would not change over time. As previously described, the trajectory of U.S. GHG emissions is trending down. As emissions decrease over the course of time, it is likely that source categories that were once above any static threshold will fall below such a threshold. Even though a source category may reduce overall U.S. GHG emissions, that source category's relative contribution to GHGs may not have changed or may have even increased based on GHG reductions in other source categories and sectors. Additionally, if emissions do decrease over time, the use of a tonnage threshold potentially results in no source category meeting the criteria for significance, even if collectively the U.S.GHG emissions continue to pose a danger to public health or welfare.

It should be noted that the U.S. GHG emissions of the EGU source category are more than an order of magnitude larger than the emissions threshold in the framework, representing 43 percent of U.S. stationary source GHG emissions. The EPA believes that it is possible for source categories with GHG emissions substantially larger than the threshold to be deemed significant on the basis of the primary criterion alone (*i.e.*, magnitude of emissions) and without consideration of the secondary criteria described elsewhere in this notice.

3. Tiers of Source Categories Based on GHG Emissions

As noted previously, the primary criterion in evaluating the significance of a source category is, again, the relative magnitude of the U.S. GHG emissions. The EPA believes that NSPS source categories may be grouped into three tiers on the basis of magnitude of the U.S. GHG emissions, as follows:

(1) *Source category with GHG emissions substantially above the threshold.* This source category has emissions of a large enough magnitude that a determination of significance can be made on the basis of the magnitude of emissions alone. As discussed later in this document, this tier is comprised solely of the EGUs source category; in other words, EGUs do not require consideration of the secondary criteria in order to determine significance.

(2) *Source categories with an intermediate magnitude of the U.S. GHG emissions (i.e., those with emissions above the threshold but less than the quantity emitted by the EGU source category).* For source categories with emissions above the threshold, evaluation of the magnitude of the U.S. GHG emissions is inconclusive. Rather, a significance determination requires an examination of the source category's magnitude of emissions combined with a more detailed look at the secondary criteria discussed elsewhere in this document.

(3) *Source categories with a small magnitude of GHG emissions (i.e., those with emissions below the threshold).* Source categories with a small magnitude of emissions will be deemed insignificant based on evaluation of the primary criterion alone, without detailed consideration of any secondary criteria.

*D. Secondary Criteria for Determining Significance*

As described above, the EPA is determining that the U.S. GHG emissions from a source category are the primary and most important criterion for making a determination of significance for a source category. However, there may be instances where the U.S. GHG emissions from a source category do not give a comprehensive enough picture to make a determination of significance. The threshold that the EPA has described above in Section IV.B would provide a clear indication that the U.S. GHG emissions from source categories below that threshold are necessarily insignificant. However, under this framework, for any source category that is above that threshold, there are other source-category specific considerations that should be evaluated in addition to GHG emissions when making a determination of significance.[14] For that reason, the EPA will consider other, secondary, criteria in the evaluation of significance for certain source categories. These other criteria are described in the subsequent subsections. It is important for the EPA to consider secondary criteria in the evaluation of significance for certain source categories because the criteria provide unique context to the source category beyond the information provided by the magnitude of the source category's GHG emissions.

[14] Although there is no source category other than EGUs above the 3% threshold, because the threshold is a percentage and as previously described, other source categories may move into this tier as overall GHG emissions decrease and other source category emissions increase.

1. Evaluation and Context of GHG Emissions

Under the introduced framework, the evaluation of the magnitude of the U.S. GHG emissions from a source category is a substantial indicator of whether a source category is significant, but in the specific instance of source categories that have greater GHG emissions than the threshold, an evaluation based on the magnitude of the U.S. GHG emissions may be inconclusive. Within the introduced framework, there are other emissions-based metrics that must be evaluated to clarify and make a significance determination for these source categories.

a. Source Category Trends

An important criterion that can help illuminate and contextualize a significance determination is an evaluation of the trends in emissions and number of designated facilities within a source category. Primarily, the EPA is evaluating whether a source category is on a trajectory of the U.S. GHG emission decline. If the source category, as a whole, is decreasing its GHG emissions, an explanation for why it is on the decline may aid in making a significance determination. In one scenario, if the source category is decreasing emissions because the source category is declining in production or other output (*e.g.*, due to decreasing demand for goods or other market conditions, due to relocation overseas, or due to the cumulative effect of regulations), it may lend towards an insignificance determination as the emissions are already declining and expected to continue to decline even without further regulation. In a separate scenario, if a source category's GHG emissions are declining due to increased efficiency and updated technology, it may lend towards a determination of significance. This would allow the EPA the ability to regulate the source category in order to ensure that efficiency and technology improvements become standard across the source category through both an NSPS (111(b) regulation) for new, modified and reconstructed sources and an emission guidelines (111(d) regulation) for existing sources.

In a scenario in which the EPA were to find a source category to be growing in either emissions or number of designated facilities (or both), it could lend towards that source category being found to be significant. This would allow EPA to regulate and mitigate emissions from new, modified and/or reconstructed designated facilities

within that source category under CAA section 111(b) (*i.e.*, via a NSPS).

If the EPA were to evaluate the trend in the number of designated facilities and emissions of a source category, it might show a static number of existing facilities with a constant or slightly increasing quantity of the U.S. GHG emissions. In this scenario, there may be little utility in determining significance for that source category and consequentially developing a NSPS as there are little to no emissions that would be subject to such a standard. However, creating a NSPS for a source category and pollutant is a necessary predicate to regulating existing sources under CAA section 111(d). Hence, in the scenario of a static number of existing facilities, a finding of significance for the source category may be warranted as it would allow eventual regulation of a group of existing source categories. Under this framework, the EPA expects the prospect of regulating a source category under CAA section 111(d) for existing sources to be a compelling reason for determining significance.

b. Source Category Emissions With Global Context

Another important criterion that the EPA considers, as a secondary factor, is the relative contribution of GHG emissions from the U.S. in a specific source category compared to worldwide emissions of similar sources. As previously described, Section 111(b)(1)(A) of the CAA states that the Administrator shall include source categories that contribute significantly to endangerment of health and welfare. When evaluating a global pollutant such as GHGs, the EPA views the impact of domestic emissions from domestic sources as a more germane consideration when determining whether a pollutant contributes significantly to endangerment of health or welfare. Because every ton of GHG contributes to the global problem, a domestic ton will still have some impact in the U.S. Accordingly, it is reasonable for the EPA to evaluate whether a source category is well-regulated internationally and whether the U.S. emissions from that sector make up a relatively large share of GHG emissions on a worldwide scale, as such evaluation in turn would inform whether U.S. emissions are significantly contributing to domestic impacts. If the emissions from the U.S. are comparatively a large contribution to source category/sector emissions worldwide, it may lend towards a finding of significance for the source category based on the U.S.'s substantial global contribution to the source category. If, however they are relatively small, it would suggest less benefit from the EPA regulation of that source category.

The EPA also considers, as one of the secondary criteria, an evaluation of whether a source category is vulnerable to being trade exposed (*i.e.* whether the source category is constrained in the sources' ability to pass through carbon costs due to actual or potential international competition). The EPA evaluates whether regulation of the source category would create a financial incentive for that source category/industry to move into, or increase production in, another country. This could be manifested as either a shift in production to facilities internationally or a complete closure of existing designated facilities in the U.S. It is not the EPA's intention in regulating source categories to drive production from the U.S. to other countries, and there is an environmental concern in pushing industries to other international locations. This concern is based on the potential for these new international emissions to increase compared to the corresponding displaced U.S. emissions.[15] While this is always a concern for the EPA in the regulation of industry within the U.S., it even more pronounced with the consideration of GHG emissions. As discussed, previously, the U.S. GHG emissions are a global pollutant that also have domestic impacts. As such, if a smaller quantity of domestic GHG emissions would be displaced, due to a regulation, by a greater quantity of international GHG emissions it may support a finding of insignificance for a given source category. This would occur if the U.S. sources are already significantly lower emitting in GHG emissions than sources in other countries. It should also be noted that source categories whose sources in the U.S. make up a relatively smaller proportion of the world's emissions from corresponding international sectors may be particularly vulnerable to being trade exposed as there is likely a greater international capacity to absorb the displaced U.S. production.

Given the global nature of GHG emissions, assessing and understanding the estimated potential net emissions impact of GHG control technologies provides useful context in which to consider the significance of a given set of GHG emissions In addition, there may also be value in evaluating and considering the technology with the associated source category (*i.e.*, intrinsic to the process of the source category)—a prime example of reductions associated with this evaluation might be assessing the likely impacts of efficiency improvements. From a public welfare and human health perspective, targeting source categories that provide the largest overall possible scope for emissions reductions could be an intrinsic part of determining the significance of a given magnitude of emissions. Thus, the EPA is determining that it is appropriate in a given instance to consider feasible technologies (including efficiency improvements) for further context in the Agency's determination of significance of a source category's overall emissions. Here, the magnitude of GHG emissions from EGUs coupled with the reductions available through efficiency improvements supports the EPA's determination of significance.

d. Temporal Evaluation of Criteria

As introduced in this framework, the evaluation of the secondary criteria is not intended to be performed in isolation. Rather, the EPA considers the weight of evidence of all the factors (both primary and secondary) to make an informed and comprehensive decision as to whether a source category that exceeds the 3-percent threshold contributes significantly to the U.S. GHG emissions. The consideration of criteria also has a temporal consideration to a significance determination. A source category's determination can be reevaluated in the future as the status and criteria described here may have changed for that source category. For example, the technology to adequately regulate GHGs from a source category may not be readily available at this time, but in the future that technology may become more broadly available causing the EPA to then make a SCF.

*E. Significant Contribution Finding for EGUs*

As noted above, the Agency is finalizing a determination that GHG emissions from EGUs[16] contribute significantly to dangerous air pollution. The primary criterion in determining

[15] If U.S. production shifted overseas to a jurisdiction that has laxer environmental regulations, for a global pollutant such as mercury or GHGs, there could be both increased local environmental and health impacts at the new overseas location and domestic impacts to the U.S. resulting from the increased U.S. GHG emissions.

[16] For this purpose, EGUs include the affected sources in the combined source category for boilers and turbines. In the 2015 Rule, the EPA "combine[d] the two categories of EGUs—steam generators and combustion turbines—into a single category of fossil fuel-fired EGUs for purposes of promulgating standards of performance for $CO_2$ emissions." 80 FR 64529 (2015 Rule).

whether to make a SCF is the magnitude of GHG emissions from a given source category. It is readily apparent that EGUs emit a uniquely large amount of GHGs compared to all other categories of stationary sources. The EPA made this clear in the 2015 Rule, quoted above, and reiterated it in the 2020 Oil & Gas Rule: "the unique $CO_2$ emissions profile of fossil fuel-fired EGUs should be noted: the volume of emissions from EGUs dwarfs the amount of GHG emissions from every other source category." 85 FR 57039, n.49.

Although GHG emissions from EGUs have fallen since the EPA promulgated the 2015 Rule, they still remain uniquely large among stationary source categories. The EPA's Inventory of U.S. Greenhouse Gas Emissions [17] indicates that, as of 2018, the Electric Power sector directly emitted 1,778.5 MMT of GHGs.[18] This amount was more than twice the amount of GHGs emitted by all other industrial sources combined and more than all other industrial, commercial, and residential stationary combustion sources combined.[19] In addition, direct GHG emissions from EGUs account for approximately 27 percent of total U.S. GHG emissions and 43 percent of U.S. stationary source emissions. The direct GHG emissions from EGUs account for approximately 4 percent of total worldwide GHG emissions and are greater than the emissions of all but four countries.[20] These facts confirm that at current emission levels, EGUs have measurable impacts on both the U.S. contribution to GHG emissions and the worldwide total GHG emissions and continue to be uniquely large stationary source emitters of GHGs. It should be noted that if domestic EGUs no longer emitted any GHG emissions, there would be a measurable impact on worldwide GHG emissions and between 2020 and 2100, there would be a reduction in the projected increase in global temperatures by 0.049 degrees Celsius (° C).

Because EGUs represent by far the largest stationary source of GHGs from combustion of fossil fuels, the EPA believes that this is the most appropriate place for the EPA, states, and sources to devote resources to reducing GHGs from stationary sources. Indeed, this uniquely large magnitude of emissions is the reason over the last 8 years, the Agency has devoted significant effort to determine how to best reduce GHGs from EGUs. Because EGUs are a relatively large U.S. source of emissions in an overall large pool of international EGU sources, regulation over time could help produce practices and technologies that have application to EGUs worldwide.

It is noteworthy that GHG emissions from EGUs are approximately an order of magnitude greater than the estimated emissions of the second largest stationary source category of GHGs attributed to combustion, industrial boilers. Because the magnitude of GHG emissions from EGUs is large compared to other stationary sources, this makes them clearly significant even without detailed consideration of other factors. As mentioned earlier, the EPA is also introducing a framework under which a source category that emits above a threshold of 3 percent of U.S. stationary source GHG emissions may contribute significantly to dangerous GHG air pollution. For those source categories above that threshold, the EPA is also determining that consideration of certain secondary criteria may, collectively, also inform the evaluation of whether a source category should be considered to significantly contribute. However, within this framework, that analysis of secondary criteria is not necessary in the case of EGUs, due to the overwhelmingly large emissions of the source category; it is clear that controlling GHG emissions from the EGU source category will be necessary to appropriately address dangerous air pollution. This conclusion is consistent with the EPA's 2018 Proposal where the Agency explained that if the EPA was required to evaluate significance, EGUs would be considered significant.

1. Secondary Criteria

The EPA is determining that the uniquely large GHG emissions from EGUs makes a finding of significant contribution and regulation appropriate by itself. Under the introduced framework, while the EPA does not think it is necessary to consider secondary criteria because of the uniquely large emissions from the EGU source category, as explained below, the EPA would make the same determination even if it did consider those criteria.

a. Source Category Trends

As mentioned earlier, an important criterion is the evaluation of the trends in emissions and number of designated facilities within a source category, such that the EPA can evaluate whether a source category is on a trajectory of U.S. GHG emission decline.

While electricity demand is projected to increase the U.S., due to the increased use of less carbon intensive generation technologies and more efficient generation, GHG emissions from the power sector are projected to remain relatively steady for the foreseeable future. However, EGUs are projected to remain the single largest stationary source of GHG emissions, and while the Agency expects few, if any, new coal-fired EGUs will be built to meet the demand for electricity, coal-fired EGUs are expected to continue to supply electricity and emit significant GHG emissions for the foreseeable future.[21] The EGU source category also includes stationary combustion turbines. The EPA expects new simple cycle and combined cycle combustion turbine EGUs will be built in the future and that the existing fleet of combustion turbines will continue to operate.[22] Therefore, efficient generation technology could eventually become standard for all new and existing EGUs. Consequently, the EPA would consider the source category trends as supporting the regulation of GHG emissions from EGUs.

b. Source Category Emissions With Global Context

The EPA is also determining that it can consider, as a secondary criterion, the relative contribution of GHG emissions from the U.S. in the specific source category compared to worldwide emissions of similar sources. Accordingly, the EPA evaluates whether a source category is well-regulated internationally and whether the U.S. emissions from that sector make up a relatively large share of global GHG emissions, as such evaluation in turn would inform whether U.S. emissions are significantly contributing to

[17] *See* Table 3–9, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990–2018, Report 430–R–20–002, April 13, 2020, *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2018.*

[18] The global warming potential (GWP) of a greenhouse gas is defined as the ratio of the accumulated radiative forcing within a specific time horizon relative to that of the reference gas $CO_2$. Total GHG emissions are the GWP-weighted emissions of all GHG emissions and reported in million metric tons of $CO_2$ equivalent (MMT $CO_2$e.).

[19] See Table 3–9, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990–2018, Report 430–R–20–002, April 13, 2020, *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2018.*

[20] In 2016, worldwide GHG emissions were estimated to have been 49.4 gigaton (Gt) $CO_2$e. The GHG emissions of China, India, Russia, and Indonesia are 11,577, 3,235, 2,391, and 2,229 MMT $CO_2$e respectively. *https://www.wri.org/blog/2020/02/greenhouse-gas-emissions-by-country-sector.*

[21] According to Table 8 of the Annual Energy Outlook (AEO) 2020, while coal fired generation will decline between 2019 and 2025 from 959 billion kWh to 709 billion kWh, generation from coal-fired EGUs is projected to subsequently remain relatively steady through 2050.

[22] According to Table 8 of the AEO 2020, natural gas fired generation is projected to increase from 1,322 billion kWh to 1,629 billion kWh.

domestic impacts. In this instance, this criteria points towards a finding of significance given that U.S. EGUs make up a sizeable portion (13 percent of the emissions) from EGUs worldwide.[23]

As mentioned earlier in this notice, the EPA is also introducing that one of the secondary criteria is an evaluation of whether a source category is vulnerable to being trade exposed (*i.e.,* whether the source category is constrained in its ability to absorb regulatory costs due to actual or potential international competition). Concerns about international competition would not impact the Agency's decision to regulate EGUs because electricity must be transported over power lines and it is not as easy to relocate or shift production locations as it is for other source categories. The ability to locate generation in Mexico and Canada and transmit the power to the U.S. is limited because of constraints on existing transmission lines and the expense to build additional transmission capacity. The only additional transmission capacity currently being considered is for electricity generated from hydroelectric power in Canada to supply power to New England. Since this electricity has a low carbon intensity, it would not contribute to an overall increase in GHG emissions. Furthermore, the emission standards in this rule will not increase the costs of electricity from a new coal-fired EGU such that it might be financially advantageous to locate new production internationally to countries with less stringent regulations. If international competition were a concern, the Agency would compare the forecast GHG emissions from international sources (in this case, EGUs in Canada and Mexico) against the forecast GHG emissions from domestic sources (in this case domestic EGUs) in both the absence of and implementation of the NSPS. In addition, since few, if any, new coal-fired EGUs are forecast to be built in the U.S., the standards in this final rule will not impact electricity prices to end users to an extent that other industries would be incentivized to relocate internationally due to increased electricity costs. Therefore, domestic reductions in GHG emissions from regulating EGUs will not be offset by increased international GHG emissions. In contrast, for source categories that supply raw materials to other domestic source categories, the impact of international competition on those source categories and the resultant GHG impacts could be considered when determining an appropriate NSPS. It is conceivable that an overly stringent NSPS could result in an increase in global GHG emissions, if the increase in international emissions is greater than the reduction in domestic emissions.

## V. Summary of Cost, Environmental, and Economic Impacts

### *A. What are the affected facilities?*

This rule takes final action affecting fossil fuel-fired EGUs. These EGUs take two forms that are relevant for present purposes: Steam generating units (utility boilers and gasification units) and stationary combustion turbines. Fossil fuel-fired steam generating units can burn natural gas, oil, or coal. However, coal is the dominant fuel for electric utility steam generating units. Coal-fired steam generating units are primarily either PC or fluidized bed (FB) steam generating units.[24] At a PC steam generating unit, the coal is crushed (pulverized) into a powder to increase its surface area. The coal powder is then blown into a steam generating unit and burned. In a fossil fuel-fired steam generating unit using FB combustion, the solid fuel is burned in a layer of heated particles suspended in flowing air. Power can also be generated from coal or other fuels using gasification technology. An Integrated Gasification Combined Cycle (IGCC) unit gasifies coal or petroleum coke to form a synthetic gas (or syngas) composed of carbon monoxide (CO) and hydrogen ($H_2$), which can be combusted in a combined cycle system to generate power. Stationary combustion turbines include both fossil fuel-fired simple cycle and combined cycle combustion turbine EGUs.

### *B. What are the air quality impacts?*

The EPA does not anticipate that this final rule for fossil-fuel-fired EGUs will result in significant $CO_2$ emission changes.

### *C. What are the energy impacts?*

This final rule for fossil-fuel-fired EGUs is not anticipated to have an effect on the supply, distribution, or use of energy.

### *D. What are the cost impacts?*

The EPA does not believe that this final rule for fossil-fuel-fired EGUs will have compliance costs associated with it.

### *E. What are the economic impacts?*

The EPA does not anticipate that this final rule for fossil-fuel-fired EGUs will result in economic or employment impacts. Likewise, the EPA believes this rule will not have any impacts on the price of electricity, employment or labor markets, or the U.S. economy.

### *F. What are the benefits?*

The EPA does not anticipate emission changes resulting from the final rule for fossil-fuel-fired EGUs.

## VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket.

### *B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs*

This action is not expected to be an Executive Order 13771 regulatory action. There are no quantified cost estimates for this final rule because the EPA does not anticipate this action to result in costs or cost savings.

### *C. Paperwork Reduction Act (PRA)*

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing parts 75 and 98 regulations and has assigned OMB control numbers 2060–0626 and 2060–0629, respectively.

### *D. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a

[23] U.S. EGU emissions from the Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990–2018, Report 430–R–20–002, April 13, 2020, *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2018.* Worldwide EGU emissions from the International Energy Agency estimates IEA (2020), $CO_2$ Emissions from Fuel Combustion, *https://www.iea.org/subscribe-to-data-services/co2-emissions-statistics.*

[24] Fossil fuel-fired utility steam generating units (*i.e.,* boilers) are most often operated using coal as the primary fuel. However, some utility boilers use natural gas and/or fuel oil as the primary fuel.

substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. The EPA expects there to be few, if any, new, modified, or reconstructed coal-fired EGUs. As such, this final rule would not impose significant requirements on those sources, including any that are owned by small entities. The EPA has, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

*G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175. It would neither impose substantial direct compliance costs on tribal governments, nor preempt Tribal law. The EPA is aware of three coal-fired EGUs located in Indian Country but is not aware of any EGUs owned or operated by tribal entities. The EPA notes that this action would affect only existing sources such as the three coal-fired EGUs located in Indian Country if those EGUs were to take actions constituting modifications or reconstructions as defined under the EPA's NSPS regulations. However, as previously stated, the EPA expects there to be few, if any, new, reconstructed, or modified EGUs. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA offered consultation with tribal officials during the development of this action; however, the Agency did not receive a request for consultation. The EPA held meetings with tribal environmental staff during the public comment period to inform them of the content of the proposed rule and to encourage them to submit comments on the proposed rule.

*H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health or safety risk.

*I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs (OIRA). This final action is not anticipated to have impacts on emissions, costs, or energy supply decisions for the affected electric utility industry.

*J. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

*K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specific in Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not affect the level of protection provided to human health or the environment. As previously stated, the EPA expects that few, if any, coal-fired EGUs would be affected by this action.

*L. Congressional Review Act (CRA)*

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

**Andrew Wheeler,**

*Administrator.*

[FR Doc. 2021–00389 Filed 1–12–21; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

### 44 CFR Part 64

**[Docket ID FEMA–2021–0003; Internal Agency Docket No. FEMA–8661]**

### Suspension of Community Eligibility

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

**SUMMARY:** This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur. Information identifying the current participation status of a community can be obtained from FEMA's CSB available at *www.fema.gov/flood-insurance/work-with-nfip/community-status-book.* Please note that per Revisions to Publication Requirements for Community Eligibility Status Information Under the National Flood Insurance Program, notices such as this one for scheduled suspension will no longer be published in the **Federal Register** as of June 2021 but will be available at *www.fema.gov.* Individuals without internet access will be able to contact their local floodplain management official and/or State NFIP Coordinating Office directly for assistance.

**DATES:** The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

**FOR FURTHER INFORMATION CONTACT:** If you want to determine whether a particular community was suspended on the suspension date or for further

Message

**From**: DeLuca, Isabel [DeLuca.Isabel@epa.gov]
**Sent**: 3/12/2021 9:40:40 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]; Millett, John [Millett.John@epa.gov]; Rakosnik, Delaney [rakosnik.delaney@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: CAAAC talkers
**Attachments**: 3-15-21 CAAAC Goffman v2.docx

Hi Joe,
Attached are some draft talkers to consider for the CAAAC meeting on Monday. John Shoaff and Shanika Whitehurst kindly provided input as well. It's pretty short, but you, Tomás, and Ale can embellish with your bios…

Thanks,
Isabel

**Isabel DeLuca**
Office of Air and Radiation, US EPA
(202) 343-9247

Message

**From:** POLITICO Pro Energy [alert@email.politicopro.com]
**Sent:** 1/26/2021 12:59:18 AM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** De Blasio, Stringer announce $4B fossil fuel divestment

**De Blasio, Stringer announce $4B fossil fuel divestment**

By David Giambusso

01/25/2021 06:59 PM EST

The fossil fuel divestment movement is on the verge of one of its biggest victories with Monday's announcement that two of New York City's five pension funds will drop about $4 billion in fossil fuel holdings from their portfolios and another could follow suit shortly.

**What happened:** Roughly two years after setting a goal to drop fossil fuel funds, the New York City Employees' Retirement System and New York City Teachers' Retirement System voted to approve divestment Monday, and the New York City Board of Education Retirement System is expected to do the same "imminently," according to a joint announcement from Mayor Bill de Blasio and Comptroller Scott Stringer, who's running for mayor this year.

The process had been slow-moving for some time, with pension system leaders examining the financial effects of dropping oil and gas from their portfolios.

"Our goal throughout was to proceed in a manner that protected NYCERS' assets and the retirement security of our many thousands of members," said Henry Garrido, executive director of District Council 37 and a fund trustee. "NYCERS voted today to embrace the future and a better life for us all."

**Details:** The city has yet to identify which companies it will drop, but will do so after the shares have been sold. While citing $4 billion as the total amount, much of that will depend on the market when the city sells off its holdings. It's unclear if that figure represents the entirety of the funds' fossil fuel holdings.

The $4 billion sum represents the two pension funds that voted Monday, which are by far the two biggest in the city's $240 billion pension fund. The teachers' fund has about $91.5 billion in total assets while NYCERS holds about $77.4 billion.

Stringer and de Blasio have been political foes through much of the mayor's tenure, and did not schedule a joint press conference which would normally be expected for an announcement of this magnitude. Instead, they issued identical but separate releases within several minutes of each other.

"Divestment is a bold investment in our children and grandchildren, and our planet," de Blasio said in a statement. "I applaud the trustees, advocates and experts for their hard work, and I look forward to seeing more cities around the world join this call for change."

"Climate change is the fight of our lives, and we must face it head on with everything we've got – for our planet, for our children, and for our retirees," Stringer said.

Fire and Police funds are monitoring the process but have not yet committed to divesting.

Bill McKibben, co-founder of the group 350.org, which has led the divestment push for years, applauded the announcement in a tweet, saying "this is hard work and it makes a huge difference, especially in the center of world finance!"

**Is it real this time?** Unlike in recent years when de Blasio insisted the city had already divested, now it appears to actually be going forward.

**What's next:** The mayor and comptroller expect the $4 billion to be dropped by 2023, which comports with the five-year timeline they laid out in 2018.

*To view online*:
https://subscriber.politicopro.com/energy/article/2021/01/de-blasio-stringer-announce-4b-fossil-fuel-divestment-2030621

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**From:** POLITICO Pro Energy [alert@email.politicopro.com]
**Sent:** 1/26/2021 12:58:22 AM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject:** De Blasio, Stringer announce $4B fossil fuel divestment

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**What happened:** Roughly two years after setting a goal to drop fossil fuel funds, the New York City Employees' Retirement System and New York City Teachers' Retirement System voted to approve divestment Monday, and the New York City Board of Education Retirement System is expected to do the same "imminently," according to a joint announcement from Mayor Bill de Blasio and Comptroller Scott Stringer, who's running for mayor this year.

The process had been slow-moving for some time, with pension system leaders examining the financial effects of dropping oil and gas from their portfolios.

"Our goal throughout was to proceed in a manner that protected NYCERS' assets and the retirement security of our many thousands of members," said Henry Garrido, executive director of District Council 37 and a fund trustee. "NYCERS voted today to embrace the future and a better life for us all."

**Details:** The city has yet to identify which companies it will drop, but will do so after the shares have been sold. While citing $4 billion as the total amount, much of that will depend on the market when the city sells off its holdings. It's unclear if that figure represents the entirety of the funds' fossil fuel holdings.

The $4 billion sum represents the two pension funds that voted Monday, which are by far the two biggest in the city's $240 billion pension fund. The teachers' fund has about $91.5 billion in total assets while NYCERS holds about $77.4 billion.

Stringer and de Blasio have been political foes through much of the mayor's tenure, and did not schedule a joint press conference which would normally be expected for an announcement of this magnitude. Instead, they issued identical but separate releases within several minutes of each other.

"Divestment is a bold investment in our children and grandchildren, and our planet," de Blasio said in a statement. "I applaud the trustees, advocates and experts for their hard work, and I look forward to seeing more cities around the world join this call for change."

"Climate change is the fight of our lives, and we must face it head on with everything we've got – for our planet, for our children, and for our retirees," Stringer said.

Fire and Police funds are monitoring the process but have not yet committed to divesting.

Bill McKibben, co-founder of the group 350.org, which has led the divestment push for years, applauded the announcement in a tweet, saying "this is hard work and it makes a huge difference, especially in the center of world finance!"

**Is it real this time?** Unlike in recent years when de Blasio insisted the city had already divested, now it appears to actually be going forward.

**What's next:** The mayor and comptroller expect the $4 billion to be dropped by 2023, which comports with the five-year timeline they laid out in 2018.

*To view online*:
https://subscriber.politicopro.com/sustainability/article/2021/01/de-blasio-stringer-announce-4b-fossil-fuel-divestment-2030621

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This email was sent to goffman.joseph@epa.gov by:
POLITICO, LLC
1000 Wilson Blvd.
Arlington, VA 22209
USA

Message

**From**: Campbell, Ann [Campbell.Ann@epa.gov]
**Sent**: 3/15/2021 1:56:13 PM
**To**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Goffman, Joseph [Goffman.Joseph@epa.gov]
**Subject**: FOR YOUR REVIEW: CSAPR RLSO
**Attachments**: Draft Revised CSAPR Update RTC 3.14.docx; Estimating PM2.5- and Ozone-Attributable Health Benefits TSD_RLSO March 12 2021.docx; CSAPR Final Revised Update RIA 03-14-2021 OMB Second Passback.docx; EO12866_RIN2060-AU84_RevisedCSAPRUpdate_Final Rule_FRdocument_2021-03-14.docx

See Dan's note below.

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

---

**From:** Hooper, Daniel <hooper.daniel@epa.gov>
**Sent:** Monday, March 15, 2021 9:54 AM
**To:** Campbell, Ann <Campbell.Ann@epa.gov>; Kocchi, Suzanne <Kocchi.Suzanne@epa.gov>; Harvey, Reid <Harvey.Reid@epa.gov>
**Subject:** FW: eo12866 csapr deliberative

Hi Ann,

Please see the most recent pass backs from EPA to OMB attached. This includes the following documents in RLSO:

1. Preamble/reg text (includes FR review edits in tracked changes)
2. RIA
3. Benefits TSD
4. RTC

Daniel Hooper
Clean Air Markets Division, US EPA
hooper.daniel@epa.gov
202.343.9167 office

*Pronouns: He/Him/His*

---

**From:** Hooper, Daniel
**Sent:** Sunday, March 14, 2021 4:59 PM
**To:** Hodson Marten, Elke L. EOP/OMB <Elke.L.HodsonMarten@omb.eop.gov>; Miller, Sofie E. EOP/OMB <Sofie.E.Miller@omb.eop.gov>
**Cc:** Schillo, Bruce <Schillo.Bruce@epa.gov>
**Subject:** RE: eo12866 csapr deliberative

Hi Elke,

Please see EPA's pass backs attached for the following documents:

1. Preamble/reg text (includes FR review edits in tracked changes)

2. RIA
3. Benefits TSD
4. RTC

Thank you,
Dan

Daniel Hooper
Clean Air Markets Division, US EPA
hooper.daniel@epa.gov
202.343.9167 office

*Pronouns: He/Him/His*

Message

**From:** Kim, Eun [Kim.Eun@epa.gov]
**Sent:** 3/11/2021 11:36:58 PM
**To:** Goffman, Joseph [Goffman.Joseph@epa.gov]
**CC:** Campbell, Ann [Campbell.Ann@epa.gov]
**Subject:** READING: Materials for Friday, March 12, 2021
**Attachments:** BCA CRA pro-con background FYI; OAR Background on CARB Collaboration_March 10 2021_v2.docx; Timing interactions re SAFE actions 03102021_to OAR.docx; Agenda_Light-duty Vehicle Weekly with OAR_March 12 2021.docx; Talking Points for OAR Leadership March 2021 Auto Meetings, 3.4.2021, DRAFT.docx; PRDFlareWPS.OAR.03.12.21.docx; HFC briefing_3_11_2021 rev1.pptx; HFC-23 briefing paper_3.12.21.docx; Tab 7 - Memorandum of Law_draft for EPA political review_consolidated edits.docx; EPA methane briefing WH 03.10.21.pptx

**Goffman, Joseph Calendar**
Goffman.Joseph@epa.gov
On Friday, March 12, 2021
Time zone: (UTC-05:00) Eastern Time (US & Canada)
(Adjusted for Daylight Saving Time)

**March 2021**

| Su | Mo | Tu | We | Th | Fr | Sa |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | 29 | 30 | 31 | | | |

Busy | Tentative | Free
Out of Office | Working Elsewhere | Outside of Working Hours

March 2021

**Fri, Mar 12**

| | | |
|---|---|---|
| | **Before 8:00 AM** | **Free** |
| | **8:00 AM – 9:00 AM** | **Free** |
| | 9:00 AM – 9:30 AM | Management Roundtable |
| | 9:15 AM – 10:00 AM | Air Issues Meeting |
| | 10:00 AM – 10:45 AM | To discuss pending CAA actions (attached previous BCA CRA email) |
| | **10:45 AM – 11:00 AM** | **Free** |
| | 11:00 AM – 11:45 AM | Light-Duty Vehicles Update (materials attached, 3 docs) |
| | **11:45 AM – 12:00 PM** | **Free** |

| | | |
|---|---|---|
| ■ | 12:00 PM – 12:30 PM | CPO-NHTSA-CARB-EPA meeting (1 doc from LD Vehicles meeting, "OAR Background on CARB") |
| ■ | 12:30 PM – 1:00 PM | Lunch/Management time |
| ■ | 1:00 PM – 1:30 PM | Meet and Greet with BMW (attached previous OTAQ talking points doc) |
| □ | **1:30 PM – 1:45 PM** | **Free** |
| ■ | 1:45 PM – 2:30 PM | Work Practice Standards for Pressure Relief Devices and Flares (materials attached, 1 doc) |
| ■ | 2:30 PM – 3:00 PM | One-on-One with Sarah Dunham |
| ■ | 3:00 PM – 3:45 PM | EPA HFCs briefing (materials attached, 1 ppt) |
| □ | **3:45 PM – 4:00 PM** | **Free** |
| ■ | 4:00 PM – 4:30 PM | Bi-Weekly with OAR/OCSPP |
| ■ | 4:30 PM – 5:00 PM | EPA Methane Briefing (materials attached, 1 ppt) |
| ■ | 5:00 PM – 5:30 PM | HFC 23 Byproducts Meeting (materials attached, 2 docs) |
| ■ | 5:30 PM – 6:00 PM | Management Time |
| □ | **After 6:00 PM** | **Free** |

---

Eunjung Kim
Special Assistant
Office of Air and Radiation
(202) 815-7252

Message

**From**: Shoaff, John [Shoaff.John@epa.gov]
**Sent**: 3/9/2021 8:09:15 PM
**To**: Goffman, Joseph [Goffman.Joseph@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]; Kim, Eun [Kim.Eun@epa.gov]
**CC**: Campbell, Ann [Campbell.Ann@epa.gov]; Hockstad, Leif [Hockstad.Leif@epa.gov]
**Subject**: BCA CRA pro-con background FYI
**Attachments**: BCA CRA pros and cons.pdf; CAA significant regulations 2021-030121.docx

**Flag**: Follow up

Joe et al,

For awareness, here's what OGC is pulling together, though it's still working its way thru their chain (so you may get a rev. from others or I will pass if I also see), re: a pro-con of BCA CRA and per David Hayes Mon. 3:13 email. Think this will feed into a 1:00 Thur. mtg. with Gina. Also appending the list of potentially impacted actions that Leif shared with our BCA OS and excerpting the tentative BCA Interim Final Rule schedule below to the extent that might help inform with discussions. Thanks.

John

**Ex. 5 Deliberative Process (DP)**

**JOHN SHOAFF** (HE/HIM/HIS) | DIRECTOR
OFFICE OF AIR POLICY & PROGRAM SUPPORT (OAPPS)
OFFICE OF AIR & RADIATION | U.S. EPA | WJC NORTH 5442-C
1200 PENNSYLVANIA AVE. NW | MC 6103A | WASHINGTON, D.C. | 20460 | USA
Shoaff.john@epa.gov | **1-202-564-0531 DIRECT | 1-202-257-1755 MOBILE**

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/10/2021 4:34:27 PM
**To**: Dunham, Sarah (Dunham.Sarah@epa.gov) [Dunham.Sarah@epa.gov]; Benjamin Hengst [Hengst.Benjamin@epa.gov]
**Subject**: FW: E15: Station Update and 20B Consumer Miles Driven
**Attachments**: InfrastructureUpdate03082021_CB.pdf; American Drivers Reach 20 Billion Miles.pdf

There's an easily surmisable and innocent explanation for the unheralded arrival of this email in my inbox – which case, thank you, and bravo for the efficiency! Or there's a sinister explanation, in which case we have a cyber security problem.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Chris Bliley <cbliley@growthenergy.org>
**Sent:** Wednesday, March 10, 2021 11:07 AM
**Subject:** E15: Station Update and 20B Consumer Miles Driven

All, as of January 2021, we now have 2341 stations selling E15 as well as 219 terminals offering E15 – updated maps attached. Additionally, we've now had 20 billion consumer miles driven on E15 (release attached). If you have any questions, please let me know.

Chris

Chris Bliley | Senior Vice President, Regulatory Affairs
**Growth Energy**
701 8th St NW Suite 450
Washington DC 20001
OFFICE 202.545.4023 CELL 202.579.7418
TWITTER @GrowthEnergy
FACEBOOK growthenergy.org/facebook
WEBSITE www.growthenergy.org

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America's Ethanol Supporters

**FOR IMMEDIATE RELEASE**
March 9, 2021
GrowthEnergy.org/press

**PRESS CONTACT**
Leigh Claffey, 706-829-0213
LClaffey@GrowthEnergy.org

# Growth Energy: American Drivers Reach 20 Billion Miles on E15

WASHINGTON, D.C. - Today, Growth Energy announced that drivers across the United States have reached a new milestone, logging 20 billion miles on the road using E15, a fifteen percent ethanol blended fuel and known to consumers at the pump as Unleaded 88.

"In an unprecedented year, hitting this milestone is a huge testament to the benefits E15 offers drivers who use it and retailers who sell it," said Growth Energy CEO Emily Skor. "According to the retailers we work with day-in and day-out, selling E15 gives them a competitive advantage over other retailers, and most importantly, American drivers are showing they will keep coming back for a fuel that not only holds down costs, but also protects our air and our climate.

"Opening new markets for E15 is at the heart of Growth Energy's mission, and we're proud of this 20 billion mile marker. While we're celebrating this achievement today, and 2021 is shaping up to be a game-changer for America's biofuel sector, 20 billion miles is another milestone that we look forward to putting in the rearview mirror at a record pace."

Despite its challenges, 2020 brought expanded retail growth for E15, with the number of retail sites selling E15 growing by 10 percent, bringing E15 to more than 2,300 stations across 30 states. Growth Energy works with leading retailers including Casey's, Cumberland Farms, Family Express, Holiday, Kum & Go, Kwik Trip, Minnoco, Murphy USA, Protec Fuel, QuikTrip, RaceTrac, Royal Farms, Rutters, Sheetz, and Thorntons to give more drivers access to cleaner burning, high-octane E15 at stations across the U.S.

Read more about E15's success in 2020 in Ethanol Producer Magazine here, and hear from retailers on why E15 gives them a competitive advantage here.

# # #

**ABOUT GROWTH ENERGY**
Growth Energy represents producers and supporters of ethanol working to bring consumers better choices at the fuel pump, grow America's economy and improve the environment for future generations. For more information on our organization, visit us at GrowthEnergy.org, follow us on Twitter @GrowthEnergy, or connect with us on Facebook.

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/12/2021 1:38:10 PM
**To**: Millett, John [Millett.John@epa.gov]
**CC**: Campbell, Ann [Campbell.Ann@epa.gov]; DeLuca, Isabel [DeLuca.Isabel@epa.gov]
**Subject**: RE: Draft statement Re: Current ACE memo and other documents

Ex. 5 Deliberative Process (DP)

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Millett, John <Millett.John@epa.gov>
**Sent:** Thursday, February 11, 2021 5:14 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>; DeLuca, Isabel <DeLuca.Isabel@epa.gov>
**Subject:** Draft statement Re: Current ACE memo and other documents

**Here's our stab at it —**

**Statement**

Ex. 5 Deliberative Process (DP)

# Ex. 5 Deliberative Process (DP)

Sent from my iPhone

On Feb 11, 2021, at 3:15 PM, Goffman, Joseph <Goffman.Joseph@epa.gov> wrote:

On the off chance that DOJ files this evening or first thing tomorrow AM, are we comms-ready? Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Garbow, Avi <Garbow.Avi@epa.gov>
**Sent:** Thursday, February 11, 2021 2:38 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** RE: Current ACE memo and other documents

These are the current versions. I will review them again.
avi

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Thursday, February 11, 2021 2:33 PM
**To:** Garbow, Avi <Garbow.Avi@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** FW: Current ACE memo and other documents

Avi – Could you please confirm/review? I am tied up for the next couple of hours. Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Campbell, Ann <Campbell.Ann@epa.gov>
**Sent:** Thursday, February 11, 2021 2:32 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** FW: Current ACE memo and other documents

Are these the correct versions?

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

---

**From:** Culligan, Kevin <Culligan.Kevin@epa.gov>
**Sent:** Thursday, February 11, 2021 2:20 PM

**To:** Campbell, Ann <Campbell.Ann@epa.gov>
**Cc:** Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>
**Subject:** Current ACE memo and other documents

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/9/2021 12:17:18 AM
**To**: Kim, Eun [Kim.Eun@epa.gov]
**CC**: Ann Campbell (Campbell.Ann@epa.gov) [Campbell.Ann@epa.gov]
**Subject**: FW: OAP and Children's Health
**Attachments**: OAPandOCHP 1pager_3.8.21.docx

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Grundler, Christopher <grundler.christopher@epa.gov>
**Sent:** Monday, March 8, 2021 7:00 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Nunez, Alejandra <Nunez.Alejandra@epa.gov>
**Subject:** OAP and Children's Health

Hi Joe:
Rona Birnbaum helpfully pulled the attached 1-pager as background for your meeting on Thursday. It describes much of what Jeanne and I talked about before your arrival. The attached covers 1) our previous collaboration; 2) our ongoing work that has relevance to children's health, and 3) some ideas for future collaboration.

Chris

---

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
202.343.9140 (o)
734.645.5221 (m)

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/8/2021 10:35:18 PM
**To**: Grundler, Christopher [grundler.christopher@epa.gov]
**CC**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Fawcett, Allen [Fawcett.Allen@epa.gov]; Gunning, Paul [Gunning.Paul@epa.gov]; Kocchi, Suzanne [Kocchi.Suzanne@epa.gov]
**Subject**: RE: SCC draft TSD -- Key Points

Thanks, Chris and Allen. Seems to me that Allen is correct – this is a good place to have landed. Very good work here. Now, let's hold ground. Thanks, again.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Grundler, Christopher <grundler.christopher@epa.gov>
**Sent:** Monday, February 8, 2021 5:29 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Fawcett, Allen <Fawcett.Allen@epa.gov>; Gunning, Paul <Gunning.Paul@epa.gov>; Kocchi, Suzanne <Kocchi.Suzanne@epa.gov>
**Subject:** SCC draft TSD -- Key Points

Joe-

I asked Allen Fawcett to bottom line where he and OP landed. Here is a summary he provided me that you may find useful:

From Allen:

**Ex. 5 Deliberative Process (DP)**

# Ex. 5 Deliberative Process (DP)

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
202.343.9140 (o)
734.645.5221 (m)

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/2/2021 6:34:51 PM
**To**: Alejandra Nunez (Nunez.Alejandra@epa.gov) [Nunez.Alejandra@epa.gov]; Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Kim, Eun [Kim.Eun@epa.gov]
**Subject**: FW: For Discussion

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Campbell, Ann <Campbell.Ann@epa.gov>
**Sent:** Tuesday, March 2, 2021 11:23 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** For Discussion

Joe, a week or so ago we spoke a little about a management approach to cover the various aspects of the program. As you are meeting as a leadership team today, I wanted to provide a list of the various streams of work for the team to consider.

Programs:
IO: Program Planning, BCA, PFAS, EJ
OAQPS: *generally Tomas*
OAP: Climate, Clean Air Markets, Kigali, Montreal, SNAP, Energy Star, Trading Programs/CSAPR, 608/Refrigerants/AIM
OTAQ: *generally Ale*
ORIA: Radiation/emergency response/nuclear fuels, Indoor air/radon

Cross-Cutters:
Climate (WH)
International (OITA)
Enforcement (OECA)
Science/Research (ORD)
Communications (OPA/OPEEE) but also Correspondence generally
Regulatory Mgmt (OP/OMB)
Legal (OGC/DOJ)
Congressional/State (OCIR)
Federal (DOT/NHTSA, State Dept., USDA),
FOIA

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/17/2021 12:28:56 AM
**To**: Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: FW: Air office hires
**Attachments**: Nsachs resume 2021.pdf

Another riddle: I don't know this person and I don't think a direct response is appropriate. Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Noah Sachs < Ex. 6 Personal Privacy (PP)
**Sent:** Tuesday, February 16, 2021 5:56 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** Air office hires

Dear Joe,

Ex. 6 Personal Privacy (PP)

Regards,

Noah Sachs

Noah Sachs

Ex. 6 Personal Privacy (PP)

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/17/2021 12:26:40 AM
**To**: Rakosnik, Delaney [rakosnik.delaney@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: RE: Hi / greetings / long time...

# Ex. 5 Deliberative Process (DP)

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Rakosnik, Delaney <rakosnik.delaney@epa.gov>
**Sent:** Tuesday, February 16, 2021 6:55 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** RE: Hi / greetings / long time...

I'll take this on. Do you want to meet with him?

---

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Tuesday, February 16, 2021 5:06 PM
**To:** Campbell, Ann <Campbell.Ann@epa.gov>; Rakosnik, Delaney <rakosnik.delaney@epa.gov>
**Subject:** FW: Hi / greetings / long time...

Help!

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Robert Hahn <robert.hahn@smithschool.ox.ac.uk>
**Sent:** Tuesday, February 16, 2021 5:04 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** Hi / greetings / long time...

Hi Joe, Rumour has it that you still exist. Can you please confirm receipt of this email when convenient? Tx. Best, Bob

---

**From:** Robert Hahn
**Sent:** Thursday, February 11, 2021 12:07 PM
**To:** Goffman.joseph@epa.gov
**Subject:** Hi / greetings / long time...

Hi Joe,

Hope you are safe. Where are you these days (geographically)? I'm back from UK and living in FL and DC area.

I'd enjoy catching up to plot strategy (not quite bringing back the band, but …)

Topics: SAB, evidence, markets for climate, life/catchup

Might you have some time in the next week for a short call? If so, I'll send an invite.

Thanks.

All best,

Bob

This email may have used speech recognition. Please excuse typos.

Robert Hahn
Smith School, Oxford
Technology Policy Institute
robertwhahn.com

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/16/2021 4:46:54 PM
**To**: Adhar, Radha [Adhar.Radha@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]
**CC**: Haman, Patricia [Haman.Patricia@epa.gov]; Dunham, Sarah [Dunham.Sarah@epa.gov]; Hengst, Benjamin [Hengst.Benjamin@epa.gov]
**Subject**: RE: Technical Assistance on the RFS

Please work with Sarah and Ben to put the right resources on this task. Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** Adhar, Radha <Adhar.Radha@epa.gov>
**Sent:** Tuesday, February 16, 2021 10:19 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Nunez, Alejandra <Nunez.Alejandra@epa.gov>
**Cc:** Haman, Patricia <Haman.Patricia@epa.gov>
**Subject:** FW: Technical Assistance on the RFS

Hi Joe and Ale,

Hope you had a wonderful weekend. Wanted to share this TA request Pat received. Can you please advise who is best suited from your team to connect with Senator Carper's office? Laura mentioned Ben Hengst in a separate note last week. We can help schedule.

Thanks in advance,
Radha

---

**From:** Gillam, Laura Haynes (EPW) <Laura_Gillam@epw.senate.gov>
**Sent:** Friday, February 12, 2021 12:33 PM
**To:** Haman, Patricia <Haman.Patricia@epa.gov>
**Cc:** Dotson, Greg (EPW) <Greg_Dotson@epw.senate.gov>; Tulou, Christophe (EPW) <Christophe_Tulou@epw.senate.gov>; Repko, Mary Frances (EPW) <MaryFrances_Repko@epw.senate.gov>; Adhar, Radha <Adhar.Radha@epa.gov>
**Subject:** Technical Assistance on the RFS

Hi Pat, can we please connect with staff on the RFS in the next week? Thank you.

Laura Haynes Gillam
Senior Policy Advisor for Clean Air and Climate
U.S. Senate Environment and Public Works Committee, Democratic Staff
Laura_gillam@epw.senate.gov

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/4/2021 12:39:08 PM
**To**: Millett, John [Millett.John@epa.gov]
**CC**: Nunez, Alejandra [Nunez.Alejandra@epa.gov]; Kim, Eun [Kim.Eun@epa.gov]
**Subject**: Re: Bipartisan support for EPA pick — Graham tapped for EPW — BOEM restarts Vineyard Wind process

Thanks

Sent from my iPhone

On Feb 4, 2021, at 7:36 AM, Millett, John <Millett.John@epa.gov> wrote:

Good Morning! -- In case you're not yet receiving these . . .

**From:** POLITICO Pro's Morning Energy <newsletter@email.politicopro.com>
**Sent:** Thursday, February 04, 2021 6:04 AM
**To:** Millett, John <Millett.John@epa.gov>
**Subject:** Bipartisan support for EPA pick — Graham tapped for EPW — BOEM restarts Vineyard Wind process

Feb 04, 2021 View in browser

POLITICOPRO

# Morning Energy

BY **KELSEY TAMBORRINO**

Presented by The Wilderness Society

*With help from Leah Nylen, Zack Colman , Jennifer Scholtes, Caitlin Emma and Eric Wolff*

**Listen to today's POLITICO Energy podcast!**

## QUICK FIX

— **President Joe Biden's pick to lead EPA, Michael Regan, was lauded by multiple Republicans** during his confirmation hearing, even as they slammed the president's early moves to claw back Trump rules.

— **Sen. Lindsey Graham will join the Environment and Public Works Committee this Congress,** Minority Leader Mitch McConnell announced late Wednesday.

— **The Bureau of Ocean Energy Management is restarting the permitting process** for Vineyard Wind's proposed offshore wind project.

**IT'S THURSDAY!** I'm your host, Kelsey Tamborrino. Congrats to Climate Nexus' Nathan Kauffman for knowing California has elected the most women to Congress. For today: What team scored the first touchdown in Super Bowl history? Send your tips and trivia answers to ktamborrino@politico.com.

*Check out the POLITICO Energy podcast — all the energy and environmental politics and policy news you need to start your day, in just five minutes. Listen and subscribe for free at politico.com/energy-podcast.*

A message from The Wilderness Society

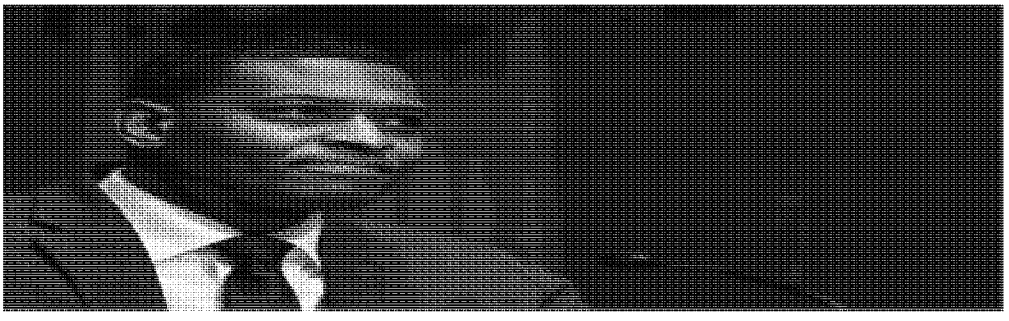
President Biden recently took strong action to fight the climate crisis and protect public lands by setting a goal of protecting 30 percent of U.S. lands and waters by 2030; pausing new oil and gas leasing on public lands; supporting conservation and clean energy jobs; and prioritizing environmental justice across the government. These

actions set a necessary course for the nation to tackle climate change and prioritize the health of our communities and economy. Learn More

## DRIVING THE DAY

**BIPARTISAN SUPPORT FOR EPA PICK:** Michael Regan, the North Carolina environmental regulator picked by President Joe Biden to lead EPA, appears on a glide path to bipartisan confirmation.

**At his confirmation hearing Wednesday,** multiple Republican senators lauded Regan for his reputation as a good listener and consensus builder during his time at the helm of North Carolina's Department of Environmental Quality, even as they slammed Biden's early moves, Pro's Annie Snider, Alex Guillén and Eric Wolff report.



EPA Administrator nominee Michael Regan testifies during his confirmation hearing before the Senate Environment and Public Works committee on Feb. 3, 2021. | Brandon Bell-Pool/Getty Images

**Regan repeatedly promised to listen to lawmakers,** meet with "stakeholders" and travel to communities affected by EPA moves. "With this administrator, we're going to have an open-door policy," he said.

**On specific policy areas of contention** — including power plant and vehicle carbon emissions, the Renewable Fuel Standard and water regulation — Regan largely dodged specifics.

**"I do believe that we are facing a dire situation with climate change** and [its] impacts. But I don't think that's to negate the fact

that we all understand the anxiety and the fear as we make this transition that folks in your states have," Regan said after Sen. John Barrasso (R-Wyo.) hammered Biden's early moves on Keystone XL and the Paris agreement.

**Sen. Shelley Moore Capito (R-W.Va.) meanwhile homed in** on Regan's plans to regulate power plant greenhouse gas emissions, saying she still felt "stung" by the Obama administration's Clean Power Plan. Regan sought to put that plan behind him, telling the lawmaker that since neither the Obama nor the Trump EPA power plant is rule in place, "it presents a significant opportunity for the Environmental Protection Agency to take a clean slate and look at how do we best move forward."

## ON THE HILL

**ON THE REPUBLICAN ROSTER:** Sen. Lindsey Graham (R-S.C.), who a decade ago negotiated for months on ultimately unsuccessful cap and trade legislation, is joining the Environment and Public Works Committee — the highest profile GOP move on energy and environment panels, Pro's Anthony Adragna reports.

**Freshman Sen. Cynthia Lummis (Wyo.) also joins the committee** with jurisdiction over EPA and infrastructure matters, as Barrasso and Sens. Mike Braun (Ind.) and Mike Rounds (S.D.) depart the panel. Barrasso, of course, becomes the ranking member of the Energy and Natural Resources Committee. Sens. James Lankford (Okla.) and Roger Marshall (Kan.) are the new Republican members of that panel, replacing former Sens. Cory Gardner (Colo.) and Lamar Alexander (Tenn.).

**BUCKLE UP:** Senate Democrats trying to muscle Biden's pandemic aid plan through the chamber will have to endure a barrage of amendments from Republicans during an unbridled evening of "vote-a-rama" today. As of Wednesday night, Republicans had already readied more than 400 amendments — signaling a brutal evening of speeches and votes ahead, Pro's Jennifer Scholtes and Caitlin Emma report.

**Among the amendments:** Louisiana Sen. John Neely Kennedy has introduced an amendment to establish a deficit neutral reserve fund to prohibit the use of taxpayer funding for the Interior secretary to eliminate oil and gas jobs. Montana Sen. Steve Daines introduced another to reverse Biden's action on the Keystone XL pipeline and Lummis also plans to offer an amendment to require the president to seek congressional approval before restricting energy development on federal lands.

**CLIMATE HEARINGS ARE COMING:** Senate Majority Leader Chuck Schumer has told his Democratic committee chairs to begin holding hearings to find solutions to address climate change, Anthony reports. "It's long past time for the Senate to take a leading role in combating the existential threat of our time: climate," Schumer said on the floor Wednesday.

**LAWMAKERS INTRODUCE CLIMATE EMERGENCY BILL:** Vermont Sen. Bernie Sanders (I) and Democratic Reps. Earl Blumenauer (Ore.) and Alexandria Ocasio-Cortez (N.Y.) will introduce legislation today that would require the president to declare a national climate emergency under the National Emergencies Act of 1976. "President Biden has done an outstanding job of prioritizing climate in the first days of his administration, but after years of blatant ignorance from Trump and Congressional Republicans, an even larger mobilization is needed," Blumenauer said in a statement.

**The National Climate Emergency Act** would also require the president to deliver a report within one year of enactment that details actions taken in response to the national emergency, including investments in large-scale mitigation and resiliency projects and to enable a "racially and socially just transition" to a clean energy economy.

**The trio has previously sought for Congress** to declare a climate emergency, and today's bill builds on H. Con. Res. 52 (116) , a climate emergency resolution from the last Congress. But the idea got a renewed focus recently when Schumer called on Biden to do so — although the extent of such powers is untested.

**SHIPPING DOWN TO CONGRESS:** It's Boston Mayor Marty Walsh's turn on Capitol Hill. The nominee for Labor secretary will appear this morning for his confirmation hearing before the Senate HELP Committee. ME will be watching for how Walsh describes the department's role in balancing labor and environmental interests as the Biden administration seeks to transition to a clean energy economy.

**Prior to being tapped for the Labor Department**, Walsh was briefly the chair of Climate Mayors and as mayor pledged to make Boston a carbon-neutral city by 2050. A former top union leader, his nomination was also applauded by labor groups like the United Association of Union Plumbers and Pipefitters and North America's Building Trades Unions.

**ANTITRUST OVERHAUL TO BE INTRODUCED TODAY:** The incoming Senate Judiciary antitrust chair is dropping her big antitrust reform bill today and it's not just the big tech players who need to watch out. Sen. Amy Klobuchar (D-Minn.) is proposing a major revamp that would make it much harder for the biggest U.S. companies to do deals. Any company with more than $100 billion in annual revenue would have a higher bar for acquisitions: They'd need to show the merger would not hamper competition. Based on the Fortune 500 rankings for 2020, that would impact companies including Exxon Mobil, Chevron, Marathon Petroleum and Valero Energy. (For more on the bill, Pro's antitrust guru Leah Nylen has the full details.)

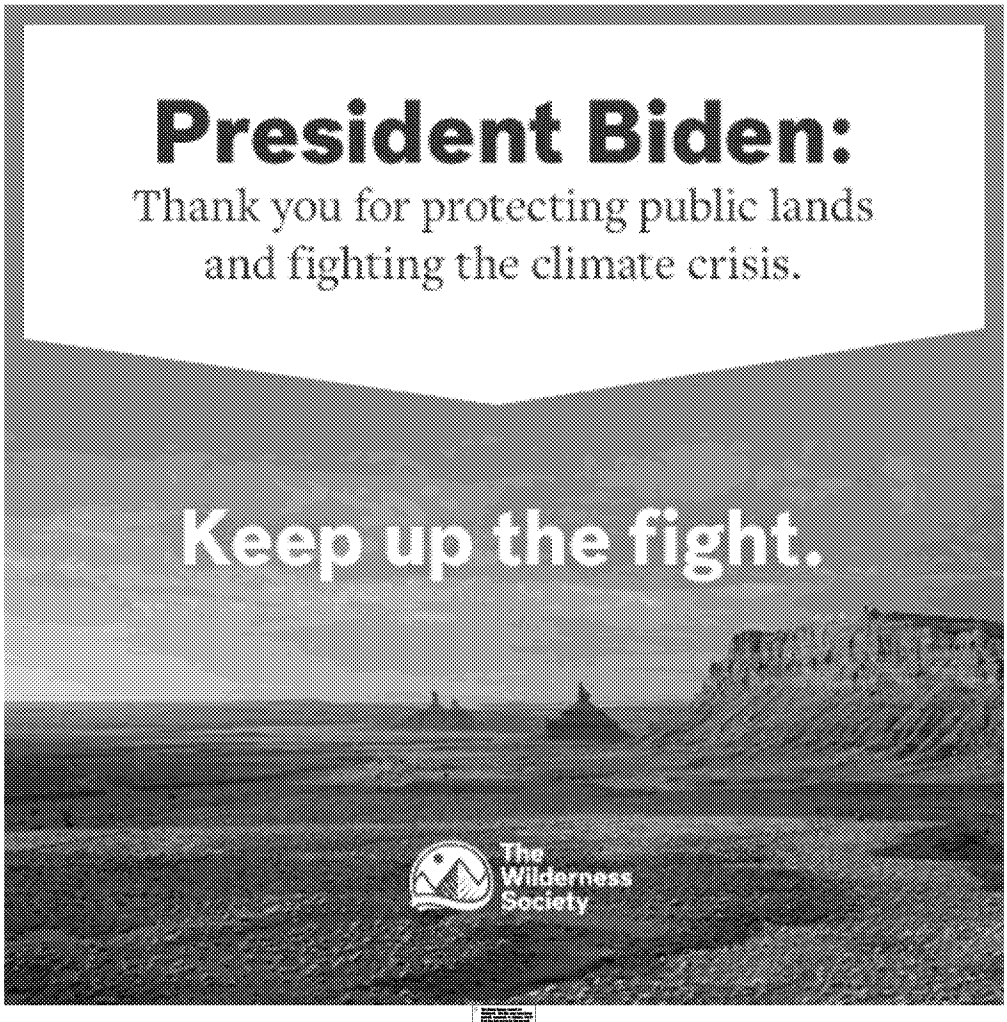
**BIPARTISAN BILL WOULD FORCE EPA TO REASSESS BIOFUEL EMISSIONS:** Sens. John Thune (R-S.D.) and Klobuchar, along with four of their colleagues, introduced legislation Wednesday that would require EPA to update its modeling on biofuel greenhouse gas emissions. With Biden's EPA likely to tighten greenhouse gas requirements for cars and trucks, biofuel producers are desperate to prove that their product can be an alternative to electric vehicles for reducing carbon emissions in the transportation sector.

**But EPA's current models only credit ethanol** with being 20 percent lower emitting than gasoline, while recent research suggests

that new farming and production techniques have cut biofuel's emissions substantially. "It is critical that the EPA's decade old greenhouse gas modeling for ethanol and biodiesel be updated to fully reflect the newest science and technology," Klobuchar said in a statement.

**GRANHOLM MOVES TO FULL SENATE:** The Senate Energy Committee advanced the nomination of Jennifer Granholm to be Energy secretary on Wednesday in a 13-4 vote.

A message from The Wilderness Society:




## AROUND THE AGENCIES

**INTERIOR RESTARTS VINEYARD WIND PROCESS:** The Interior Department will resume the permitting process for Vineyard Wind's proposed offshore wind project off the coast of Massachusetts — restarting the process after the Trump administration halted it in its waning weeks, your ME host reports for Pros. The Bureau of Ocean Energy Management announced Wednesday it intends to restart the environmental review for the project and proceed with development of its final environmental impact statement.

**"Offshore wind has the potential** to help our nation combat climate change, improve resilience through reliable power, and spur economic development to create good-paying jobs," said BOEM Director Amanda Lefton, who was named head of the agency on Monday.

**Recall:** Vineyard Wind had asked BOEM late last month to resume the federal permitting process for the 800-megawatt Vineyard Wind 1 project. The process was halted by the Trump administration after the company requested to temporarily withdraw the construction and operations plans, so it could proceed with a final technical review of GE's Haliade-X wind turbine generators.

**INTERIOR STAFFS UP:** The department announced a spate of appointees to its leadership ranks on Wednesday. The additions mean the political team is now made up of 50 percent people who identify as black, Indigenous and people of color and 80 percent women, according to DOI.

**NASA'S NEW CLIMATE ROLE:** NASA on Wednesday named Gavin Schmidt its senior climate adviser, a newly created position within the agency. Schmidt, director of NASA's Goddard Institute for Space Science in New York, will serve in an acting capacity until a permanent appointment is made. "This position will provide NASA leadership critical insights and recommendations for the agency's full spectrum of science, technology, and infrastructure programs related to climate," said acting NASA Administrator Steve Jurczyk in a statement.

**NOPE ON MOPR:** FERC Chair Rich Glick promised a new approach to capacity markets, saying minimum offer price rules are "not sustainable" as part of a speech on Wednesday where he laid out his

priorities before the Energy Storage Association. Glick, long a critic of MOPRs, said the rules in New York, PJM Interconnection and New England drove up power prices to prop up legacy fossil fuel generation, Eric reports.

**"I think around the country** ... there's a growing understanding that these programs don't have a long life in the future — people realize they're not sustainable," he said. "They raise prices excessively."

## SUPREME COURT

**HIGH COURT TAKES UP PENNEAST REVIEW:** The Supreme Court announced Wednesday it will review a case revolving around whether, under the federal Natural Gas Act, the PennEast Pipeline Company should be able to seize state-owned land for construction of the nearly 120-mile proposed natural gas pipeline, which would run from Luzerne County, Pa., to Mercer County, N.J., Pro's Samantha Maldonado reports. At stake is whether a company exercising federal eminent domain power takes precedence over a state's sovereign immunity from lawsuits filed by private parties in federal court under the 11th Amendment to the U.S. Constitution.

## BEYOND THE BELTWAY

**SOLAR COMPANIES PLEDGE NOT TO USE PRODUCTS LINKED TO FORCED LABOR:** More than 175 solar companies promised today to ensure that none of their products or their supply chains are linked to forced labor. The companies, which include some of the largest solar developers, like Tesla, SunPower, and SunRun, are responding to U.S. efforts to block the exploitation of Uighur Muslims in China. "To assist in these efforts, we support the development of an industry-led solar supply chain traceability protocol as a tool for identifying the source of primary raw materials and inputs and tracking their incorporation into finished products, including solar modules," they say in the pledge.

**The pledge comes amid allegations of widespread forced labor** used by major Chinese panel suppliers in the Xinjiang region, brought to light in a New York Times investigation last month. The

Department of Homeland Security in January blocked imports of cotton and tomatoes from the region.

**GOLDMAN SACHS JOINS OPEN CLIMATE DATA INITIATIVE:** Goldman Sachs became the first major U.S. bank to join OS-Climate, a nonprofit coalition of companies seeking to democratize access to data used for climate financial risk analysis. While many companies have popped up in recent years offering products detailing the climate risk to portfolios and assets, much of that information is proprietary and expensive. OS-Climate, which is funded by the Linux Foundation and includes Allianz, Amazon, S&P Global and Microsoft as members, attempts to provide such data in an open source format. It expects Goldman Sachs to offer insight regarding climate risk, investment product creation and financial reporting to aid investors, asset managers and companies in pursuits to reduce their greenhouse gas emissions.

A message from The Wilderness Society.

Thank you, President Biden, for showing us that clean air matters, clean water matters, environmental justice matters, jobs matter and people matter. After four years of division and disregard for truth, science and justice we are ready to make our public lands part of the climate solution. Keep up the fight.

## MOVERS AND SHAKERS

— **Paul Dabbar**, the former Energy undersecretary for science, joins ClearPath's advisory board. Dabbar is currently chair and CEO of Bohr Quantum Technologies.

## THE GRID

— "WTO deputy promotes reviving talks on environmental goods," via POLITICO Pro.

— "EPA emails suggest predetermined Trump turnaround on veto," via E&E News.

— " Oil drilling on sensitive New Mexico public lands puts drinking water, rare caves at risk," via National Geographic.

— "Waiting 10 years to start eliminating emissions will cost the US more than $3.5 trillion," via Quartz.

— " Biden team in talks with utilities, car companies about emissions: climate adviser," via Reuters.

— "Meet the corporate lobbying powerhouses that bankrolled Joe Biden's star-studded, fireworks-filled inauguration bash," via Business Insider.

## ON THE CALENDAR

**10 a.m.** Senate Health, Education, Labor and Pensions Committee hearing on the nomination of Marty Walsh to serve as secretary of Labor.

**Noon** Bipartisan Policy Center webinar on "Meeting the Climate Challenge in a Divided Congress: A Fireside Chat with Sen. Joe Manchin ."

*Did we miss anything?* Send future events to: energycalendar@politicopro.com.

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POLITICO

This email was sent to Millett.john@epa.gov by: POLITICO, LLC 1000 Wilson Blvd. Arlington, VA, 22209, USA

Message

**From:** Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent:** 3/1/2021 2:03:15 PM
**To:** Dunham, Sarah (Dunham.Sarah@epa.gov) [Dunham.Sarah@epa.gov]
**CC:** Alejandra Nunez (Nunez.Alejandra@epa.gov) [Nunez.Alejandra@epa.gov]
**Subject:** FW: Biointermediates

FYI.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Ryan Mulvenon <rmulvenon@cassidy.com>
**Sent:** Monday, March 1, 2021 8:54 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** Biointermediates

Joe: I'm reaching out on behalf of Fulcrum BioEnergy to raise/highlight the subject of biointermediates. I figured after the WH meeting last week w/ folks from the aviation sector & climate, the timing was right to raise this item with you, as Fulcrum has a nexus with that universe.

I'll spare you even an abridged history (but some of that is included below should you want/need), but very little progress has been made on this subject since the Obama-era w/ the REGS rule. And the four-plus year delay is now having real consequences which I can detail with you and/or others over the phone. The QFR submission on the subject from Senators Whitehouse and I ***think*** Braun were done at the request of the Nevadans (Cortez Masto and Rosen), because it is hugely important to an advanced biofuel project in Northern Nevada.

I think most/all folks would acknowledge this is a problem that needs to be solved for, but the previous EPA leadership never game the staff the direction needed in the past to solve for it.

If this isn't an item already on your radar, I'm hoping we can discuss it in the near future as timing here with Fulcrum is an acute issue.

**********

**Biointermediates History**

This effort most notably began in November 2016 when the EPA noted:

*"the use of biointermediates to produce renewable fuels is a reasonable and positive development in this developing industry and holds considerable promise for the future growth in production of the cellulosic and advanced biofuels. While near-term production may be modest, significant potential for further growth in the long-term exists, as these technologies can lower the cost of using cellulosic and other feedstocks for the production of renewable fuels by reducing the storage and transportation costs."*

Within the proposed rulemaking, among other items, the EPA proposed to create an updated regulatory structure for biointermediates that would allow biofuel producers to:

*"partially process renewable feedstocks at one facility and further process them into renewable fuels at another facility under existing pathways. This would increase the economics and efficiency for the production of biofuels, particularly advanced and cellulosic fuels that have the lower carbon footprints."*

In the proposed rule, the EPA noted that it may be:

*"preferable for economic or practical reasons for renewable biomass to be subjected to substantial pre-processing at one facility before being sent to a different facility where it is converted into renewable fuel."*

The EPA also noted that biointermediates will:

*"likely provide an important component of the growth in renewable fuel production in the future, particularly for advanced and cellulosic biofuels,"* and proposed *"changes in the RFS regulations to clearly specify requirements that apply when renewable fuel is produced through sequential operations at more than one facility."*

In January 2019, then Administrator Wheeler responded to questions submitted by this Committee on the timing for the completion of the rulemaking by stating:

> *"At this time, we do not have a timeline to share..."*

In July 2019, a bipartisan and bicameral group wrote to then Administrator Wheeler on the issue of biointermediates to "handle this matter with a sense of urgency by correction the omission and sending a clear signal to encourage the continued economic development and job creation in the advanced and cellulosic biofuels sector." In December 2019, Anne Idsal in her capacity as Acting Assistant Administrator responded by stating that EPA did not:

> "*have a firm timetable to respond to share on next steps*."

Congress responded with direction in Senate Report 116-123 by emphasizing the need for the EPA to act on the matter of biointermediates via the following language:

> *"Biointermediates. The Committee is aware that the Agency included provisions on the production, transfer, and use of biointermediates in its proposed rulemaking 'Renewables Enhancement and Growth Support' [REGS rule]. The Committee notes that some stakeholders believe a multi-facility approach to biointermediates, allowing biofuel feedstocks to be produced, partially processed, or both at one or more locations and refined at another location, enhances feedstock and product flexibility, addressing the need for continued growth in the production of second generation biofuels. Further, the Committee notes that the Agency receives renewable fuel pathway petitions that, despite meeting all of the other requirements under the regulations, are deemed ineligible due to the use of biointermediates as feedstock.*
>
> *The Committee recommends the Agency finalize a rule permitting the production, transfer, and use of biointermediates in renewable fuel production, as soon as practicable, consistent with the biointermediates provisions included in the REGS rule, the record of the public hearing held on December 16, 2016, and public comments received in the docket associated with the proposed rule. Further, the Committee recommends that the Administrator, consistent with the pathway provisions in the REGS rule addressing coprocessing, review the renewable fuel pathways so as to ensure the inclusion of biointermediates, including those coprocessed with petroleum to produce cellulosic gasoline, diesel, jet fuel, and heating oil, and revise the definition of cellulosic diesel to permit renewable fuel that is coprocessed with petroleum to qualify.*

> *The Committee encourages the Agency to allow the use of either of the two methods for determining the renewable content of co-processed fuels currently found at 40 CFR 80.1426(f)(4). The Committee directs the Agency to provide a report on these efforts, including the number of renewable fuel pathway petitions approved during the fiscal year that use biointermediates and coprocessing."*

In August 2020, bipartisan members of Congress again wrote to Administrator Wheeler in a bipartisan and bicameral fashion and urged him to "swiftly complete its review of the biointermediates and co-processing rules so projects and investments in the advanced and cellulosic fuels sector can move forward." To date, the EPA has not responded to this letter.

Congress responded by including the following language in Division G of the Joint Explanatory Statement to accompany H.R. 133 by stating:

> *"Biointermediates. The Agency is directed to continue to follow the guidance contained in Senate Report 116-123 regarding biointermediates. The Committees appreciate the work of the Agency to address the coprocessing of biointermediates. Consistent with the guidance in Senate Report 116-123, the Committees expect the Agency to finalize a rule permitting the production, transfer, and use of biointermediates within 90 days of the date of enactment of this Act. The Committees direct the Agency to brief the Committees within 60 days of enactment of this Act about its plans for action."*

**********

*Cassidy & Associates has moved, effective January 6th.*
*Please update your contact information with our new office address: 607 14th Street NW, Suite 400, Washington, DC 20005*

Ryan Mulvenon
Senior Vice President
Cassidy & Associates
607 14th Street, NW, Suite 400
Washington DC 20005
D: 202-585-2305
C: 202-257-6555
rmulvenon@cassidy.com
CASSIDY&ASSOCIATES

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/10/2021 3:23:02 AM
**To**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]
**CC**: Campbell, Ann [Campbell.Ann@epa.gov]; Koerber, Mike [Koerber.Mike@epa.gov]
**Subject**: RE: Seeking approval for five OAQPS "frozen" actions

Tomas – Thank you very much for providing these recommendations. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Sent:** Tuesday, February 9, 2021 11:32 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Nunez, Alejandra <Nunez.Alejandra@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** RE: Seeking approval for five OAQPS "frozen" actions

Ex. 5 Deliberative Process (DP)

Tomás

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**From:** Carbonell, Tomas
**Sent:** Tuesday, February 9, 2021 9:14 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Nunez, Alejandra <Nunez.Alejandra@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** RE: Seeking approval for five OAQPS "frozen" actions

Hi Joe, thanks – a few thoughts below. Please let me know if you'd like me to follow up with Peter and Mike re 1-BP. Best,

Tomás

Ex. 5 Deliberative Process (DP)

# Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Monday, February 8, 2021 11:11 PM
**To:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Nunez, Alejandra <Nunez.Alejandra@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** FW: Seeking approval for five OAQPS "frozen" actions

Any views on any of these? Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Koerber, Mike <Koerber.Mike@epa.gov>
**Sent:** Monday, February 8, 2021 4:53 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>; Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Cc:** Senter, Stephen <Senter.Stephen@epa.gov>; Iglesias, Amber <Iglesias.Amber@epa.gov>; Cozzie, David <Cozzie.David@epa.gov>
**Subject:** Seeking approval for five OAQPS "frozen" actions

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/10/2021 3:10:35 AM
**To**: Grundler, Christopher [grundler.christopher@epa.gov]; Arroyo, Victoria [Arroyo.Victoria@epa.gov]; Cassady, Alison [Cassady.Alison@epa.gov]
**Subject**: RE: What we know about the NDC development process

Appreciate the read-out, Chris. Look forward to the post-meeting de-brief, and, of course, to hearing from Rick. Thanks, again.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** Grundler, Christopher <grundler.christopher@epa.gov>
**Sent:** Tuesday, February 9, 2021 8:05 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Arroyo, Victoria <Arroyo.Victoria@epa.gov>; Cassady, Alison <Cassady.Alison@epa.gov>
**Subject:** What we know about the NDC development process

Joe and colleagues:

**Ex. 5 Deliberative Process (DP)**

# Ex. 5 Deliberative Process (DP)

Chris

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
(202) 343-9140 (Office)
(734) 645-5221 (Mobile)

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/10/2021 11:31:55 PM
**To**: Campbell, Ann [Campbell.Ann@epa.gov]; Kim, Eun [Kim.Eun@epa.gov]
**Subject**: RE: READING: Materials for Thursday, March 11, 2021

Thanks, Ann.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Campbell, Ann <Campbell.Ann@epa.gov>
**Sent:** Wednesday, March 10, 2021 6:31 PM
**To:** Kim, Eun <Kim.Eun@epa.gov>; Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** RE: READING: Materials for Thursday, March 11, 2021

Adding the draft Declaration Kevin Culligan sent to you for review as well. Also adding the presentation for the Administrator. Jon Edwards has been added to that briefing.

Ann (Campbell) Ferrio
Chief of Staff
EPA/Office of Air and Radiation
Office: 202 566 1370

---

**From:** Kim, Eun <Kim.Eun@epa.gov>
**Sent:** Wednesday, March 10, 2021 5:40 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>
**Subject:** READING: Materials for Thursday, March 11, 2021

Additional Materials Attached:

Signed Wildland Fire MOU – sent in advance of Monday's meeting.

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**Goffman, Joseph Calendar**
Goffman.Joseph@epa.gov
On Thursday, March 11, 2021
Time zone: (UTC-05:00) Eastern Time (US & Canada)
(Adjusted for Daylight Saving Time)

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**March 2021**

| Su | Mo | Tu | We | Th | Fr | Sa |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | **11** | 12 | 13 |

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28 29 30 31

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|---|---|---|---|---|---|
| | Busy | | Tentative | | Free |
| | Out of Office | | Working Elsewhere | | Outside of Working Hours |

## March 2021

### Thu, Mar 11

| | | |
|---|---|---|
| | **Before 8:00 AM** | **Free** |
| | **8:00 AM – 8:30 AM** | **Free** |
| | 8:30 AM – 9:00 AM | Check-In |
| | 9:00 AM – 9:15 AM | Timecard approval |
| | 9:15 AM – 10:00 AM | Air Issues Meeting |
| | 10:00 AM – 10:30 AM | Management Roundtable |
| | 10:30 AM – 11:00 AM | Comms weekly |
| | 11:00 AM – 12:00 PM | 2015 Ozone Transport: Clean Air Act Authorities and Analytic Options (materials attached, 1 doc) |
| | 11:00 AM – 12:00 PM | Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information; Vacatur Rule: Options Selection (attached Strengthening Transparency Vacatur Rule email) |
| | 12:00 PM – 12:45 PM | To discuss pending CAA actions (attached BCA CRA email) |
| | **12:45 PM – 1:00 PM** | **Free** |
| | 1:00 PM – 1:30 PM | CRA Discussion (attached BCA CRA email) |
| | 1:30 PM – 2:00 PM | Check-in (Alex, Peter, Joseph) |
| | **2:00 PM – 2:30 PM** | **Free** |
| | 2:30 PM – 3:00 PM | EPA prep for ECOS spring meeting |
| | 2:30 PM – 3:15 PM | Cars Check-in |
| | 2:30 PM – 3:30 PM | Video-Call: OAR Program Briefing |
| | 3:30 PM – 4:00 PM | CAAAC Pre-Brief (materials attached, 2 docs) |
| | 4:00 PM – 4:30 PM | Meeting with Boeing re: CO2 & nvPM |
| | 4:30 PM – 5:00 PM | Meet and Greet with General Motors (previous doc from OTAQ for automakers meetings attached) |
| | 5:00 PM – 6:00 PM | Management Time |
| | **After 6:00 PM** | **Free** |

Eunjung Kim
Special Assistant
Office of Air and Radiation
(202) 815-7252

Appointment

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/25/2021 9:00:27 PM
**To**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]

**Subject**: Accepted: Determinations of Attainment by the Attainment Date and Reclassifications for the 2008 and 2015 Ozone National Ambient Air Quality Standards
**Location**: Microsoft Teams Meeting

**Start**: 3/11/2021 7:00:00 PM
**End**: 3/11/2021 7:45:00 PM

**Recurrence**: (none)

Message

**From:** Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent:** 3/1/2021 1:39:42 PM
**To:** Dunham, Sarah [Dunham.Sarah@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]
**Subject:** RE: Invite to participate in US/Canada policy webinar

OK by me. Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Dunham, Sarah <Dunham.Sarah@epa.gov>
**Sent:** Thursday, February 25, 2021 2:54 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Nunez, Alejandra <Nunez.Alejandra@epa.gov>
**Subject:** FW: Invite to participate in US/Canada policy webinar

I mentioned last week a speaking invitation I received from UC Davis. FYI, below is more information about the invitation to talk at an upcoming webinar on "Sustainable Transport Policy in Canada and the US: New Paths Forward" hosted by UC Davis.

**Ex. 5 Deliberative Process (DP)**

**Ex. 5 Deliberative Process (DP)**

**Webinar:** Sustainable Transport Policy in Canada and the US: New Paths Forward

**Description:** This panel discussion will continue the US-Canada conversation started with SPI's January's "Biden's climate plan" webinar. We will shift the focus to sustainable transportation, with a focus on uptake of electric vehicles, clean fuels, and managing travel growth while expanding mobility options to historically disadvantaged communities. We will convene 4 key experts/policy makers - 2 from the US and 2 from Canada - with varied perspectives on the federal and provincial/state roles in setting various types of policy, and how this is likely to evolve with the Biden and Trudeau administrations each proposing bold visions for a low carbon future. What are the hot sustainable transportation issues that will be addressed over the coming year and beyond? How can both countries and their states and provinces coordinate in a way that maximizes progress toward a low carbon future?

Invited participants:

**Sarah Dunham,** Director, Office of Air and Radiation, US EPA
**Helen Ryan,** Associate Assistant Deputy Minister, Environment and Climate Change Canada
**Dan Sperling,** Board member, California Air Resources Board
**Merran Smith,** Executive Director, Clean Energy Canada (confirmed)
**Moderator:** Lew Fulton, Director, STEPS+ Program, University of California Davis

**New date possibilities: March 15, 16 or 17 at 1pm or 2pm (TBD) Sustainable Transport Policy in Canada and the US: New Paths Forward**

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/10/2021 3:07:53 AM
**To**: Grundler, Christopher [grundler.christopher@epa.gov]
**Subject**: RE: Heads Up: Your call with ORD PDAA David Frey tomorrow

Thanks, Chris. Appreciate the heads-up and background.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** Grundler, Christopher <grundler.christopher@epa.gov>
**Sent:** Tuesday, February 9, 2021 8:29 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** Heads Up: Your call with ORD PDAA David Frey tomorrow

Joe:

Ex. 5 Deliberative Process (DP)

I asked Paul why they would do this? What follows is his answer:

**********

Ex. 5 Deliberative Process (DP)

<END>

**Ex. 5 Deliberative Process (DP)**

Chris

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
(202) 343-9140 (Office)
(734) 645-5221 (Mobile)

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/4/2021 3:31:49 AM
**To**: Ann Campbell (Campbell.Ann@epa.gov) [Campbell.Ann@epa.gov]
**Subject**: Heavy Duty FRM Action Memo 030321.doc
**Attachments**: Heavy Duty FRM Action Memo 030321.doc

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/8/2021 10:05:42 PM
**To**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: FW: CANADA: Maximizing Climate Action Requires U.S.-Canada Cooperation
**Attachments**: Climate Matrix - Canadian Lines of Action with Bilateral Linkages.xlsx; WCI participatingjurisdiction-comparativetable-en.pdf; 2021.02.08 CABLE Climate Engagement w Canada 21-Ottawa-164.docx

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** Kasman, Mark <Kasman.Mark@epa.gov>
**Sent:** Monday, February 8, 2021 5:03 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Shoaff, John <Shoaff.John@epa.gov>; Ferland, Henry <Ferland.Henry@epa.gov>
**Cc:** Dieu, Martin <Dieu.Martin@epa.gov>
**Subject:** FW: CANADA: Maximizing Climate Action Requires U.S.-Canada Cooperation

Joe,

I thought you and your staff might be interested in this cable, and additional information from the U.S. Embassy in Ottawa about Canada's climate plans and hopes to partner with the United States.

Mark

Mark S. Kasman
Acting Assistant Administrator
Office of International and Tribal Affairs
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Tel: (202)564-2024

SENSITIVE BUT UNCLASSIFIED

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**Subject:** CANADA: Maximizing Climate Action Requires U.S.-Canada Cooperation

UNCLASSIFIED
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# Ex. 5 Deliberative Process (DP)

Message

**From:** Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent:** 2/26/2021 1:47:40 PM
**To:** Campbell, Ann [Campbell.Ann@epa.gov]
**Subject:** FW: Biden-Harris climate team
**Attachments:** David W Cash_Cover Letter_January_21_2021.docx.pdf; David W Cash_Cover Letter_01_21_2021.docx

May have sent this already, but any advice on what to do with this? Thanks

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** David Cash <dcash Ex. 6 Personal Privacy (PP)
**Sent:** Sunday, February 14, 2021 12:07 PM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** Fwd: Biden-Harris climate team

I am assuming this is a better email address for EPA business than your Harvard email to which I sent an email recently...

Dear Joe,

It is incredible to see how quickly and comprehensively the Administration is moving forward on climate, and it's great to see you back on the team!

The challenges and opportunities of creating a just energy transition are enormous now, and I would be thrilled to be part of the Biden-Harris Administration moving the country forward. Might I be able to grab a short conversation with you in the next couple of days to explore possible opportunities with you?

With my background as state assistant secretary for energy and environment, utilities commissioner, and environment commissioner driving large-scale climate transformation, I would hope to help shape and implement transformative national policy and reclaim a United States leadership role in the global community.

Although not limited to these, the following are the kinds of positions that I seek, helping coordinate climate and clean energy policy across the federal government and catalyzing collaboration with states:

- **EPA or DOE,** Principal Deputy Assistant Administrator/Secretary, Senior Advisor or other similar position
- **Council on Environmental Quality (CEQ)**, Principal Deputy Associate Director for Energy and Climate Change
- **Office of Science and Technology Policy (OSTP)**, Associate Director for Environment
- **Executive Director,** US Global Change Research Program
-

As I am sure you know, the transition team has created an application portal for those who worked on policy committees during the campaign. As a member of the Climate, Energy and Environment Policy Committee and co-lead of the Climate Federalism Working Group, I submitted application materials, so I am in the system.

I have attached my cover letter and CV for your perusal and to forward as you see fit, and perhaps we can have a quick conversation about possible opportunities?

Warmly,

David

David W. Cash, PhD

Personal:
Ex. 6 Personal Privacy (PP)

Professional:
Dean
John W. McCormack Graduate School of Policy and Global Studies
University of Massachusetts Boston
+1 617-287-5511 (office); david.cash@umb.edu

In the media:
The Boston Globe: *The intersection of the climate crisis and social justice*
Tampa Bay Times: *Ending the myth of the environment versus the economy*
McCormack Speaks Blog: *From COVID economy to clean energy economy*

6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 63**

**[EPA-HQ-OAR-2004-0094; FRL-10019-05-OAR]**

**RIN 2060-AU98**

**Amendment of 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1) to Reflect Court Vacatur of Exemption from Emission Standards During Periods of Startup, Shutdown, and Malfunction**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) is amending the Code of Federal Regulations (CFR) to reflect a court order regarding the General Provisions for National Emissions Standards for Hazardous Air Pollutants (NESHAP) issued on December 19, 2008, by the United States Court of Appeals for the District of Columbia Circuit (the court). The court vacated two provisions in the General Provisions that exempted sources from hazardous air pollutant (HAP) non-opacity and opacity emission standards during periods of startup, shutdown, and malfunction (SSM). The court held that under the Clean Air Act (CAA), emissions standards or limitations must be continuous in nature and that the SSM exemptions in these two provisions violate this requirement. This ministerial action revises these two NESHAP General Provisions in the CFR to conform to the court's order.

**DATES:** This final rule is effective on **[Insert date of publication in the Federal Register]**.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2004-0094. All documents in the docket are listed in *https://www.regulations.gov/*. Although listed, some information is not publicly available, *e.g.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. With the exception of such material, publicly available docket materials are available electronically in *https://www.regulations.gov/*. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. The EPA

continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID-19. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets* or call the Public Reading Room at (202) 566-1744 or the EPA Docket Center at (202) 566-1742.

**FOR FURTHER INFORMATION CONTACT:** Lisa Conner, Sector Policies and Programs Division (D205-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541-5060; fax number: (919) 541-4991; email address: *conner.lisa@epa.gov*. You may also consult your state or local permitting representative or the appropriate EPA Regional office representative.

**SUPPLEMENTARY INFORMATION:**

*Organization of this document*. The information in this preamble is organized as follows:

I. Why is the EPA issuing this final rule?
II. Background
III. Which provisions are being amended?
IV. Statutory and Executive Order Reviews

**I. Why is the EPA issuing this final rule?**

This action is amending the CFR to reflect the 2008 court decision in *Sierra Club v. EPA* vacating 40 CFR 63.6(f)(1) and (h)(1). Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B) provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that there is good cause for amending these provisions without prior proposal and opportunity for public procedures because the correction of the CFR is a ministerial act to effectuate the court order and public notice and comment is unnecessary and would serve no useful purpose. Removal of the two SSM exemptions in the General Provisions of the NESHAP at 40 CFR 63.6(f)(1) and (h)(1) has no legal effect beyond fulfilling the court's vacatur in *Sierra Club v. EPA*, 551 F. 3d 1019 (D.C. Cir. 2008) and is ministerial in nature. The court issued the mandate for its decision on October 16, 2009, at which point the vacatur became effective.

**II. Background**

The NESHAP program implementing requirements in section 112 of the CAA regulates over 100 industrial source categories that emit HAP. The NESHAP regulations applicable to specific source categories are organized by subparts within part 63 of 40 CFR.[1] As a component of 40 CFR part 63, the EPA established subpart A which contains the General Provisions and, when incorporated by reference within a specific source category NESHAP, eliminates unnecessary repetition of general information and requirements that often apply (*e.g.,* emission testing, monitoring, recordkeeping, and reporting provisions). As a result, the General Provisions contain requirements that are general in nature and apply only if the source category-specific NESHAP subpart states that some (or all) of the subpart A requirements apply. *See* 59 FR 12408, 12408/3 (March 16, 1994) ("1994 Rule"). The General Provisions have the legal force and effect of emission standards when incorporated by reference into a NESHAP. 40 CFR 63.1(a)(4).

Beginning in 2002, the Sierra Club and various other environmental groups filed petitions seeking judicial review of the SSM exemptions in the NESHAP General Provisions in 40 CFR part 63, subpart A. In response to these petitions, the court vacated portions of two provisions governing the emissions of HAP during periods of SSM. *Sierra Club v. EPA*, 551 F. 3d 1019 (D.C. Cir. 2008). Specifically, the court vacated the SSM exemptions contained in 40 CFR 63.6(f)(1) and (h)(1) of the General Provisions. When incorporated by reference into the NESHAP regulations for specific source categories, these two provisions exempted sources from the requirement to comply with the otherwise applicable emission standards during periods of SSM. The court held that under CAA section 302(k), emissions standards or limitations issued pursuant to section 112 of the CAA must be continuous in nature and that the SSM exemptions in 40 CFR 63.6(f)(1) and (h)(1) violate this CAA requirement.

As noted above, the court mandated its decision on October 16, 2009, making it immediately effective. However, 40 CFR part 63, subpart A has not yet been amended in the record. Since then, the EPA has been codifying the court decision by modifying SSM exemptions in individual NESHAP as they are opened for review and modification.

**III. Which provisions are being amended?**

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[1] A list of the source categories regulated in the NESHAP program can be found at: *https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-9*.

This final rule amends the NESHAP General Provisions at 40 CFR part 63, subpart A, to remove universally the SSM exemptions contained in 40 CFR 63.6(f)(1) and (h)(1) from non-opacity and opacity emission standards, respectively, by deleting the phrase "except during periods of startup, shutdown, and malfunction." As explained above, removal of the exemptions corrects the CFR to conform to the court's order in *Sierra Club v. EPA* and so is ministerial in nature and has no legal effect. The legal effect of the vacatur occurred upon the court's decision in 2008 and subsequently in the court's mandate issued in 2009.

**IV. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget for review.

*B. Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA.

*C. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. This regulatory action is ministerial in nature as it codifies a court issued mandate vacating regulatory provisions. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

*D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

*E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175. The action presents no additional burden on implementing authorities beyond existing requirements. Thus, Executive Order 13175 does not apply to this action.

*G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act*

This rulemaking does not involve technical standards.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action is ministerial in nature as it codifies a court issued mandate vacating regulatory provisions and does not have any impact on human health or the environment.

K. *Congressional Review Act (CRA)*

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes

a good cause finding that notice and comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule in section I of this preamble, including the basis for that finding.

**List of Subjects for 40 CFR Part 63**

Environmental protection, Administrative practice and procedures, Air pollution control, General Provisions, Hazardous substances.

**Jane Nishida**,
*Acting Administrator*.

For the reasons set forth in the preamble, the EPA amends 40 CFR part 63 as follows:

**PART 63 – NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES**

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

**Subpart A- General Provisions**

2. Amend §§63.6(f)(1) and (h)(1) to read as follows:

**§63.6 Compliance with standards and maintenance requirements.**

* * * * *

(f) *Compliance with nonopacity emission standards*—(1) *Applicability.* The non-opacity emission standards set forth in this part shall apply at all times except as otherwise specified in an applicable subpart. If a startup, shutdown, or malfunction of one portion of an affected source does not affect the ability of particular emission points within other portions of the affected source to comply with the non-opacity emission standards set forth in this part, then that emission point must still be required to comply with the non-opacity emission standards and other applicable requirements.

* * * * *

(h) *Compliance with opacity and visible emission standards*—(1) *Applicability.* The opacity and visible emission standards set forth in this part must apply at all times except as otherwise specified in an applicable subpart. If a startup, shutdown, or malfunction of one portion of an affected source does not affect the ability of particular emission points within other portions of the affected source to comply with the opacity and visible emission standards set forth in this part, then that emission point shall still be required to comply with the opacity and visible emission standards and other applicable requirements.

* * * * *

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/26/2021 1:46:29 PM
**To**: Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: FW: BIO Statement for the Record for Ag Climate Hearing
**Attachments**: 210225 BIO Statment to House Ag Climate Hearing.pdf

Quick note of thanks?

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

---

**From:** Erick Lutt <elutt@bio.org>
**Sent:** Friday, February 26, 2021 7:59 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** BIO Statement for the Record for Ag Climate Hearing

Hey Joe,
I wanted to share a copy of the Biotechnology Innovation Organization's (BIO) statement for the record for yesterday's House Committee on Agriculture hearing, "Climate Change and the U.S. Agriculture and Forestry Sectors."

All the best,
Erick

**Erick Lutt**
Senior Director
Biotechnology Innovation Organization
Mobile: 202.701.8153
elutt@bio.org

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Biotechnology Innovation Organization

February 25, 2021

The Honorable David Scott
Chairman
Committee on Agriculture
U.S. House of Representatives
1301 Longworth HOB
Washington, DC 20515

The Honorable Glenn "GT" Thompson
Ranking Member
Committee on Agriculture
U.S. House of Representatives
1010 Longworth HOB
Washington, DC 20515

Dear Chairman Scott, Ranking Member Thompson, and Members of the Committee:

The Biotechnology Innovation Organization (BIO) is pleased to submit a statement for the record to the to the United States House of Representatives Committee on Agriculture hearing entitled, "Climate Change and the U.S. Agriculture and Forestry Sectors."

## Introduction

BIO[1] represents 1,000 members in a biotech ecosystem with a central mission – to advance public policy that supports a wide range of companies and academic research centers that are working to apply biology and technology in the energy, agriculture, manufacturing, and health sectors to improve the lives of people and the health of the planet. BIO is committed to speaking up for the millions of families around the globe who depend upon our success. We will drive a revolution that aims to cure patients, protect our climate, and nourish humanity.

## Fighting Climate Change Through Biotechnology Innovation

BIO applauds the Committee for putting its immediate focus on the climate crisis. As we outline in our attached "100 Days of Innovation" Blueprint[2] (Appendix I), our nation is at a critical juncture. The start of the new administration and new Congress presents a unique opportunity to come together to galvanize our nation's scientific and entrepreneurial capacity, to mobilize new waves of homegrown innovation and American ingenuity to tackle the climate crisis, end the pandemic, and get more Americans back to work.

COVID-19 has also exposed the vulnerabilities and inequalities in how communities are disproportionately impacted, our capacity to respond to crisis, our ability to maintain our supply chains, and to withstand an economic downturn. These challenges will only grow more prevalent and damaging because of climate change.

To meet the challenge of climate change, it is crucial to lead with science and U.S. innovation. We must incentivize the adoption of innovative, sustainable

[1] https://www.bio.org/
[2] https://archive.bio.org/sites/default/files/docs/toolkit/BIO_100_Days_of_Innovation.pdf

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technologies and practices; and streamline and expedite regulatory pathways for breakthrough technology solutions. Investment and deployment of cutting-edge technologies will be crucial to ensure farmers, ranchers, sustainable fuel producers, and manufacturers are able to respond to climate change and maintain the U.S.'s global leadership in agriculture. This includes removing barriers and assisting beginning and socially disadvantaged farmers and ranchers to access and utilize these technologies, so all producers can adapt to the challenges ahead. By accelerating and deploying innovation, American agriculture can be resilient, self-sustaining, and drive our economic recovery.

BIO supports legislative action on climate change that catalyzes resilient and sustainable biobased economies. Federal climate policy should use science-based targets to increase the use of biobased manufacturing, low-carbon fuels, and sustainable agricultural solutions. Science-based policy will promote resilient and sustainable supply chains across economic sectors including translating sustainability to best practices to all bioindustries. If done right, climate legislation will create market pull incentives for investment in and use of innovative technologies and products that fight climate change.[3] This will enable U.S. agriculture to combat climate change while producing enough food, feed, fuel, and fiber for a growing world.

**Biotech Achievements**

The adoption of biotechnology in agriculture and the development of biobased technologies has already contributed to food security, sustainability, and climate change solutions. The acceptance of biotechnology has enabled large shifts in agronomic practices that have led to significant and widespread environmental benefits. Some biotech climate solutions include:

- Biotech crops, such as those that require no-tilling, have saved 27.1 billion kg of carbon dioxide, equivalent to taking 16.7 million cars off the road.[4]

- Synthetic biology enables farmers to enhance soil health to grow more food on less land, manufacturers to create new food ingredients and alternative proteins, and industrial biotech companies to revolutionize manufacturing by optimizing processes for producing sustainable chemicals, biobased products, and biofuels.[5]

- The use of feed additives for ruminant livestock, has been demonstrated to reduce methane levels produced by ruminants by up to 30 percent[6] while the addition of enzymes[7] to chicken feed promotes better protein digestibility, which helps reduce residual nitrogen emissions from manure.

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[3] https://www.bio.org/strategic-vision
[4] https://www.isaaa.org/resources/publications/briefs/54/executivesummary/default.asp
[5] https://www.bio.org/blogs/synthetic-biology-sustain-agriculture-and-transform-food-system
[6] https://newfoodeconomy.org/feed-additive-methane-cow-burps/
[7] https://www.novozymes.com/en/news/news-archive/2017/03/more-from-one-acre-new-report

- New research[8] shows emissions from sustainable fuels made from corn are 46 percent lower than gasoline. Advanced and cellulosic biofuel technologies can reduce emissions from 101 to 115 percent.[9]

- Renewable chemicals and biobased products removed 12.7 million metric tons of $CO_2$ from the manufacturing sector in 2016 alone, and can continue to green our supply chains, reduce plastic pollution, and provide sustainable alternatives to fossil-based products.[10]

To learn more about these technologies and the innovative breakthroughs that can reduce greenhouse gas emissions throughout agricultural supply chains, please see BIO's attached comments[11] (Appendix II) to the U.S. Department of Agriculture's (USDA) Solicitation of Input from Stakeholders on Agricultural Innovations.[12]

**Policy Recommendations**

As the Committee and Congress examine policies to combat climate change, while also aiming to strengthen the economy and create jobs, BIO recommends the following policy approaches:

- ***Incentivize Modern Ag Techniques.*** Enable America's farmers, ranchers, and foresters to combat climate change by incentivizing the adoption of modern agricultural techniques and innovative technologies, including carbon sequestration, enhancing animal feed with enzymes, microbes to reduce emissions from livestock, precision plant breeding, and biostimulants and microbial inoculants – which boost production by building up soil carbon and using less fertilizer. This also includes:
    - Helping producers solve the technical entry barriers to participating in carbon credit markets as proposed in the *Growing Climate Solutions Act*.
    - Incentivizing farm management decisions that have large impact on reducing GHG emissions and increasing soil organic carbon, such as expanding section 45Q of the tax code to credit.
    - Bolster U.S. Department of Agriculture (USDA)conservation programs to promote improved soil health and carbon sequestration.

- ***Certify Sustainable Ag Practices***. Create a certification program at USDA to allow producers to participate in carbon credit markets which will enable the manufacturers of biobased fuels, chemicals, plastics, food, animal feed, veterinary products, and everyday materials to reliably demonstrate their true environmental benefit – from farm to consumer.

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[8] https://iopscience.iop.org/article/10.1088/1748-9326/abde08
[9] https://www.eesi.org/articles/view/biofuels-versus-gasoline-the-emissions-gap-is-widening#:~:targetText=Argonne%20researchers%20show%20that%20compared,for%20the%20RFS%20from%202010.
[10] https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2018.pdf
[11] https://www.bio.org/letters-testimony-comments/bio-submits-comments-usda-ag-innovation
[12] https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06825.pdf

- ***Promote Animal Biotechnology Innovations***. Genetic innovation in animals can help prevent and respond to future infectious diseases. These technologies hold enormous potential to address numerous agricultural, environmental, humanitarian, and public health challenges associated with climate change by enabling animal agriculture to produce more protein with fewer animals and adapting livestock to a warming world. We need to streamline oversight of animal biotechnology to create a clear, timely, and science-based regulatory approval process that provides a viable path to market for these critical new innovations.

- ***Streamline Approval Process for Innovative Feed Additives.*** Feed additives are key for promoting robustness and resilience in livestock through improved nutrition. Furthermore, they improve the return on investment for farmers and-reduce greenhouse gas emissions. Unfortunately, many of these new innovative products lack a suitable regulatory product category to ensure timely approval nationwide. An improved regulatory process is necessary to bring these innovative technologies to market to address climate change.

- ***Modernize Evaluation of Veterinary Products.*** Disruptive innovations and advances in veterinary products can increase protein production while decreasing emissions from livestock. To better account for these environmental benefits, the U.S. Food and Drug Administration and USDA's methods to evaluate the efficacy of these technologies must also evolve to properly measure the climate and sustainability improvements they provide.

- ***Boost Access to Nutrition***. Utilize technology to boost the nutrient levels of fruits and vegetables. Biotech enables crops to maintain yields in the face of drought and less water, which has a direct bearing on improved food security and poverty alleviation. Increased production from biotechnology crops can help combat global hunger and malnutrition by increasing the vitamin and mineral contents of plants.

- ***Eliminate Food Deserts and Reduce Food Waste.*** Incentivize the use of biotech in specialty crops to address the lack of fresh fruits and vegetables in food deserts in urban and rural communities. Biotech advancements allow for fewer blemishes, such as bruises, that lead to more sellable crops for farmers requiring less acreage. These technologies can also extend the shelf life of produce, cutting down on food waste, which creates eight percent of all global emissions.[1] Ensure biotech products are used to achieve the U.S. Environmental Protection Agency (EPA) and USDA's Food Loss and Waste Reduction Goal in alignment with Target 12.3 of the UN Sustainable Development Goal to reduce food waste by 50 percent by 2030. Additionally, support the development of bioplastics from sustainable chemicals that can be recyclable, biodegradable, or compostable to divert food packaging waste from landfills.

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[1] http://www.fao.org/fileadmin/templates/nr/sustainability_pathways/docs/FWF_and_climate_change.pdf

- ***Ensure Regulatory and Government Support Keep Pace with Technology Advancements.*** Innovations like synthetic biology, gene editing, cell culturing, and fermentation hold tremendous potential to solve urgent challenges throughout the agricultural supply chain which will only be compounded by climate change. Producers and developers will need access to these innovative technologies to increase production while cutting down on their environmental footprint. Enabling regulatory systems to keep pace with advancements in biology is essential if society is expected to fully benefit from food, health, and industrial products developed using the very latest cutting-edge platform technologies. Furthermore, domestic regulatory pathways must provide for more expedient approval timelines to ensure the economics of new product development are not a deterrent to bringing new products to market. In the absence of a predictable and well-designed regulatory product approval system developers may choose to invest in more mature markets with better approval timelines. Investments by the government in next generation of biotechnologies and genomics will also be critical to meet the challenge of climate change.

- ***Support Federal Biobased Procurement and Sustainability Programs to Buy "Green"***. Enhance USDA Biopreferred program to ensure that agencies are fulfilling their obligation to shop Biopreferred. While the program has been successful in certifying products over the years, procurement agencies have not been held accountable to buy Biopreferred options where available.

  Also critical to the development of the biobased economy is determining its value and identifying the segments which need investment and research and development. Key to this is updating the North American Industry Classification System (NAICS) codes to establish measurements for biobased products as required under the 2018 Farm Bill.

- ***Accelerate Public and Private Research and Development to Drive Investment in New Tools***. Provide significant advances in foundational tool development and practical applications through supportive grants for research and development of new tool start-ups. Foster coordination across agencies to advance research and development in biomanufacturing, strengthening and broadening the U.S.' synthetic biology capabilities and developing the future bioeconomy workforce.

- ***Expand incentives for Carbon Capture Utilization, and Sequestration***. This technology presents a significant opportunity to transform the manufacturing sector and reduce greenhouse gas emission by turning carbon into value added products. Extend and expand incentives to support carbon utilization and innovative technologies to bolster the potential of direct air capture technologies. USDA should develop a verification methodology suitable for products of biological carbon capture and utilization (CCU) to expand opportunities for U.S. biomanufacturing as directed by the 2018 Farm Bill.

- ***Incentivize green manufacturing infrastructure***. Spur investment and development of biobased manufacturing through supportive grants and tax incentives.

- ***Develop a federal Low Carbon Fuel Standard (LCFS).*** A LCFS that is technology and feedstock neutral and builds on the success of the Renewable Fuel Standard (RFS) to ensure agriculture and low carbon, sustainable fuels are part of the solution will significantly reduce emissions in transport.

- ***Incentivize Advanced and Cellulosic Fuel Development***. Ensuring the growth of advanced and cellulosic biofuels industry will require long-term tax incentives to avoid creating uncertainty for investors and companies trying to raise capital. The development of a long-term sustainable aviation fuel specific blender's tax credit could attract significant investment and address existing structural and policy disincentives that have prevented the aviation biofuels industry from taking off.

- ***Bring New Sustainable Fuel Technologies to Market and Recognize Environmental Benefit.*** Direct the EPA to approve stalled pathways and facility registrations for advanced and cellulosic biofuel technologies to spur investment and development in sustainable fuels projects as proposed in S. 193. Because of biotech innovations, the production of biofuels is becoming more efficient and environmentally sustainable. To reflect these improvements, EPA should update its greenhouse gas modeling as proposed in S. 218.

- ***Investment in Research and Development and Grants to Develop and Deploy Advanced Biofuels.*** To spur investment and development of new biorefineries and deployment of advanced biofuels, USDA's Biorefinery Assistance program and the Department of Energy research and development programs should be feedstock neutral. Investments in USDA's Higher Blends Infrastructure Incentive Program (HBIIP) will help consumers access low carbon fuels.

- ***One Health Approach to Public Health Preparedness***. One Health represents a much-needed collaboration that would align human health, animal health, and environmental health strategies to create smarter, multi-faceted, and coordinated efforts, including to help enhance the ability of our planet to adapt to climate change. The thoughtful and bipartisan *Advancing Emergency Preparedness Through One Health Act* (S. 1903/H.R. 3771) from the 116th Congress directs the U.S. Health and Human Services and USDA to coordinate with other agencies and state and local leaders to advance a national One Health framework to better prevent, prepare for, and respond to zoonotic disease outbreaks like COVID-19. Doing so will help insulate human populations from future infectious diseases, antimicrobial resistance (AMR), and other heath challenges arising from climate change.

- ***Advance Global Climate Solutions***. Build broad global support for the U.S. government's recent regulatory modernization for agricultural biotechnology and proactively advance biotechnology as a valuable tool to combat climate change through broad trade strategy approaches and efforts to reengage in multilateral forums.

## Conclusion

BIO is committed to working with the Committee, Congress, and the Administration to address the climate crisis. We urge you to support policy that advances pioneering technology breakthroughs. With science we can return our Nation and the world to health and prosperity by taking bold and drastic action to address the climate crisis.

# APPENDIX I

Biotechnology Innovation Organization

# 100 DAYS OF INNOVATION

Our nation is at a critical juncture and how we approach the next 100 days will be essential in terms of ending the pandemic and rebuilding our economy in a way that is more resilient, more dynamic, and more inclusive. America remains the most vibrant and entrepreneurial nation in the world. We have been tested time and time again and have always emerged stronger and more united. As the new Administration and new Congress begin, there is a unique opportunity for the private and public sectors to come together to galvanize our nation's scientific and entrepreneurial capacity, to mobilize new waves of homegrown innovation and American ingenuity and to organize our country around the clear and bold mission of ending the pandemic and getting more American's back to work. To do that we must:

## 1 ENSURE A SPEEDY TRANSITION AND AN EXPEDITED SENATE CONFIRMATION PROCESS FOR AGENCY LEADERSHIP CRITICAL TO ADVANCING PUBLIC HEALTH, NUTRITION, AND ENVIRONMENTAL GOALS.

## 2 REENGAGE AS A LEADER ON THE WORLD STAGE, INCLUDING REJOINING THE WORLD HEALTH ORGANIZATION AND THE PARIS CLIMATE ACCORDS.

## 3 DEVELOP AND APPROVE MORE VACCINES, THERAPEUTICS, AND DIAGNOSTICS TO PREVENT AND TREAT COVID–19

*Specific Recommendations*

- Provide increased R&D funding for a broad array of innovative technologies with the potential to fight COVID-19 and other emerging infectious diseases.
- Ensure ample funding to complete research priorities and procurement of existing vaccines and therapeutics.
- Expand government coordination mechanisms beyond the first wave of COVID-19 vaccines, treatments, and diagnostics.
- Encourage more public-private partnerships and private investment through sound public policy.
- Continue expedited EUA and full approval processes for existing and next wave of COVID vaccines and therapies.
- Ensure that companies can continue to partner with HHS, BARDA and DoD without regard to their current global supply chain.
- Increase funding for CDC surveillance activities to help evaluate the effectiveness of COVID vaccines and therapeutics and drive evidence-based decision making on development of updated or new medical countermeasures.

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## 4 PROMOTE ROBUST AND EQUITABLE PATIENT ACCESS TO COVID–19 VACCINES, THERAPEUTICS, AND DIAGNOSTICS

*Specific Recommendations*

- Eliminate all patient cost-sharing across government and commercial insurance markets for COVID-related vaccines, treatments, and diagnostics, including for administration and ancillary services.
- Ensure state Medicaid programs cover all FDA-approved COVID-19 treatments and diagnostics, including those approved under an EUA, without delay and without prior authorization requirements.
- Cover COVID-19 treatment for the uninsured via Medicaid at 100% federal match.
- Ensure that provider relief funds and other similar assistance is targeted to providers who serve Medicaid, the uninsured, and other vulnerable patients.
- Expand and adequately fund the range of sites administering COVID-19 vaccines and treatments beyond acute care settings, including home infusion of therapeutics.
- Mount a coordinated and well-funded national campaign to build vaccine confidence and facilitate vaccination, particularly in minority communities and among essential workers.
- Develop a national vaccination plan to accelerate distribution and administration of COVID-19 vaccines in an equitable manner.
- Leverage federal research funding to diversify federal clinical trial networks and promote minority inclusion in COVID-19 trials.
- Encourage governors to expand the vaccine eligible populations to the ACIP recommendations expediently.

## 5 BETTER PREPARE FOR FUTURE INFECTIOUS DISEASE OUTBREAKS

*Specific Recommendations*

- Support a steady-state of public and private R&D on emerging infectious diseases by providing tax incentives for private investment in early-stage clinical R&D of medical countermeasures.
- Adequately fund and resource agencies engaged in biodefense and emergency preparedness such as ASPR, BARDA, USDA, and the CDC, so they have the infrastructure in place for immediate response and can improve long-term strategic preparedness planning.
- Enable the creation, maintenance, and utilization of advanced manufacturing capabilities domestically, particularly for biological products by incentivizing private investment in facilities and equipment, supporting initiatives for training a new and expanded workforce, and ensuring a clear regulatory pathway.
- Increase physical and virtual inventories of critical emergency supplies in the Strategic National Stockpile.
- Pursue a "One Health" coordination approach across the government that recognizes the interrelationship between human, animal, and environmental health.
- Rebuild and invest in the state and local public health infrastructure.

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## 6 DRIVE ECONOMIC REVIVAL AND RESILIENCY THROUGH ADOPTION OF ADVANCED BIOTECHNOLOGY SOLUTIONS

*Specific Recommendations*

- Develop streamlined and expedited regulatory pathways for breakthrough technology solutions to climate change and nutrition challenges.
- Expand support for scale-up of biorefineries and other biobased manufacturing.
- Incentivize the adoption of sustainable agricultural practices and low-carbon fuels.
- Enforce requirements that Federal agencies should be purchasing biobased products — "Buy Green America."
- Incentivize the use of existing or future COVID-19 relief and recovery funding to purchase biobased products to meet the demand for personal protection equipment (PPE), sterilizing and cleaning equipment and cleaning products, and with respect to broader efforts to "build back better."
- In addition to these immediate actions, BIO calls on the federal government, working with state, local, and private sector partners, to conduct a comprehensive review of COVID outbreak and pandemic response to identify additional steps that could/should have been taken or that could improve the nation's response and recovery in the future.

# BIO'S PLEDGE

### WORKING WITH OUR MEMBER COMPANIES AND OTHER PARTNERS, BIO WILL:

- Expand covidvaccinefacts.org to provide the public with easily understandable, transparent, and credible information about the safety and efficacy of COVID-19 vaccines and how they can obtain access to them.
- Facilitate cooperative agreements to expand manufacturing capabilities of vaccines to meet the demand.
- Promote continued diversity in COVID clinical trials.
- Always stand up for science.
- Highlight steps being taken by the Administration, Congress, and BIO's member companies to resolve the COVID-19 pandemic in BIO's public communication portals, meetings and events.

# APPENDIX II

Biotechnology Innovation Organization

July 31, 2020

The Honorable Sonny Perdue
Secretary
U.S. Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250

Re: U.S. Department of Agriculture *Solicitation of Input from Stakeholders on Agricultural Innovations* (Docket No. USDA-2020-0003)

Dear Secretary Purdue,

The Biotechnology Innovation Organization (BIO) is pleased to respond to the U.S. Department of Agriculture's (USDA) *Solicitation of Input from Stakeholders on Agricultural Innovations*.[1]

BIO represents 1,000 members from the biotech ecosystem around a central mission – to advance public policy that supports a wide range of companies and academic research centers that are applying biology and technology to improve the lives of people and the health of the planet. Our members operate at the nexus of environmental, human, and animal health. They are developing biology-based technologies to enhance cultivation and food production and produce sustainable fuels, renewable chemicals, and biobased products. With our growing understanding of the plant, animal, and microbial worlds and supportive policies and regulations we can modernize agriculture, energy, and manufacturing.

These innovative breakthroughs can reduce greenhouse gas emissions throughout agricultural supply chains and strengthen producers resiliency to climate change while increasing production and help tackling hunger by bringing more nutritious offerings to all tables; and protect against this pandemic and the next by enhancing the response to public health emergencies and speed the transition of the U.S. economy to one that is more biobased and resilient. Already, innovative technologies have been widely adopted to increase productivity while reducing the footprint of agricultural production. Increasing use and acceptance of these technologies will enable U.S. agriculture to meet the Department's goal set forth in the Agriculture Innovation Agenda (AIA) of increasing agricultural production by 40 percent to meet the needs of the global population in 2050 while cutting the environmental footprint in half.

The U.S. has led the way in developing these innovations due to thoughtful, bipartisan public policy. This has created a favorable climate in which to undertake the lengthy and risky job of investing and developing the next biotech breakthroughs; allowed producers to use new technologies; and ensured a pathway to market for new products. However, America's continued success and leadership are not guaranteed, and it should not take its global leadership for granted. Foreign countries are taking overt steps to streamline regulatory systems and speed pathways to market, often with direct government support as part of national bioeconomy strategies.

[1] https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06825.pdf

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COVID-19 has also exposed the vulnerabilities and inequalities in how communities are disproportionately impacted, our capacity to respond to crisis, our ability to maintain our supply chains, and to withstand an economic downturn. These challenges will only grow more prevalent and damaging because of climate change. To ensure America is able to respond to future challenges in cleaner, more efficient ways, maintain its global leadership, and allow its farmers, ranchers, sustainable fuel producers, and manufacturers to have access to cutting edge technologies, the United State must invest in new technologies and have risk-proportionate regulations that spur biological innovations. The government should also focus on removing barriers and assisting beginning and socially disadvantaged farmers and ranchers in accessing and utilizing these technologies, so all producers can adapt to the challenges ahead. By accelerating and deploying innovation American agriculture can be resilient, self-sustaining, and drive our economic recovery.

Below are five key drivers for successful growth of the bioeconomy and to enable U.S. agriculture to meet the Department's goals set forth in AIA:

1. **Advance Modern Regulatory Approaches to Keep Pace with Innovation –** Innovative biotechnologies have allowed producers to increase crop yields, enhance food animal production, improve soil health, and provide biomass and waste feedstocks for sustainable fuels and biobased manufacturing. Expanding the adoption of innovative technologies and practices that reduce the environmental footprint of agriculture while combatting climate change will be necessary to provide the world with adequate food, feed, fuel, and fiber.

   As such, it is critical that the government establish risk-proportionate, transparent regulations that spur biological innovations while protecting health and the environment. Enabling regulatory systems to keep pace with advancements in biology is essential if society is expected to fully benefit from food, health, and industrial products developed using the very latest cutting-edge platform technologies; such as, gene editing, synthetic biology, cell culturing, and fermentation.

2. **Provide Robust Funding of Public and Private Sector Scientific Research –** We must foster an innovation ecosystem that unleashes the transformative potential of science and take steps to ensure the gains from these innovations are broadly shared for the benefit of humanity. This research and development will require the strong support of land-grant universities and Historically Black Colleges and Universities (HBCUs), to produce and develop young scientists and engineers critical to moving the industry forward.

   Federal research programs under USDA's National Institute of Food and Agriculture (NIFA) Agriculture and Food Research Initiative (AFRI) have been fundamental to the applied research, extension, and education of food and agricultural sciences to improve rural economies and create new sources of energy. These programs have been essential for the foundational research and agricultural workforce development that complements and underpins large systems-level research, education, and extension activities needed to maintain America's global preeminence in food, agricultural, and bioenergy production.

Other federal government research and development programs have been essential to the development of clean energy technologies that strengthen the economy, protect the environment, and reduce dependence on foreign oil. While there has been increasing research and development in biotechnology platform technologies—such as gene editing, synthetic biology, cell culturing, and fermentation—increased federal funding and coordination between agencies will be critical to maintain America's leadership in an increasingly competitive race to generate breakthroughs. The new innovations unlocked from supportive scientific research and development will enable agriculture to increase production while reducing greenhouse gas emissions across agriculture, transportation, and industry.

3. **Modernize Infrastructure –** Ensuring farmers and ranchers can deploy innovative technologies that increase production to create a resilient bioeconomy while reducing pollution will also require important investments in infrastructure. This includes, but is not limited to increased lab capacity, widespread access to broadband internet technology, pipelines and distribution capacity for carbon dioxide and sustainable fuels. It will also require the government working with financial institutions and investors to promote access to capital for startups and scaleup in the biobased manufacturing sectors across agricultural, energy, and material products.

4. **Incentivize Farmers** – Supporting America's farmers, ranchers, and foresters who want to adopt new technologies and innovative practices will be critical to USDA achieving the goals set forth in the AIA. To foster sustainability and economic resiliency in agriculture and preserve America's rich environmental diversity all producers must have access to and benefit from new markets that reward practices for reducing the environmental impact of agriculture.

5. **Build Public Support and Increase Market Access for Innovative Technologies –** Innovation flourishes when science and consumer values are aligned and complement one another. BIO understands that consumers want more information about innovative biotechnologies; to know what is in their food and whether their food is safe. Moreover, it should be clear that biofuels and biobased products are sustainable. As such, the government must help build trust and foster an inclusive environment to address our most pressing societal, nutritional, and environmental concerns to achieve the goals put forward in the AIA.

The following comments expands on these principles, highlights existing and developing technologies describing how increasing the utilization of biological innovations will enable U.S. agriculture to meet the Department's goals set forth in AIA for the betterment of society.

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# Advance Modern Regulatory Approaches to Keep Pace with Innovation

## I. Food and Farm Applications

### Plant Biotech – Plant Biotech Innovations Benefits

Biotech crops have already contributed to food security, sustainability, and climate change solutions. The acceptance of biotechnology has enabled large shifts in agronomic practices that have led to significant and widespread environmental benefits. No-till agriculture has been widely adopted due to the superior weed control from biotech crops that are able to tolerate the newer class of lower-impact herbicides. In addition, a reduction in plowing has also enabled farmers to significantly lower the consumption of fuel and decrease greenhouse gas emissions. No-till farming also leads to better conservation of soil and water and a decrease in soil erosion and soil compaction. Biotechnology has also made possible pest control measures that are more precisely targeted at specific problem pests while dramatically reducing impacts on non-target species. According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA)[2] biotech-enhanced farming systems saved 452 million acres of lands from plowing and cultivation, and decreased use of pesticides by 8.2 percent since 1996.

Biotech has also enabled plants maintain yields in the face of drought and less water. While high-yielding biotech crops have a direct bearing on improved food security and poverty alleviation with increased production. As highlighted by the United Nations biotechnology can contribute to combating global hunger and malnutrition. Approximately 140 million children in low-income groups are deficient in Vitamin A. This situation has compounded into a public health challenge. The World Health Organization reports that an estimated 250,000 to 500,000 Vitamin A-deficient children become blind every year, half of them dying within 12 months of losing their sight. Golden Rice, a crop produced using the tools of biotechnology, contains three new genes that helps it to produce provitamin A.[3] Because of these benefits, 150 Nobel Laureates and 13,270 scientists and citizens wrote in support of crops and foods improved through biotechnology.[4]

As great as these developments have been towards enabling agriculture to increase production while reducing its environmental impact; developing and deploying new innovations in crop production will be critical in adapting to the challenges brought on by climate change

### Future Plant Biotech Opportunities

Gene editing is a process scientists use to make targeted modifications to a plant's DNA to strengthen the plant. Gene editing is the most recent breakthrough in a continuum of breeding methods that have been used to develop more beneficial food, fiber, and fuel for centuries. Our growing understanding of DNA allows this to happen in years, rather than decades. In many cases, the changes made through gene editing could happen naturally

[2] http://www.isaaa.org/resources/publications/briefs/54/executivesummary/default.asp
[3] https://unchronicle.un.org/article/biotechnology-solution-hunger
[4] https://www.supportprecisionagriculture.org/nobel-laureate-gmo-letter_rjr.html

through an evolutionary process, making the gene-edited plant the same or very similar to products developed through other existing breeding methods.[5]

Gene editing can fast track genetic improvements in food, fiber, and fuel crops to keep pace with global warming and a growing human population[6] and enable growers to produce higher yields with lower fertilizer, water, and nitrogen inputs.[7] Environmental stressors cause $14 to $19 billion in plant losses every year. The single biggest cause of those losses is limited water, and that will likely get worse with climate change.[8] This technology can help us create more resilient crops able to withstand more variable weather events due to climate change by increasing plant tolerance to heat, floods, salinity, droughts and extreme cold.

Climate change will also exacerbate crop loss from insects by 10 to 25 percent because insect populations and their appetites surge in warm temperatures.[9] However, researchers are using gene editing to limit the threat to crops. Gene edited insects, like the genetically modified diamondback moths have the potential to reduce wild pest populations.[10] Gene editing hold great potential help plants become more resilient to a range of environmental stressors including pest and disease. As an example, the deadly fungus – *Fusarium oxysporum* Tropical Race 4 (TR4) –has decimated banana plantations in southeast Asia for 30 years and has made its way to Latin America.[11] However, gene editing is being used to create a banana resistant to TR4. Not only can this technology create disease-resistant varieties, it can also bring more genetic diversity to the fruit to mitigate future disease.[12]

Gene editing can also boost the nutrient levels of fruits and vegetables. Increasing the vitamin and mineral contents of plants, particularly staple crops, such as, potatoes, corn, soybeans, and wheat can address hunger issues globally and, in the U.S., where large portions of the population do not meet their nutrient requirements.[13]

Incentivizing the utilization of biotech in specialty crops can also help address the lack of fresh fruits and vegetables in food deserts in urban and rural communities. Consumers are already enjoying non-browning features in apples and potatoes. Extending the shelf life of produce can increase the availability of fruits and vegetables.

Not only will this innovation make nutritional food more available to consumers, it will cut down on food waste. According to USDA, in 2018 Americans threw away roughly 150,000 tons of food each day with fruits and vegetable accounting for 40 percent of that total.[14] Globally, the U.N. Food and Agriculture Organization (FAO)[15] estimates that worldwide, the amount of food wasted is enough to feed 2 billion people – more than double the number of people struggling with hunger. The global carbon footprint of all this wasted food was about

[5] https://innovature.com/basics
[6] https://www.nytimes.com/2019/06/17/science/food-agriculture-genetics.html#click=https://t.co/yb95Eso0kY
[7] https://innovature.com/article/dr-kasia-glowacka-plants-may-thrive-less-water
[8] https://www.nsf.gov/awardsearch/showAward?AWD_ID=0820126
[9] https://science.sciencemag.org/content/361/6405/916
[10] https://www.cnn.com/2020/01/29/us/genetically-engineered-moths-crop-protection-study-scn/index.html
[11] https://www.wired.co.uk/article/banana-disease-tr4-latin-america
[12] https://www.bio.org/blogs/bananas-are-brink-extinction-gene-editing-can-reverse
[13] https://innovature.com/article/dr-taylor-wallace-gene-editing-could-mean-healthier-foods-and-healthier-planet
[14] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0195405
[15] https://www.wfpusa.org/articles/8-facts-to-know-about-food-waste-and-hunger/

3.3 billion tons of carbon-dioxide equivalents, 7 percent of all global emissions.[16] Using technology to cut down on food waste can help us address hunger and tackle climate change.

Synthetic biology also has major potential to improve agricultural production. Using tools in the synthetic biology toolbox, scientists typically stitch together long stretches of DNA and insert them into an organism's genome[17].

Innovations like gene editing and synthetic biology hold tremendous potential to solve urgent challenges in agriculture which will only be compounded by climate change. Producers will need access to these innovative technologies to increase production while cutting down on their environmental footprint. Ensuring regulatory systems keep pace with these advancements will be essential for agricultural production to keep up with a growing population while reducing the environmental impacts.

**Modernize Plant Biotech Regulations**

A regulatory climate that fosters innovation is an important component to ensuring the development and deployment of tools producers will need for meeting the agricultural and environmental challenges in the future. A 2011 study found that between 2008-2012, bringing a new plant biotechnology trait to market cost $136 million and took approximately 13.1 years, with regulatory requirements accounting for more than one-third of the time required. The study also projected these costs and timeframes to increase in future years[18]. These costly barriers for market entry have historically prohibited the participation of many academics and small- and medium-sized businesses in this sector and has unfortunately limited the deployment of these innovations to crops where these significant costs can be recouped[19].

**Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products (E.O. 13874)**

BIO appreciates the Administration and USDA's efforts to create a predictable, streamlined, science-based regulatory system to spur investment in and deployment of innovative solutions. Last year's Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products (E.O. 13874)[20] set forth agency reforms that could facilitate the growth of technological innovation in agriculture for the foreseeable future. E.O. 13874 builds on calls to improve the regulatory process that has spanned multiple administrations.[21]

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[16] https://www.washingtonpost.com/news/energy-environment/wp/2016/03/28/the-enormous-carbon-footprint-of-the-food-we-never-eat/
[17] https://www.genome.gov/about-genomics/policy-issues/Synthetic-Biology
[18] https://croplife.org/wp-content/uploads/pdf_files/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf
[19] https://www.cast-science.org/publication/regulatory-barriers-to-the-development-of-innovative-agricultural-biotechnology-by-small-businesses-and-universities/
[20] https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/
[21] https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf

**SECURE Rule**

USDA's Animal and Plant Health Inspection Service (APHIS) Final Rule for biotechnology regulations, 7 CFR part 340, issued on May 14, 2020 also helps ensure that regulations keep up with innovation. Referred to as the SECURE rule[22], which stands for Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient, is the first comprehensive revision of APHIS' biotechnology regulations since they were established in 1987.
BIO, overall, supports the USDA's final revisions to its plant biotechnology regulatory system. USDA has an excellent track record regulating plant biotechnology based on science and risk. The final rule acknowledges a history of safe use of plant biotechnology and the similarity of many gene edited plants to those derived from conventional breeding techniques.[23]

**Regulatory Barriers to Address**

The SECURE rule is a meaningful step forward in fostering innovation, enabled by its use of exemptions for certain, familiar, and low-risk plants and adoption of a new, more efficient risk assessment system. However, the lengthy timeframe over which the new rules will be implemented, and relatively narrow exemptions will delay development and commercialization for many innovative products. Those issues will need to be resolved going forward to ensure that innovative products face a clear, risk-based timely path to market. Visibly absent from this rule however were any revisions to the part 340 regulatory systems for future advances relevant to non-plant GE organisms. Also, because the SECURE rule allows developers to self-certify exemption from USDA regulations without notifying the agency, the rule raises issues related to transparency about products entering the marketplace. As discussed in more detail later in our comments, BIO will continue to drive a process to develop an inclusive and impactful approach to transparency for biotechnology in food and agriculture.

**Microbial Biotech – Benefits of Microbial Technology in Farm, Food, and Feed Applications**

**Farm**

Synthetic biology can be used in a variety of ways to reduce agriculture's environmental impact. One example is through the development of soil microbes.[24] Globally 4 percent of greenhouse gases are attributed to making ammonia, nitrogen fertilizer. When applied, half goes to crops and half ends up in water due to runoff. This excess nitrogen runoff can lead to "dead zones" in our large lakes and oceans. [25] Plants like soybeans and other legumes have microbes in their roots that take on this chemical engineering process naturally fertilizing themselves. Corn, wheat, and rice, which make up half the global fertilizer usage do not have these microbes. Using synthetic biology you can take the DNA code from the microbes in soybeans, redesign it to work with the microbes in corn. [26] Then you apply it as

[22] https://www.usda.gov/media/press-releases/2020/05/14/usda-secure-rule-paves-way-agricultural-innovation
[23] https://archive.bio.org/sites/default/files/docs/toolkit/USDA_Part_340_Issue_Brief_FINAL.pdf?_ga=2.217235934.974532664.1591207008-377855674.1537910566
[24] https://www.bio.org/blogs/synthetic-biology-sustain-agriculture-and-transform-food-system
[25] https://www.bloomberg.com/news/features/2019-11-06/ginkgo-bioworks-ceo-wants-biology-to-manufacture-physical-goods
[26] https://onezero.medium.com/how-microbes-could-upend-americas-toxic-dependence-on-nitrogen-fertilizer-548451117a63

a seed treatment, and it will fertilize that crop so you can wean corn off fertilizer over time. By creating the right combination of microbes, scientists can make more resilient, efficient cropping systems.[27]

Plant biostimulants can improve a plant's natural nutritional processes, which results in enhanced tolerance to abiotic and other environmental stresses that improves overall plant health, growth, quality, and yield. In doing so, these products can increase the uptake and utilization of existing and applied nutrients. Plant biostimulants also can increase yield and quality without increasing applied fertilizer, water, or expanding planted acres, thus, sustainably enhancing the efficient use of these inputs and natural resources. Comprehensively, these technologies will not only result in a significant reduction in agriculture's climate and water-quality footprint, but it is a win-win for farmers, as the costs for their crop inputs and labor needs would decrease.

**Food**

Altering microbes with synthetic biology also gives us new ways to sustainably develop food ingredients. Vanillin—one of the most popular synthetic ingredients in the world—makes up 99 percent of vanilla flavoring consumed but relies on coal and oil mining to produce. Through synthetic biology we can make vanillin that is molecularly identical to the bean without burning fossil fuels.[28] Separately, using synthetic biology to edit brewer's yeast to produce hemoglobin is key to the development of new alternative proteins.[29] This is the base technology that makes product taste like meat, i.e. the high concentration of heme, gives meat its signature texture and is key to several alternative meats such as the impossible burger.

Using microbials and synthetic biology, we can boost nature's ability to grow more food on less land and create food ingredients without harming the environment.

**Feed**

Applications of biology-based innovation to animal feed holds potential for providing additional agricultural solutions. Enteric fermentation from ruminant animals – such as cows, sheep, goats, and buffalo are a major contributor of greenhouse gas emissions from agriculture. These animals, which use microflora to assist in the digestion of otherwise indigestible starchy plants, such as grasses, produce significant volumes of methane as a byproduct of the digestive process.[30]

Despite trends in plant-based protein, animal protein production is not expected to decrease any time soon. Not only has U.S. consumption of meat and poultry continued to increase,[31] but global animal protein consumption is expected to jump 15 percent by 2027, especially in areas with growing global middle classes with increased access to disposable income.[32] Due

[27] https://innovature.com/article/microbes-nourish-plants-naturally
[28] https://wholefoodsmagazine.com/columns/debates/synthetic-biology-key-to-a-healthier-planet-or-threat-to-organic/
[29] https://www.bio.org/blogs/synthetic-biology-sustain-agriculture-and-transform-food-system
[30] http://www.fao.org/in-action/enteric-methane/background/what-is-enteric-methane/en/
[31]: https://www.nationalchickencouncil.org/about-the-industry/statistics/per-capita-consumption-of-poultry-and-livestock-1965-to-estimated-2012-in-pounds/
[32] https://www.agri-pulse.com/articles/11933-plant-based-animal-protein-demand-shows-no-sign-of-letting-up

to methane's high, short-term global warming potential compared to $CO_2$, solutions are immediately needed to facilitate this expansion sustainably.

Existing innovations, such as feed additives for ruminant livestock, have been demonstrated to reduce methane levels in ruminant animals by up to 30 percent.[33] The addition of enzymes[34] to chicken feed promotes better protein digestibility, which helps reduce residual nitrogen emissions from manure. While probiotics[35] in animal feed help improve gut health of the animal. Using methanotrophs and other microorganisms, such as E. coli, have also demonstrated the feasibility of converting natural gas and methane into proteins for animal feed. Where feasible, anaerobic digestion can be applied to convert manure and other carbonaceous wastes into renewable natural gas. However, many of these post-excrement solutions are not practical for free range ruminates. Innovation in ruminant feeds and animal genetics will be critical to expand upon these environmental benefits as growth in animal protein continues.

## Regulatory Barriers to Address

### Barriers to Microbial Technologies

While the SECURE Rule will help streamline the deployment of innovative plant technologies, it has created uncertainty for microbial technology. Under the previous regulations. developers of innovative microbial products could confirm whether a particular product was subject to regulation using USDA's "Am I Regulated Process. The SECURE rule provides less certainty and fewer mechanisms for evaluating whether a product is subject to regulation, resulting in an unclear and uncertain regulatory process for microbial products of biotechnology.

BIO requested in its comments[36] on the proposed rule, *Movement of Certain Genetically Engineered Organisms*[37] develop, propose, and implement a plan to facilitate research, develop, and commercialize non-plant GE organisms, including microbes and insects. The comment noted failure to do so will create a significant competitive disadvantage for these products and delay their introduction to the market.

The SECURE rule is lacking a clear and predictable regulatory framework for non-plant GE organisms potentially subject to part 340. This uncertainty has significant potential to slow research, development, and commercialization of entire categories of innovative agricultural products with the potential to present novel lasting solutions to some of agriculture's most pressing challenges.

Accordingly, BIO urges APHIS to promptly develop and issue guidance for non-plant GE organisms' potentially subject to regulation under Part 340. Without guidance, developers of non-plant GE organisms will lack any semblance of clear, predictable, risk-based regulatory options. In the absence of leadership from USDA companies may choose to commercialize their product in countries with a more predictable regulatory framework and path to commercialization. APHIS, should ensure any movement restrictions imposed on non-plant organisms, whether microorganisms or invertebrates, should be based on the fact that the

[33] https://newfoodeconomy.org/feed-additive-methane-cow-burps/
[34] https://www.novozymes.com/en/news/news-archive/2017/03/more-from-one-acre-new-report
[35] https://www.novozymes.com/en/advance-your-business/agriculture/animal-health-nutrition/product/alterion
[36] https://www.bio.org/sites/default/files/2020-04/BIO%20Comments%20on%20340FNL%20080519.pdf
[37] https://www.federalregister.gov/documents/2019/06/06

organism itself poses plant pest risk and not on the fact that the non-plant is used to control plant pests.

**Regulatory uncertainty with feed additives**

As for feed additives, many of these new innovative products lack a suitable regulatory product category for timely approval of solutions that improve animal health without being veterinary drugs. For example, if a feed additive were to address methane emissions from cattle, that product would require one of three regulatory pathways. One is GRAS (Generally Recognized As Safe) notice to FDA, which will take an estimated two years for approval and limits the claims that can be made. Two is an Association of American Feed Control Officials (AAFCO) new ingredient definition submission, which may take between three and five years, and would limit the types of claims the feed producer could make. Three is a Food Additive Petition with FDA's Center for Veterinary Medicine (CVM), which may also take three to five years for approval and would also limit the claims the producer could make because it is not a full drug approval. None of these pathways offer the kind of quick assessment that is necessary to bring innovation to market to address climate change. Faster assessment route for these technologies will be critical in addressing emissions from livestock.

**Animal Biotech**

The outbreak of COVID-19 has brought to light the interconnectedness between human and animal health. Like the current coronavirus, scientists estimate that more than six out of every ten known infectious diseases in people can be spread from animals, and three out of every four new or emerging infectious diseases in people come from animals.[38] In addition to the dreadful health implications, the resulting economic costs of a pandemic are profound. The World Bank estimates that, between 1997 and 2009, the global costs from six zoonotic outbreaks exceeded $80 billion.[39] COVID-19 has already produced one of the sharpest economic downturns in U.S. history and is costing the U.S. treasury alone trillions of dollars.

The U.S. was woefully unprepared for this pandemic. We must employ modern approaches to be ready for future outbreaks. Improvement of animal genetics will also be a critical aspect to helping livestock producers around the world adapt to climate change, develop resiliency, and reduce emissions in milk and protein production.

**<u>Benefits of Animal Biotech</u>**

**Human Health**

Innovations in animal biotechnology can yield significant benefits to human and animal health, agriculture and food production, and the environment. Among these potential benefits is the ability to prevent, prepare for, and respond to outbreaks of infectious diseases such as coronavirus, Ebola, Zika, avian influenza (HPAI), and MERS, by creating more disease-resistant animals and providing disease treatments for humans.

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[38] https://www.cdc.gov/onehealth/basics/zoonotic-diseases.html
[39] http://documents.worldbank.org/curated/en/612341468147856529/pdf/691450ESW0whit0D0ESW120PPPvol120web.pdf

Genetically designed cattle are being developed to produce fully human polyclonal antibodies to provide treatments for infectious diseases such as COVID-19. Scientists create a cow embryo with parts of human chromosomes, including human antibody genes, and turn off the animal antibody genes. Once grown, researchers inject a non-infectious part of the novel coronavirus into the cow, which produces human antibodies to the virus. Scientists draw blood from the cows, extract and purify the antibodies with the hope that these antibodies may treat the coronavirus in humans[40].

Similarly, scientists have developed a chicken that is resistant to contracting and transmitting avian influenza[41]. Other innovations in animal biotechnology may be able prevent, prepare for, and respond to outbreaks of infectious diseases by providing prevention strategies and treatments for humans. These breakthroughs are even more important given reports such as the swine flu strain with human pandemic potential increasingly found in pigs in China.[42]

Biotechnology can also strategically reduce and even eliminate the populations of insects that cause the greatest harm. Mosquitoes are not just a pest, but responsible for outbreaks of diseases like West Nile, Zika, and dengue. Genetically modified mosquitoes can be designed to help decrease and eventually diminish the overall population of mosquitoes. The U.S. Environmental Protection Agency (EPA) has granted permission to release these mosquitoes in parts of Florida and Texas. If the solution goes worldwide, we may be able to eradicate the number one killer of children in Africa, malaria.[43]

**Animal Health**

It is not just diseases transmitted between animals and humans that can have devastating consequences for the economy. In 2015, the outbreak of avian influenza devastated poultry producers in Minnesota. The outbreak infected more than 100 farms in the state, forced the destruction of millions of birds, and cost the state economy nearly $650 million[44]. Porcine Reproductive and Respiratory Syndrome (PRRS) is a disease that attacks the pigs' reproductive and respiratory systems, making it difficult for them to give birth and breathe. It can devastate an entire herd of 1,000 pigs in just two short months. African Swine Fever (ASF) has been devastating herds throughout Asia[45]. Researchers at Iowa State University (ISU) estimate an outbreak in the U.S. could cost up to $50 billion[46]. Gene editing can prevent these future outbreaks, as researchers are working to develop pigs with genetic resistance to PRRS[47], ASF[48], and Foot and Mouth Disease (FMD). These technologies can be used to make other animals resistant to disease, protecting farmers and the food supply.

**Sustainable Animal Production**

Precision breeding of animals to produce more meat or milk will allow for the reduction of the total number of animals in production, thus reducing the aggregate environmental

[40] https://www.bio.org/blogs/can-cows-help-treat-covid-19
[41] https://www.fooddive.com/news/gene-edited-chicken-cells-may-stop-the-spread-of-bird-flu/556976/
[42] https://www.sciencemag.org/news/2020/06/swine-flu-strain-human-pandemic-potential-increasingly-found-pigs-china
[43] https://www.bio.org/blogs/its-one-health-oclock
[44] https://www.mprnews.org/story/2017/03/08/bird-flu-outbreaks-elsewhere-worry-minnesota-farmers
[45] http://www.fao.org/ag/againfo/programmes/en/empres/ASF/situation_update.html
[46] https://www.card.iastate.edu/products/publications/synopsis/?p=1300
[47] https://innovature.com/article/agricultural-innovations-protect-your-favorite-foods
[48] https://innovature.com/article/gene-editing-could-protect-pigs-diseases

impact. For example, even though there are fewer than half the dairy cows in the United States today as there were in 1950s, average milk production per cow has nearly doubled, largely because of genetic improvements through traditional breeding.[49] While these improvements took over 60 years to accomplish, the use of technologies, such as gene editing, could allow us to make similar improvements in a fraction of the time.

The first bioengineered food animal approved to date, the AquAdvantage salmon, is a fish that can grow large and healthy with fewer resources, helping to reduce the environmental impact of raising fish. Through biotechnology the salmon grows to market-size using 25 percent less feed than traditional Atlantic salmon on the market today. This makes an already efficient protein producer even better because it requires fewer wild fish to be converted into salmon feed. Further by being developed in domestic facilities close to major metropolitan areas, it significantly cuts transportation distance from farm to table. Unlike imported salmon, this salmon has a carbon footprint that is 23 to 25 times less than for traditional farmed salmon.[50]

Improvement of animal genetics will also be a critical aspect to helping livestock producers around the world adapt to climate change. Globally, but especially in tropical and sub-tropical environments, protecting herds from increasing temperatures expected with climate change will be very important[51]. Research is currently being done to improve animal genetics, such as in cattle, to adapt to expected increasing temperatures.[52] The UN FAO has also reported that improving fertility, use of genomics and genetic improvement can play a significant role in reducing emissions from the livestock sector.[53]

**Regulatory Impediments**

Unfortunately, the current regulatory approach to these technologies is an impediment to innovation and commercialization. The Food and Drug Administration (FDA) uses its "new animal drug" authority under the Food, Drug, and Cosmetics Act to assess animal biotechnologies. Evaluating food animals under this pharmaceutical-based framework is essentially forcing a square peg in a round hole. Under this system, genetically engineered animals and their progeny could be considered "drugs" and farms and ranches could be regulated as "drug manufacturing facilities." For developers, the FDA's current evaluation process is time-consuming, opaque, unpredictable, and disproportionate to the actual risk posed by the products being evaluated.

FDA has announced that it plans to also regulate gene-edited animals under this system – even those products with edits that could have occurred naturally or through conventional breeding. This puts at risk an entirely new generation of technologies and threatens to drive research, jobs, and innovation overseas. Similar concerns were raised by a bipartisan group of members in the House of Representatives in a letter to FDA last year.[54]

In more than two decades, the United States has approved only one biotechnology food animal for production and sale. Fast action is needed, or the U.S. will be prevented from

[49] https://www.wpr.org/how-we-produce-more-milk-fewer-cows
[50] https://aquabounty.com/sustainable/
[51] https://www.bio.org/blogs/recombinetics-animal-gene-editing-could-transform-beef-industry
[52] https://futurism.com/scientists-want-to-genetically-engineer-heat-resistant-cows-to-survive-climate-change
[53] http://www.fao.org/3/a-i8098e.pdf
[54] https://www.bio.org/sites/default/files/2020-05/190726%20-%20EC%20Letter%20to%20FDA%20re%20Gene%20Editing.pdf

deploying this promising technology and risk losing our leadership position in livestock genetics and in global meat and dairy production and export. We are already out of sync with the rest of the world, including European authorities (and livestock breeders), who are increasingly characterizing such approaches simply as advanced breeding. Other countries, like China, Canada, Australia, and Brazil, will be deploying this technology with or without the guidance of the United States. They will also begin to become more formidable exporters of their beef, pork, poultry, and fish products[55].

As USDA rightly note in its *Task Force on Agriculture and Rural Prosperity,* federal regulations are limiting technological innovation in animal biotech[56]. To overcome these regulatory barriers, BIO supports USDA's[57] efforts to create joint agreement with FDA whereby the USDA leads regulatory oversight of biotechnology-derived food animals and the FDA leads oversight of non-food and biomedical animals. In addition, FDA should conduct a review of its process and implement specific process changes to improve its decision-making, transparency, and timelines for reviews. Developers and other stakeholders need confidence that FDA will be held accountable for approval timelines and ensure that the pathway to commercialization is predictable, clear, consistent, and based on risk.

Taking these steps will ensure America's farmers and ranchers have access to cutting-edge technologies to remain globally competitive and resilient to disease and climate change, the United States must have risk-proportionate regulations that spur biological innovations, while protecting health and environment.

**One Health**

In addition to technology, better coordination will ensure that our country is better prepared for the next pandemic. The One Health collaboration eliminates barriers that often exist between human health, animal health, and environmental health regulatory strategies to create smarter, multi-faceted and coordinated efforts. The bipartisan, *Advancing Emergency Preparedness Through One Health Act of 2019*[58], (H.R. 3771/S. 1903) would direct the U.S. Department of Health and Human Services and USDA to coordinate with other agencies and state and local leaders to advance a national One Health[59] framework to better prevent, prepare for, and respond to zoonotic disease outbreaks like COVID-19.

## II. Sustainable Fuels

**Benefits of Sustainable Fuels to Agriculture**

The development of sustainable fuels enables agriculture to be a key contributor in addressing emissions from the transportation sector, which is the leading source of greenhouse gas emissions according to the EPA.[60] Not only is this one of the largest sectors of emissions, it is growing.

[55] https://thehill.com/opinion/energy-environment/373361-regulatory-restructure-of-biotech-is-critical-to-the-future-of-us
[56] https://www.usda.gov/sites/default/files/documents/rural-prosperity-report.pdf
[57] https://www.agri-pulse.com/articles/13210-perdue-says-mou-with-fda-could-be-solution-to-animal-biotech-regulation
[58] https://www.congress.gov/bill/116th-congress/house-bill/3771
[59] https://archive.bio.org/sites/default/files/OneHealth_Final.pdf
[60] https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100WUHR.pdf

**Emissions Reductions**

Biofuels and those produced using biological systems provide a strong and immediate solution to reducing emissions from all forms of transportation, including aviation, which has an immediate and long-term nee for liquid fuels. Development of sustainable fuels allow agriculture to play a crucial role in addressing climate change. It is critical that we recognize that these are solutions that are available today, and do not require a mass turnover in vehicles. It is commonly known that carbon emissions act much like compounding interest. Just in the way that a dollar saved today is better than a dollar saved tomorrow, limiting carbon emissions today is far more valuable than limiting the same or a greater volume of emissions at a later date.[61]

Because of biotech innovations, the production of biofuels is becoming more efficient and environmentally sustainable. Biocatalysts, such as enzymes, lower energy requirements, increase reaction rates, can reduce the number of process steps necessary to make chemical transformations. Enzymes are selective, specific, and have a high catalytic rate; they are more efficient, producing chemical products with higher purity and fewer byproducts or wastes. Enzymes are enabling biofuel producers to convert corn stover, wheat straw, wood chips, sawdust, waste, and sugarcane bagasse into fuel, and to collectively increase biofuel yield and energy efficiency throughout the sector. Biocatalysts (e.g. bacteria) are enabling production of fuels and chemicals from new waste and residue streams. New bio-boosting chemicals are increasing biomass yields while eliminating the need for antibiotics in feed bioproducts for livestock. Companies have commercialized enzymes for producing cellulosic ethanol from agricultural waste and are currently operating cellulosic biorefineries.[62]

We are already reaping the benefits of the development of advanced and cellulosic biofuels. The use of low-carbon biofuels, primarily used in passenger cars, has resulted in significant greenhouse gas reductions, with cumulative $CO_2$ savings of nearly 600 million metric tons (mmt) since the RFS was enacted.[63]

The greenhouse gas emission reductions and benefits will only expand with the utilization of new conversion technologies and the development of advanced and cellulosic biofuels across all transportation sectors. As USDA highlighted last year, greenhouse gas emissions from corn-based ethanol are about 39 percent lower than gasoline. The study also states that when ethanol is refined at natural gas-powered refineries, the greenhouse gas emissions are even lower, around 43 percent below gasoline.[64] Current federal policy supporting these fuels, the RFS, requires lifecycle greenhouse gas reductions of at least 50 percent versus the relevant petroleum-based alternative for a fuel to qualify as an advanced biofuel, and at least 60 percent for cellulosic biofuels.

Existing advanced and cellulosic biofuel technologies are far surpassing these requirements. As highlighted in an Environmental and Energy Study Institute (EESI) report, "according to Argonne's GREET model, an energy crop like miscanthus can have negative greenhouse gas

[61] Frank, Jenny. "Quantifying the Comparative Value of Carbon Abatement Scenarios Over Different Investment Timing Scenarios" National Biodiesel Board Conference and Expo, 28 January 2020, Tampa, Florida. Next Generation Scientists for Biodiesel
[62] https://www.bio.org/industrial-biotechnology-unique-potential-pollution-prevention
[63] https://ethanolrfa.org/wp-content/uploads/2019/02/LCARFSGHGUpdatefinal.pdf
[64] https://www.usda.gov/media/press-releases/2019/04/02/usda-study-shows-significant-greenhouse-gas-benefits-ethanol

emissions, meaning that over the crop's life cycle, carbon sequestration outweighs emissions. Argonne researchers show that, compared to gasoline, biofuel from energy crops can reduce emissions by 101 to 115 percent. Corn stover, a residue from corn, can reduce emissions by 90 to 103 percent."[65] As the industry improves its efficiencies and practices, the greenhouse gas reductions of approved advanced and cellulosic biofuels are likely to be substantially greater. Further, new technologies such as gas fermentation, provide alternative routes to advanced biofuels, including sustainable aviation fuel (SAF), from a variety of biomass residues.

The development and expansion of algae and aquatic plant cultivation has great potential for the development of advanced biofuels. Microalgae are aquatic plants that can be induced to rapidly accumulate lipids, often greater than 60 percent of their biomass, while consuming large amounts of carbon dioxide. They can be cultivated using closed loop systems, open ponds, and photo-bioreactors, using less land, energy, and water than land crops. The characteristics of algae biofuels include high flash point, biodegradability, and low or no aromatic or sulfur compound, so they are being used to produce a variety of biofuels such as bioethanol, bio-butanol, jet fuel, biodiesel, bio gasoline, green diesels, and methane.[66]

**Air Quality Benefits**

The environmental benefits of biofuels go beyond greenhouse gas reductions. The outbreak of COVID-19 has highlighted the importance of clean air to human health. Harvard University found that small increases in exposure to long-term levels of tiny particulate matter were linked to a big jump in the mortality rate for COVID-19. Each extra microgram of fine particulate matter per cubic meter that people were exposed to over the long-term was linked to an eight per cent increase in the mortality rate.[67] Similar results were found by the University of Cambridge which overlaid nitrogen dioxide (NO2) and nitrogen oxide (NO) levels from more than 120 monitoring stations across England with figures on coronavirus infections and deaths. They found a link between poor air quality and the lethality of COVID-19 in those areas[68].

As BIO stated in its comments to the EPA Scientific Advisory Board (SAB) *Review of COVID-19 Pandemic Scientific and Technical Issues to Inform EPA's Research Actives*[69], "our member companies offer several solutions that can not only help combat this pandemic, but also lessen the impact of a future pandemic by helping to establish a resilient, sustainable bioeconomy."

Harmful tailpipe emissions, including particulate matter (PM) from the transportation sector disproportionately affect areas comprised of minority populations. For example, according to a study by the Union of Concerned Scientists (UCS), African Americans and Latinos breathe in about 40 percent more particulate matter from cars, trucks, and buses than white

[65] https://www.eesi.org/articles/view/biofuels-versus-gasoline-the-emissions-gap-is-widening#:~:targetText=Argonne%20researchers%20show%20that%20compared,for%20the%20RFS%20from%202010.
[66] https://farm-energy.extension.org/algae-for-biofuel-production/
[67] https://www.researchgate.net/publication/340492612_Exposure_to_air_pollution_and_COVID-19_mortality_in_the_United_States_A_nationwide_cross-sectional_study
[68] https://www.medrxiv.org/content/10.1101/2020.04.16.20067405v5
[69] https://yosemite.epa.gov/sab/sabproduct.nsf//0/2996BA363B41C2598525854C0048EA69?OpenDocument

Californians[70]. Another UCS study found Northeast communities of color breath 66 percent more air pollution from vehicles[71].

According to the National Bureau of Economic Research, the United States saw fine particulate pollution increase 5.5 percent between 2016 and 2018. According to the American Lung Association, State of the Air report for 2019, more than four in ten Americans live in counties that have unhealthy levels of ozone pollution or particular matter.[72] Prior to COVID-19, the World Health Organization[73] found that 4.2 million deaths[74] every year occur as a result of exposure to ambient air pollution. Since then, numerous studies have found that long-term exposure to levels of tiny particulate matter were linked to a significant increase in the mortality rate for COVID-19[75].

Sustainable fuels represent a readily available solution to addressing air quality by reducing tailpipe emissions including particulate emissions, hydrocarbons, and carbon monoxide, which helps prevent the formation of ground-level ozone. Data from 222 EPA sensing sites show that ozone levels have fallen during the period in which ethanol blending increased.[76] Additional data from the University of Illinois-Chicago (UIC) show substantial reductions in particulate matter and benzene with the addition of biofuels.[77] The American Lung Association, Upper Midwest Region found higher volumes of biofuels can reduce ozone-forming pollutants and evaporative emissions.[78]

Such benefits are not unique to ground transportation; research has demonstrated that SAF reduce contrails, particulate matter and mass emissions compared to conventional fossil jet fuels, with the potential to improve air quality near airports and reduce the climate impacts of aviation at high altitude.[79] Additionally, sustainable fuels produced via microbial fermentation of industrial waste gases can limit the impacts of carbon pollution on human and environmental health locally. Sustainable fuels can be produced from the organic fraction of municipal solid waste (MSW), a much healthier option than MSW incineration which can contribute to air pollution.

As we begin to bring the economy back online, it is critical we do so with a cleaner, more resilient energy sector. Biofuels are an immediately available path toward decarbonizing the transportation sector and improving air quality while lowering fuel prices, driving economic growth, and creating jobs. However, this will require stable policies and regulations.

## Stable Policies for Sustainable Fuels

### Renewable Fuel Standard

When allowed to work, the RFS has enabled billions of dollars of investment in new technologies that have led to the rapid growth of the renewable fuels industry, the

[70] https://www.ucsusa.org/resources/inequitable-exposure-air-pollution-vehicles-california-2019
[71] https://www.ucsusa.org/about/news/communities-color-breathe-66-more-air-pollution-vehicles
[72] http://www.stateoftheair.org/key-findings/
[73] https://www.who.int/health-topics/air-pollution#tab=tab_1
[74] https://www.who.int/gho/phe/outdoor_air_pollution/burden/en/
[75] https://www.newscientist.com/article/2241778-are-you-more-likely-to-die-of-covid-19-if-you-live-in-a-polluted-area/
[76] http://www.ethanolrfa.org/2014/12/real-world-ozone-and-particulate-data-expose-fallacy-of-minnesota-study/
[77] http://www.erc.uic.edu/assets/pdf/UIC_Cook_County_Slides.pdf
[78] https://www.cleanairchoice.org/fuels/e85.cfm
[79] https://www.nature.com/articles/nature21420

development of new fuel technologies, and the biobased economy. The growth of the biofuels industry has bolstered our rural communities and provided agriculture producers stable commodity markets, benefitting our nation's economic and energy security.

Unfortunately, the demand destruction caused by the EPA's drastic expansion of small refinery exemption waivers or SREs has had a major impact on the industry, costing jobs, stifling investment in innovation, and undermining efforts to reduce greenhouse gas emissions in the transportation sector.

In January 2020, the U.S. Court of Appeals for the Tenth Circuit ruled in *Renewable Fuels Association v. EPA* that EPA had exceeded its authority in granting SREs under the Renewable Fuel Standard to three refineries in 2016 and 2017, and that moving forward, EPA may only issue SREs to refineries that have continuously received exemptions for every compliance year since 2011.

Despite this ruling, refiners have now filed at least 58 retroactive SRE requests[80]. This comes on top of another 27 SRE applications pending for 2019 and 2020. Unfortunately, rather than comply with the ruling in the 10th Circuit and immediately reject the retroactive requests it is perpetuating the uncertainty about the RFS by letting these pending applications linger.

Beyond SREs, innovative biofuel producers are also stymied by EPA's delays in the approval of new advanced and cellulosic biofuel pathways and petitions for production facilities. These delays are arbitrarily keeping advanced and cellulosic biofuels from reaching the marketplace, hindering the growth of the industry. EPA's failure to approve the registration for corn ethanol facilities that have registered for producing cellulosic biofuel from corn kernel fiber (CKF).

As a result of the uncertainty of the RFS and the delays in new technologies coming to market, companies who have researched and developed technologies in the United States are looking to commercialize advanced and cellulosic biofuel technologies in countries like India and China which are investing heavily in biofuels to improve their air quality.

BIO appreciates USDA's continued support of the biofuels industry. To ensure success of the sustainable fuels industry, enable agriculture to reduce emissions and bring even greater job growth to rural America, we urge the Department to push EPA to end its unwarranted expansion of SREs and move forward on stalled pathways and facility registrations.

Further, we request the Department to encourage and support EPA to interpret the RFS broadly and accommodate all pathways and approve facility registrations that could fall within the existing statute. Specific areas that would have an impact immediately to accelerate the production of low carbon sustainable fuels are related to biological carbon capture and utilization (CCU), the interpretation and eligibility of "renewable biomass", the use of biointermediates, and life-cycle and tracking methodologies for sustainable fuels from waste agricultural residues such as CKF. This would have immediate benefits for the agricultural sector by create more demand for waste feedstocks and renewable biomass.

[80] https://www.epa.gov/fuels-registration-reporting-and-compliance-help/rfs-small-refinery-exemptions

**Transition from a RFS to a Clean Fuel Standard**

As the Department explores options to harness the power of agriculture to decarbonize our transportation sector, we urge it to support new policies and programs that are technology and feedstock neutral and are based off of performance and their ability to deliver carbon reductions. Toward that end it will be critical for the Department to work with Congress in developing a Clean Fuel Standard (CFS) that builds on the success of the RFS and ensures agriculture and biofuels are part of the solution in reducing emissions.

Given the success of the California model, other states[81] and regions[82] are beginning to consider establishing their own CFS programs to address emissions and air pollution. Not only does the establishment of these programs provide an additional value to biofuels, helping spur investment, production, and consumption of advanced biofuels, a national CFS would spur immediate, and additional carbon savings by allowing America's farmers to contribute by adopting practices that enhance soils natural ability to sequester carbon. When a CFS is coupled with a voluntary carbon crediting and verification program it would allow farmers to contribute quickly and effectively to fighting climate change.

Adoption of a CFS would not only incentive advanced biofuels like sustainable aviation fuel, but it would also incentivize fuels which have traditionally been left out of the RFS. Advanced technologies for the conversion of waste carbon oxides to sustainable aviation fuels and cellulosic diesels from woody residues that are poised for success today but have traditionally been left out of the RFS due to regulatory interpretations. A CFS that builds off the volumes and infrastructure put in place by the RFS is a simple, yet elegant way to steadily reduce emissions in transportation, allowing all forms of cleaner mobility to contribute, and bridge the divide between rural America and urban America.

## III. Biobased Manufacturing

**Support Farmers and Revitalize Manufacturing**

The expansion of biobased manufacturing can revolutionize industry by creating a sustainable value chain that use biological processes to convert renewable, low cost, or waste feedstocks into everyday products. It creates new markets for agricultural crops, crop residues and waste streams, as well as opportunities for innovation in producing consumer goods.

These technologies represent novel, innovative ways to address plastic pollution and climate change. Already some 8 mmt of plastics enter our ocean on top of the estimated 150 mmt that currently circulate our marine environments.[83] Through the application of biotechnology, we can create renewable chemicals, which can be used to produce sustainable plastics that are recyclable or biodegradable. While these materials are molecularly like their petrochemical equivalent, they reduce greenhouse gas emissions since they are produced from renewable or waste resources instead of oil and gas.

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[81] https://www.act-news.com/news/california-leads-with-low-carbon-fuel-standard-programs/
[82] http://blog.opisnet.com/rfs-lcfs
[83] https://oceanconservancy.org/trash-free-seas/plastics-in-the-ocean/#:~:text=Every%20year%2C%208%20million%20metric,currently%20circulate%20our%20marine%20environments.

According to the U.S. Energy Information Administration, U.S. chemical production uses 28 percent of the total energy used by all industrial sectors.[84] Without action, these emissions are expected to grow. In January, Louisiana regulators approved an air quality permit that will allow Sunshine Project, to pump 13.6 million tons of carbon dioxide into the atmosphere every year. That is equivalent to adding 2.6 million cars to the road annually. In 2018, only 13 coal plants emitted more.[85] A report in *Environmental Research Letters* identified 88 petrochemical projects along the Gulf Coast that are either in the planning stage or under construction. If all are completed, their combined emissions output could reach 150.8 mmt, the equivalent of 38 coal plants.[86,87]

However, biobased products can provide a solution to the increasing rise in emissions in petrochemical plastic production. The USDA found that the development of renewable chemicals and biobased products removed 12.7 mmt of $CO_2$ from the manufacturing sector in 2016 alone in its report, *An Economic Impact Analysis of the U.S. Biobased Products Industry*.[88] This is due to the displacement of petroleum and reduction of fossil fuels in the manufacturing and use of biobased products. The report goes on to note:

> The use of biobased products reduces the consumption of petroleum equivalents by two primary mechanisms. First, chemical feedstocks from biorefineries have replaced a significant portion of the chemical feedstocks that traditionally originate from crude oil refineries. Biorefineries currently produce an estimated 150 million gallons of raw materials per year that are used to manufacture biobased products. Second, biobased materials are increasingly being used as substitutes for petroleum-based materials, which have been used extensively for many years. An example of this petroleum displacement by a biobased material is the use of natural fibers in packing and insulating materials as an alternative to synthetic foams, such as Styrofoam. In this report we updated the oil displacement values from the 2016 report to reflect economic growth. In 2016 the estimated oil displacement is estimated to be as much as 9.4 million barrels of oil equivalents.

In addition to the environmental benefits, USDA found that the value added to the U.S. economy by biobased products was $459 billion in 2016. While employment in the industry increasing from 4.22 million jobs in 2014 to 4.65 million jobs in 2016.

Even greater reductions of greenhouse gas emissions are possible through the expansion of biotechnology in manufacturing. World Wildlife Fund found "if existing biotech solutions were used extensively in other traditional industries, such as detergent, textile, and pulp and paper manufacturing, another 52 mmt of greenhouse gas emissions reductions would be achieved annually."[89]

Biotechnology is enabling the production of biobased plastics providing a sustainable alternative to petroleum-based plastics. More than half of all plastic ever created was produced in the last 15 years, and right now, about 335 mmt of new, virgin plastic is created each year. Virtually all that new plastic will be made from oil and gas. Plastics now

[84] https://www.eia.gov/energyexplained/use-of-energy/industry.php
[85] https://www.eenews.net/climatewire/stories/1062133995
[86] Ibid.
[87] https://iopscience.iop.org/article/10.1088/1748-9326/ab5e6f/pdf
[88] https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2018.pdf
[89] http://assets.panda.org/downloads/wwf_biotech.pdf

account for 3.8 percent of global greenhouse gas emissions and at the current rate will account for 15 percent of global emissions by 2050.[90]

Because some bioplastics are derived at least in part from corn, sugarcane, or other plants, they have a smaller carbon footprint, with lower cradle-to-plant-gate greenhouse gas emissions than their fossil fuel-based counterparts.[91] Substituting the annual global demand for fossil-based polyethylene (PE) with biobased PE would save more than 42 mmt of $CO_2$. This equals the $CO_2$ emissions of 10 million flights aground the world per year.[92] Replacing conventional 1,4-Butanediol (BDO) with biobased BDO would save over seven million tons of greenhouse gas emission per year, or the equivalent of taking 1.5 million cars off the road.[93] In addition to reducing greenhouse gas emissions, biobased BDO can produce compostable plastic packaging, reducing plastic waste.

All biomanufacturing processes – whether enzymatic or microbial – share the unique characteristic of avoiding use of toxic feedstocks and process reagents, which in turn minimizes toxic waste and byproducts. Manufacturers must manage byproducts of bioprocesses to prevent pollution.[94] Just as enzymes improve biofuel production, manufacturers are using enzymes commercially to produce pharmaceuticals and other chemical compounds, food ingredients, detergents, personal care products, textiles, and paper products, avoiding use of toxic feedstocks and process reagents, which in turn minimize toxic waste and byproducts.[95] By utilizing enzymes, textile mills used less energy and reduced their $CO_2$ emissions by 12 mmt. This technology also has the added benefit of reducing the use of water in textile production by 8.1 billion cubic meters, equal to the annual consumption of 140 million households.[96]

Sugar from crops like corn and wheat can be fermented using yeast to create renewable bio-succinic acid, which is commonly used as an emollient or fragrance carrier in various skin creams and lotions. Succinic acid is effective in combating acne and reducing skin flakiness and wrinkles. By using biotechnology, many personal care products can be made using a range of renewable, sustainable resources, including agricultural feedstocks. Carbon captured from industrial processes can be recycled and fermented using microbes to create renewable non-toxic isopropanol, a common alcohol used to extract and purify oils found in skin care products, such as acne treatments. Using synthetic biology, carbon-rich gases can be used to develop esters, a class of chemical compounds used to create certain aromas and fragrances in perfumes and cosmetics. By capturing and recycling these gases to be converted to esters instead of going into the atmosphere, environmental impact is reduced. Replacing petroleum-based butylene glycol with butylene glycol produced from a sustainable and renewable sugar fermentation process reduces greenhouse gas emissions by 51 percent and allows consumers to avoid petroleum-based ingredients in their personal care products.[97]

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[90] https://www.nature.com/articles/s41558-019-0459-z?utm_source=commission_junction&utm_medium=affiliate
[91] https://ihsmarkit.com/research-analysis/bioplastics-offer-a-smaller-carbon-footprint.html
[92] https://www.european-bioplastics.org/bioplastics/environment/
[93] https://www.genomatica.com/wp-content/uploads/Genomatica-Sustainability-and-Social-Responsibility-2019.pdf
[94] http://www.bioprocessintl.com/manufacturing/facility-design-engineering/minimizing-the-environmental-footprint-of-bioprocesses-303905/
[95] https://www.thebalance.com/enzyme-biotechnology-in-everyday-life-375750
[96] https://www.novozymes.com/en/news/news-archive/2019/05/biological-solutions-on-the-catwalk-to-find-answers-for-sustainable-fashion
[97] https://www.genomatica.com/wp-content/uploads/SOFW-LCA-Article.pdf

Biotechnology can also improve the environmental footprint of textiles. Replacing petroleum based paraxylene with a bio-paraxylene produced from a mix of sugar cane and corn-based ethanol results in a 70 percent reduction in carbon emissions. Bio-paraxylene can be used to produce a 100 percent bio-polyester. This can lead to a 25 percent to 50 percent reduction in carbon emissions when compared to petroleum based polyester products. Further bio-polyester produced using bio-paraxylene can be recycled in the same recycling infrastructure as petroleum-based polyester.[98] Gas fermentation, which uses biology to convert waste industrial emissions to ethanol production, can produce textiles through conversion of this sustainable ethanol into fibers.[99]

Traditional carpets take up the second-largest amount of U.S. landfill space. Approximately 3.5 billion pounds of carpet are put in U.S. landfills every year. Carpets are made up of a complex array of chemicals, either made of nylon, polyester, or polypropylene. Biotechnology can manipulate the polyester to form every element of the carpet, from base to tufts. The flooring, when discarded, can be returned to the manufacturer, ground up, and repurposed as another carpet, reducing the need for petroleum to manufacture new carpet.[100] Biological gas fermentation combined with gasification, can convert mixed flooring wastes into the same chemicals used in carpet production.

**Overcoming Regulatory Barriers**

These novel, innovative approaches to address domestic and global climate challenges are desperately needed. Just as it did with air pollution from transportation, COVID-19 has brough to light the impact petrochemical production has on human health, particularly on communities of color. This is exemplified in what has been called "Cancer Alley" in Louisiana[101]. As Beverly Wright, the founder and executive director of the Deep South Center for Environmental Justice in New Orleans stated in the New York Times April 29, 2020 article, *'A Terrible Price': The Deadly Racial Disparities of Covid-19 in America*, "As soon as I heard about Covid, I started getting nervous about the relationship between PM 2.5 and this virus."

Regulatory proposals to address plastic waste and pollution should set a performance standard that recognizes reductions in emissions in the production of chemicals and plastics. Further government efforts to promote and incentivize recyclability and reduce plastic waste should also seek to promote the use of bioplastics. Finally, the government should give broad regulatory acceptance of, and where applicable, regulatory preference for, innovative and sustainable biobased products.

With these policies and principals we can achieve our goal of creating value added markets for commodities, rebuilding our national economy and workforce in a forward-looking, self-sufficient manner with the added benefit of addressing climate change and enhancing human health through improved air quality.

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[98] https://www.virent.com/technology/sustainability/
[99] https://www.lanzatech.com/2019/10/07/world-first-products-made-from-recycled-pollution-reduce-emissions-and-keep-carbon-in-the-ground/
[100] https://www.fastcompany.com/3067849/the-first-100-recyclable-carpets-are-here
[101] https://www.businessinsider.com/louisiana-cancer-alley-photos-oil-refineries-chemicals-pollution-2019-11

# Provide Robust Funding of Public and Private Sector Scientific Research

The federal government's long history of generously funding research is an important foundation for the nation's bioeconomy and the development of the revolutionary technologies highlighted throughout BIO's comments. The successful adoption and deployment of biotechnologies in agriculture, renewable energy, and the bioeconomy have been enabled by USDA, the U.S. Department of Energy (DOE), and the Department of Defense (DOD), among other federal agencies.

As America's foreign competitors are investing greater amounts in research to lure the development of new technology offshore, these programs to support and incentivize foundational research and development activities are ever more critical to maintaining America's global preeminence in food, agriculture, bioenergy, and biobased manufacturing production. This investment also translates into opportunities for large private sector investment in applied research and development.

## I. Invest in Agricultural Research

### Benefits of Research and Development

Research has been central to the improvements in agricultural productivity. As the National Coalition for Food and Agricultural Research (NC-FAR) highlights, recent analysis by the International Food Policy Research Institute of 292 studies of the impacts of agricultural research and extension published since 1953 found an average annual rate of return on public investments in agricultural research and extension of 48 percent – an extremely high rate of return by any benchmark.[102]

USDA Research, Education, and Economics (REE) programs have been critical to this success. USDA National Institute of Food and Agriculture (NIFA) and the Agriculture and Food Research Initiative (AFRI) have been essential for the foundational research and agricultural workforce development that complements and underpins large systems-level research, education, and extension activities. This core competitive grant program has been essential in establishing America the preeminent global leader in food, agricultural, and bioenergy production.

USDA's Agricultural Research Service (ARS) plays a critical role in partnering with the university community and industry to advance science-based solutions. Research and Extension Programs such as McIntire-Stennis, 1890 Extension, Evans Allen, Hatch Act, and Smith-Lever have been assisting farmers and ranchers in adopting best practices that increase productivity while improving soil, water, and air quality.

### Provide Greater Investment in Research and Development

Public and private investments in U.S. agricultural research and practical application have paid huge dividends to the United States. However, this unparalleled success story in the nation's food and agricultural system is in large part the product of past investments. Federal funding for food and agricultural science has been essentially flat for over 20 years

[102] https://www.ncfar.org/need.asp

despite much greater demonstrated needs and has reportedly declined by about 25 percent in real terms since 2003.[103]

As researchers with ISU CARD pointed out in its report *Measuring Public Agricultural Research and Extension and Estimating their Impacts on Agricultural Productivity: New Insights from US Evidence*[104] with the world expected to reach 9.6 billion people – a 29 percent increase over 2013 – by 2050, society must increase agricultural productivity without causing immense environmental damage and hunger. To achieve this will require greater investment in agricultural research and extension.

The need to modernize our nation's aging food and agricultural science infrastructure, both at USDA labs and universities, is critical. Greater funding should be made to strengthen land-grant universities and HBCUs. Not only to bolster research for scientific agricultural advances, but to train the next generation of ag scientists and researchers and farmers and ranchers. Additional investments in research and education is also critical in assisting producers in increasing their use of precision agriculture, deployment of new crops, and sequestering more carbon in their soil.

Programs such as USDA's Biotechnology Risk Assessment Research Grants Program (BRAG) supporting the generation of new information that will assist Federal regulatory agencies in making science-based decisions about the potential effects of introducing into the environment genetically engineered organisms, including plants, microorganisms – such as fungi, bacteria, and viruses – arthropods, fish, birds, mammals and other animals excluding humans. Continuation of programs like BRAG will be critical in supporting these technologies with advancing modern regulatory approaches need to advance innovation.

## II. Sustainable Fuels

### Benefits of Research and Development

Bolstering funding of DOE, USDA, and other government research programs is necessary for the growth of the advanced biofuels industry. DOE's Office of Energy Efficiency and Renewable Energy (EERE) invests in clean energy technologies that strengthen the economy, protect the environment, and reduce dependence on foreign oil.

According to DOE's *Aggregate Economic Return on Investment in the U.S. DOE Office of Energy Efficiency and Renewable Energy,*[105] research and development (R&D) investments provide significant economic benefits. A total taxpayer investment of $12 billion (inflation-adjusted 2015 dollars) in EERE's R&D portfolio has yielded more than $388 billion in net economic benefits to the United States.

The Bioenergy Technologies Office (BETO) within EERE funds vital research and development of technologies to convert our nation's biomass resources into clean, renewable fuels. BETO recognizes that biofuels are especially needed in the aviation industry, where liquid fuels are still the only viable fuel source for commercial airlines.

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[103] https://www.ncfar.org/NCFAR_Testimony_FY_20_House_040519.pdf
[104] https://lib.dr.iastate.edu/agpolicyreview/vol2016/iss1/3/
[105] Dowd, J. "Aggregate Economic Return on Investment in the U.S. DOE Office of Energy Efficiency and Renewable Energy." (Oct. 2017) Available at: https://www.energy.gov/sites/prod/files/2017/11/f39/Aggregate%20ROI%20impact%20for%20EERE%20RD%20-%2010-31-17.pdf

USDA regional perspective has also been critical. Research through NIFA has helped support the development and production of advanced biofuels compatible with agricultural systems. It has brought together researchers, landowners, communities, and private industry to grow bioenergy and develop new biomass crops and supply chains.

Federal Aviation Administration (FAA) programs are also critical to support the research and development, commercialization, and deployment of Sustainable Aviation Fuel. FAA's Office of Environment and Energy's R&D Program provides scientific understanding, development of new technologies, fuels and operations, and analyses to support achieving the Next Generation Air Transportation System (NextGen), and its goals of environmental protection that allow for sustained growth. The NextGen program is working with partners to develop solutions to reduce the impacts associated with aviation noise and exhaust emissions and increasing energy efficiency and availability. In alliance with research institutions and industry stakeholders, the program will accelerate the maturation of engine and airframe technologies to reduce aviation noise, fuel use, and emissions. FAA's Center of Excellence (COE) is charged with discovering, analyzing, and developing science-based solutions to the energy and environmental challenges facing the aviation industry. Through COE, FAA has been supportive of alternative jet fuel testing and analysis efforts through the ASCENT. This program is working collaboratively with its 16 main universities and five affiliate universities.

These programs have been vital to research and development and growth of the advanced and cellulosic biofuels sector.

**Greater Investments in Research and Development**

As the government seeks to reduce emissions throughout the economy its critical for the federal government to recognize that liquid fuels will remain the main source of energy for transportation and to continue to invest in research and development of technologies to convert biomass and waste feedstocks into clean renewable fuels.

Research and development in sustainable fuels should also remain feedstock neutral. To advance the next generation of biofuels, DOE should also support policy, research, and infrastructure directed to the use of using corn cobs, stover, and corn kernel fiber as a fuel to generate steam and electricity and as a source of cellulosic feedstock for ethanol.

## III. Biobased Manufacturing

**Benefits of Research and Development**

Research supported by USDA ARS has been critical in finding new uses of agricultural commodities and by products. Research related to biobased products focuses on developing technologies leading to new and improved non-food products that expand markets for farm products, replace imports and petroleum-based products, and offer opportunity to meet environmental needs. Research also addresses the development of appropriate feedstocks for biobased products.

DOE EERE programs including BETO and the Advanced Manufacturing Office (AMO) have been essential in supporting, developing, and deploying new, novel technologies that help domestic manufacturing become more sustainable resilient, adaptable, and globally competitive.

Globally, there is a strong push to decarbonize fuels and materials from wastes and residues. Conversion technologies are being developed in Europe and Asia, where there is both supportive policies and significant investment in research, development, and demonstration projects. Technologies that have been developed in the U.S. are often initially commercialized elsewhere. We urge the Department to consider support for pilot and demonstration scale projects in the U.S., and, where appropriate, provide funding to support U.S. industry partnerships with international collaborators to speed the rate of deploying U.S. based technologies at home and abroad.

**Greater Investments in Research and Development**

As USDA highlighted in its 2018 report *An Economic Impact Analysis of the U.S. Biobased Products Industry* many countries world-wide are investing in these technologies, and the U.S. should do so as well. Research is critical to spurring innovation and increasing the variety and efficacy of biobased products and fully utilizing biobased feedstocks. Many of the biobased innovation available today began in university laboratories. Supporting the source of these important developments will be vital to enhancing the growth of the industry. The government should increase opportunities for private sector and university collaboration through ongoing National Science Foundation (NSF), USDA, and DOE funding grants[106].

Also critical to the development of the biobased economy is determining its value and identifying the segments which need investment and research and development. Key to this is updating the North American Industry Classification System (NAICS) codes. BIO supported language in the 2018 Farm Bill[107]. BIO applauds USDA's comments to the 2017 NAICS Updates for 2022 to establish a measurement for biobased products[108].

Funding of base biological and environmental research also has broad implication in environmental remediation, and reengineering of microorganisms and plants with direct relevance to energy, climate, and the environment and enhancing the sustainability of biobased products and renewable fuels.

Support of land-grants and HBCUs will also be critical for STEM education so that as the bioeconomy grows, we have a domestic workforce that can take advantage of the increasing number of high-paying scientific jobs.

## IV. Investing in Platform Technologies

To achieve the goals set out in the AIA and meet the challenge of feeding a growing world and tackling climate change will require significant investments in platform technologies such as gene editing and synthetic biology.

Investments in next generation biotechnologies and genomics also have great potential to meet this challenge and achieve the Departments goals set forth in the AIA. Gene editing for multi-trait seed improvements can enable agriculture to increase production by up to 400 mmt, reduce emissions by up to 30 megatonnes of $CO_2$, reduce freshwater withdrawals

[106] https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2018.pdf
[107] https://republicans-agriculture.house.gov/uploadedfiles/greenwood_testimony.pdf
[108] https://www.regulations.gov/document?D=USBC-2020-0004-0046

by up to 180 billion cubic meters, reduce the number of micronutrient deficient by up to $100 million, while generating up to $100 billion in additional farmer income[109].

As highlighted earlier, advancements in animal biotechnology can further our nation's efforts to safeguard animal health, food safety, and the environment. Increasing genomic research in animal agriculture will also unleash enormous progress in terms of food production and security.

Just like animal biotech, research and development of plant protein and cellular agriculture can provide solutions for improving the productivity and environmental sustainability of food, feed, and animal production and addressing the increasing demand for protein in a growing world. These technologies have tremendous potential for expanding our nation's bioeconomy and diversifying our food supply to adapt and mitigate disease and environment. Supportive research by USDA AFRI can help advance the development and optimization of cell lines, cell culture media, scaffolding, and cultivators (bioreactors) for producing meat through cellular agriculture.

Increasing research in synthetic biology will unlock innovations in agriculture and food productions, energy, and manufacturing. Biotechnology companies have identified opportunities to incorporate synthetic biology[110] in groundbreaking advances in industrial biotechnology manufacturing processes. Companies have begun using science to optimize the processes for producing renewable chemicals, biobased products, and biofuels. With synthetic biology techniques, industrial biotechnology companies can save time by shortening the number of steps used in traditional processes, reducing costs while developing new products. They can also reduce the products' impact on the environment. With proper support synthetic biology can transform our economy.

Because of strong federal support, the United States is a leading nation in the development of synthetic biology. This success and high research productivity are not lost on foreign governments, including China, who are trying to kick-start their biomanufacturing sectors to catch up to, or even leapfrog, the U.S. Our continued growth will be fueled by robust scientific research, strong intellectual property rights, well-functioning technology transfer, dynamic capital investment, science- and risk-based regulation that minimizes obstacles, and public support that embraces the positive influence of biotechnology.

Supportive grants for research and development and startup will provide significant advances in foundational tool development and practical applications ranging from bioenergy, biomanufacturing, to biomedicine. The recommendations put forward by the National Academies of Sciences Engineering Medicine report, *Safeguarding the Bioeconomy*[111] can give further guidance in advancing the bioeconomy for the betterment of the U.S. and society.

BIO has also supported S. 3734, the Bioeconomy Research and Development Act[112] to strengthen and broaden engineering biology by establishing an initiative to advance research and development, advance biomanufacturing, and develop the future bioeconomy workforce. The legislation would also establish a committee to coordinate research in engineering biology across the federal agencies.

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[109] https://www.ncfar.org/HSS_20200713_Presentation.pdf
[110] https://www.bio.org/blogs/synthetic-biology-innovation-industrial-biotechnology
[111] https://www.nap.edu/resource/25525/interactive/
[112] https://www.congress.gov/bill/116th-congress/senate-bill/3734

DOD's Synbio Manufacturing MII initiative also has great potential for collaborative, pro-innovation opportunities to expand American leadership in biotechnology.

## Modernize Infrastructure

Growing a resilient bioeconomy of the future will also require important investments in infrastructure, such as increased, widespread access to broadband internet technology, pipelines, construction of bioreactors and biobased manufacturing facilities, and distribution capacity for carbon dioxide and sustainable fuels. It will also require the government working with financial institutions and investors to promote access to capital for startups in the biobased manufacturing sectors across food, material products, and energy.

COVID-19 showed the vulnerabilities in our supply chain. To mitigate the effect climate change will have on it in the future, it is critical we develop a cleaner, more resilient agricultural, energy, and manufacturing infrastructure.

### I. Access to Broadband

COVID-19 has highlighted the importance of broadband to the modern economy and the digital divide rural communities are facing. The Federal Communications Commission[113] estimated in 2017 that it would cost $80 billion to bring high-speed internet to remaining parts of the country that do not have access, while a more recent U.S. Department of Agriculture[114] report estimated it would require between $130 and $150 billion over the next five to seven years, to adequately support rural coverage and 5G wireless densification.

Despite this cost, bringing high-speed internet infrastructure to rural areas is essential to building a bioeconomy. Farmers and ranchers who participate in carbon markets will need reliable internet access to transmit the data that emissions reductions from soil carbon sequestration are real and verifiable. Reliable access to the internet is also critical to the deployment of next generation precision agriculture technologies which will be essential to sustainably increasing production.

The internet is also critical to ensuring biobased manufacturers and biofuel producers can remain economically competitive

### II. Grants and Loan Guarantees for biorefineries.

USDA has been a critical partner in supporting and providing financial support to the development of advanced biofuels and renewable chemicals.

The Biorefinery Assistance Program loan guarantee program provides manufacturers access to capital for large-scale projects in rural communities. Without the loan guarantee program, new innovative companies might never be able to pool sufficient capital to commence development of a project in rural communities with a small population. These biorefineries are proven drivers of job and economic growth for rural communities.

The 2018 Farm Bill expanded access to this program to renewable chemical and biobased product manufacturers; however, it only provided mandatory funding to the program

[113] https://transition.fcc.gov/Daily_Releases/Daily_Business/2017/db0119/DOC-343135A1.pdf
[114] https://www.usda.gov/sites/default/files/documents/case-for-rural-broadband.pdf

through Fiscal Year 2020. To spur growth of additional biorefineries in rural communities, USDA should provide loan guarantees to new projects from the funding already allocated to this program. Additional funding should be provided in future years to support the construction of additional biorefineries.

## III. Investments in Biofuels Infrastructure

### Pumps and Pipelines

USDA has been a great champion in promoting the development of infrastructure needed to expand the marketplace to supply more renewable fuel to America's drivers through the Biofuel Infrastructure Partnership (BIP) and the proposed Higher Blends Infrastructure Program (HBIIP).

In addition to funding the installation and conversion of pump infrastructure, the government should also make investments in pipelines and terminals to deliver greater volumes of sustainable fuels as well as distribute $CO_2$ developed from biofuels. Having greater distribution capacity can help avoid the supply disruption the food industry faced due to COVID-19 when the closure of ethanol facilities led to a $CO_2$ crunch.

### Sustainable Aviation Fuels

The development of sustainable aviation fuels also represents a growing opportunity for the development of biofuels producers and biomass producers. To support that effort investments should be made in infrastructure to incentivize the creation and use of sustainable aviation fuels in commercial aviation to reduce fuel costs, pollution, and the overall environmental footprint of U.S. aviation.

### USDA Collaboration

In 2016, the U.S. Navy Great Green Fleet demonstrated the potential of advanced biofuels in reducing emissions in maritime engines. Named to honor President Theodore Roosevelt's Great White Fleet, the year-long initiative in the John C. Stennis Strike Group (JCSSG) used alternative fuel sources, energy conservation measures, and operational procedures to reduce its fuel consumption. The fleet used biofuels made from 10 percent beef tallow provided from farmers in the Midwest and 90 percent marine diesel, and it was cost competitive with traditional fuels. It is used as a drop-in alternative, meaning no modifications to engines or operational procedures are required.[115]

The Great Green Fleet was the result of the DOD, USDA, and DOE, providing funding under the Defense Production Act toward the construction of biorefineries that produce cost-competitive, drop-in military biofuels.[116] As a result, these refineries are now coming online, capable of producing fuels for the military and aviation sector.

The military is the nation's largest single consumer of fuel, so the Navy's purchase of 450,000 gallons of biofuel for the exercise signaled a potentially huge defense market for

[115] https://www.navy.mil/submit/display.asp?story_id=95398
[116] http://www.biofuelsdigest.com/bdigest/2014/09/19/breaking-news-us-navy-doe-usda-award-210m-for-3-biorefineries-and-mil-spec-fuels/

liquid renewables. However, when the program essentially ended in 2017, along with the Navy's issuance of short-term contracts, it left investors wary of financing biofuel refineries.

Given the size of the military's fuel demand issuing a requirement for federal agencies to use a certain volume of biofuels could spur long-term investment[117] in the development of sustainable fuel facilities.

## IV. Tax Incentives

The biobased economy and industrial biotechnology contribute greatly to the U.S. economy. Enacting sustained, supportive tax policy will lead to even greater growth domestically in this industry. Targeted tax policies will enable emerging technologies in advanced biofuels, renewable chemicals, and biobased products to overcome the challenging capital environment for first-of-a-kind biorefinery construction and allow them to bring their technologies to commercial deployment. This will unleash our members' scientific innovation potential and grow the bioeconomy.

### Biofuels

Biofuel tax provisions supporting the development of advanced and cellulosic biofuels – particularly the Second Generation Biofuel Producer Tax Credit (PTC), the Special Depreciation Allowance for Second Generation Biofuel Plant Property, the Biodiesel and Renewable Diesel Fuels Credit, and the Alternative Fuel Vehicle Refueling Property Credit – are incredibly important to our companies that are making significant investments to create new agricultural supply chains, build infrastructure for liquid biofuels, and develop innovative new technologies. These credits have enabled our industry to create new jobs, contribute to rural prosperity, and diversify our nation's energy supply. For example, the biodiesel tax credit has supported the production of biofuels used in aviation.[118]

The expiration and continued on-again off-again nature of these incentives has created uncertainty for investors and the industry about the availability of these credits, jeopardizing the long-term investments necessary for the development of biofuels. While these tax incentives enjoy broad[119] bipartisan[120,121] support[122] for these tax incentives their short-term availability makes it difficult for companies to make long-term planning decisions. Ensuring the growth of advanced and cellulosic biofuels industry will require long-term tax incentives to avoid creating uncertainty for investors and companies trying to raise capital.

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[117] https://www.bloomberg.com/news/articles/2020-07-09/biofuel-revolution-was-doomed-by-policy-and-investment-failures

[118] https://www.nata.aero/assets/Site_18/files/GIA/121SMS/Aviation%20Industry%20Coalition%20Support%20for%20Biodiesel%20credit%20extension%20Neal%20Brady.pdf

[119] https://finkenauer.house.gov/sites/finkenauer.house.gov/files/documents/Second%20Gen%20Biofuels%20Extender%20Support.pdf

[120] https://www.biotech-now.org/wp-content/uploads/2019/11/Second-Gen-Biofuels-Letter-11-26-18.pdf?_ga=2.27182452.850446835.1573066958-1287514846.1535039721

[121] http://kce.informz.net/KCE/data/images/Final%20Signed%20Feb%202019%20Loebsack%20LaHood%20Biodiesel%20Letter.pdf

[122] https://finkenauer.house.gov/sites/finkenauer.house.gov/files/3435_001.pdf

The development of a long-term SAF specific blender's tax credit[123] could attract significant investment to the sector and address existing structural and policy disincentives that have prevented the aviation biofuels industry from taking off.

**Renewable Chemicals**

To realize the full potential of the domestic renewable chemicals industry, existing renewable energy, manufacturing, or environmental tax incentive regimes should be opened to renewable chemicals. Providing a federal income tax credit for domestically produced renewable chemicals, could create domestic jobs and other economic activity that can help secure America's leadership in the important arena of green chemistry. Like current law for renewable electricity production credits, the credits would be general business credits available for a limited period per facility.

**Carbon Capture and Utilization**

Maintaining and extending the 45Q tax credits for CCUS will help drive investment and development of innovative new technologies which can capture carbon. The credit monetizes carbon to produce valuable products. Capturing waste carbon from power plants and manufacturing facilities can be converted into valuable products such as advanced biofuels, animal feed, and chemicals. As a result, CCUS helps displace petroleum and other carbon feedstocks. Already, integrating CCUS with biofuels projects is producing negative emissions fuels.[124]

**Opportunity Zones**

The Opportunity Zone (OZ) tax incentive has spurred investment in undercapitalized communities. Any corporation or individual with capital gains can qualify. However, the OZ guidance is unclear to investors and developers if biobased technologies can qualify for OZ tax incentivizes. A relatively minor clarification to OZ Guidance could potentially unlock billions of development dollars for bioeconomy manufacturing facilities.

## V. Bolstering the Supply Chain

Biobased manufacturing can be a solution to making sure those on the ground fighting the pandemic have the protection they need. Demand for personal protective equipment (PPE) is currently outpacing supply. To ensure that we can adequately fight the virus, it is critical that doctors, nurses, first responders, and scientists developing potential cures have access to PPE.

Increasing production of renewable chemicals made from innovative biotechnologies and synthetic biology will help us meet the growing demand of PPE. Development of PPE and other products from biobased materials can also help address the increase in waste from disposable masks and other PPE which is posing new problems for the Earth's oceans.[125] One study estimated if every person in the United Kingdom used a single-use face mask a day for a year it would create an additional 66,000 metric tons of contaminated waste and

[123] https://www.bio.org/letters-testimony-comments/sustainable-aviation-fuels-saf-tax-incentive-letter-congress
[124] https://www.gasworld.com/velocys-signs-ccus-agreement-with-oxy/2017915.article
[125] https://www.fastcompany.com/90520661/masks-gloves-and-other-coronavirus-waste-are-starting-to-fill-up-our-oceans?

57,000 metric tons of plastic packaging.[126] Since these products can be biodegradable or recyclable, they can significantly reduce the amount of waste. It will also increase the demand for biomass feedstocks as producers are faced with a downturn in commodity prices.
In addition to PPE, biobased products can help meet the growing need for testing products to track the virus and research cures. It can also help us meet the demand for sterilizing and cleaning products. In addition to ethanol producers, biotech companies are developing key ingredients that can help in the production of hand sanitizers. Green surface cleaners can meet the growing demand to sterilize surfaces in hospitals, public places, and homes. While enzyme developers are enhancing detergents that can increase cleaning efficacy even in low temperature washing, circumventing the need for hot water and reducing the environmental footprint of the sterilization process.

To meet this demand, the Department and the Administration need to make greater investments in research, development, and deployment of biobased products to tackle COVID-19. We would encourage USDA to use whatever authorities it has to bolster the biobased sector, including expedited distribution of loans under the Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program to build expedited capacity for biorefineries producing renewable chemicals, increasing promotion of the benefits biobased products can provide in addressing the COVID-19 under the BioPreferred Program and ensuring federal agencies are adhering to the program's procurement requirements.

# Incentivize Farmers

## I. Carbon Sequestration

To increase agricultural production while reducing the environmental impacts and emissions from production will require incentivizes throughout the entire value chain, especially at the farm level.

Promoting greater utilization of crops and practices that impart more carbon into the soil and out of the atmosphere through their roots will be critical to keeping warming below 2 degrees Celsius. This can be accomplished through simple, low-cost incentives to farmers for capturing carbon. The FAO noted that soils can sequester approximately 20 petagrams of carbon in 25 years, that's more than 10 percent of anthropogenic emissions.[127] The *United States Mid-Century Strategy for Deep Decarbonization* estimated that U.S. lands have been a net "carbon sink" for the last three decades and through enhancement they could offset up to 45 percent of economy wide emissions by 2050.

What is needed from government is the establishment of infrastructure to measure and verify those carbon sequestrations at the local farm level. Furthermore, farmers need assistance in understanding and accessing the current voluntary and compliance markets for these credits. Common sense policy will make sure that America agriculture continues to lead on this new frontier of climate change mitigation and restoration.

[126] https://www.greenbiz.com/article/how-face-masks-gloves-and-other-coronavirus-waste-are-polluting-ocean
127 http://www.fao.org/fileadmin/user_upload/soils-2015/docs/Fact_sheets/En_IYS_ClCng_Print.pdf

Toward this end, BIO is supportive[128] of the Growing Climate Solutions Act[129] (GCSA) (S.3894/H.R. 7393) introduced by Senators Mike Braun (R-IN) and Debbie Stabenow (D-MI) and Representatives Abigail Spanberger (D-VA) and Don Bacon (R-NE) This bill will support America's farmers, ranchers, and foresters who want to adopt innovative practices that combat climate change, while continuing to provide the world with food, feed, and fiber.

### II. Incentivizing New Technologies

GCSA or other carbon markets can foster acceptance for new technologies that can further reduce the environmental impact of agriculture, including tools like precision plant breeding, biostimulants, and microbial inoculants and enhancing animal feed with enzymes and other additives to reduce emissions in livestock. These improved agricultural practices increase crop yields and provide several environmental benefits including capturing nitrogen directly from the atmosphere and increasing root growth that binds carbon to the soil.

Combined with modern agricultural techniques and sustainable farming practices such as planting cover crops and no-till, these innovative technologies that enhance productivity can play a key role in sequestering carbon dioxide in the soil, improving soil health, and protecting America's waterways.

To further encourage the use of these technologies additional incentivizes could be created. The Section 45Q provides a performance-based tax credit to power plants and industrial facilities that capture, store, and/or utilize carbon oxides that would otherwise be emitted into the atmosphere as $CO_2$. Expanding the credit to new technologies that are being developed to amplify soil carbon sequestration through forestry and crops would incentivize producers to utilize this technology reducing atmospheric carbon.

## Build Public Support and Increase Market Access for Innovative Technologies

### I. Build Public Support and Market Access

**Growing Trust in Innovation**

Innovation flourishes when science and consumer values are aligned and complement one another. The U.S. government's regulatory approach toward innovative products should be supported by credible transparency measures. A proactive approach to transparency stands to build trust with the broader agri-food ecosystem.

During the public comment period on the SECURE Rule,[130] BIO advocated[131] for a process to improve public access to information about new agricultural biotechnology products. While the final rule does not contain a mechanism for mandatory notification, BIO encourages increased openness about products entering the marketplace and best practices developers use in advancing beneficial products to the commercial marketplace.

[128] https://www.bio.org/press-release/bio-supports-growing-climate-solutions-act
[129] https://www.congress.gov/bill/116th-congress/senate-bill/3894
[130] https://www.bio.org/letters-testimony-comments/bio-comments-usdas-proposed-part-340-revisions
[131] https://www.bio.org/letters-testimony-comments/bio-submits-letter-office-management-and-budget-part-340

BIO is advocating that the U.S. government play a role in driving an inclusive and impactful approach to transparency. We encourage agencies to ensure that regulatory policies are durable and legally defensible. Further, we encourage agencies to articulate to the public the rationale for their approach, including safety assessments.

The U.S. government should establish a biotechnology clearinghouse that is geared toward consumers and builds off the Food and Drug Administration's Agricultural Biotechnology Education and Outreach Initiative[132]. This clearinghouse should provide information about common uses of biotechnology, like gene editing, and the safety of innovations commonly used in the food and agricultural system.

We look forward to working with agency experts to evaluate mechanisms to affirm and communicate the safety and benefits of biotechnology.

To learn more please visit BIO's Growing Trust in Innovation webpage: https://www.bio.org/growing-trust-innovation

**BioPreferred**

Managed by USDA, the goal of the BioPreferred program is to increase the purchase and use of bio-based products from agricultural feedstocks. The BioPreferred Program was created by the 2002 Farm Bill and reauthorized and expanded in the 2018 Farm Bill. The program's purpose is to spur economic development, create new jobs and provide new markets for farm commodities. The increased development, purchase, and use of biobased products reduces our nation's reliance on petroleum, increases the use of renewable agricultural resources, and mitigates adverse environmental and health impacts.[133] Prior to the 2018 Farm Bill, due to limitations in verification methodology, the BioPreferred program only incentivized procurement of plant-based products. The 2018 Farm Bill requests USDA to develop verification methods for products made from biological CCU. This will expand opportunities for biobased products made from waste resources.

The BioPreferred Program is transforming the marketplace for biobased products through two initiatives: purchasing requirements for Federal agencies and their contractors; and voluntary product certification and labeling. As highlighted above, the label is helping drive consumer recognition of biobased products that are displacing about 300 million gallons of petroleum per year – the equivalent to taking 200,000 cars off the road.[134] However, while federal law, the Federal Acquisition Regulation, and Presidential Executive Orders direct all federal agencies and their contractors to purchase biobased products in categories identified by USDA through the BioPreferred Program,[135] oftentimes federal agencies fail to give preference to bio-based products. To ensure the BioPreferred Program drives growth of the bioeconomy, the Administration should ensure federal agencies follow through with the requirements to give preference to bio-based products and identify noncompliance.

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[132] https://www.fda.gov/food/agricultural-biotechnology/agricultural-biotechnology-education-and-outreach-initiative

[133] https://www.biopreferred.gov/BioPreferred/faces/pages/AboutBioPreferred.xhtml

[134] https://www.usda.gov/media/press-releases/2016/10/03/usda-report-shows-growing-biobased-products-industry-contributes

[135] https://www.gsa.gov/governmentwide-initiatives/sustainability/buy-green-products-services-and-vehicles/buy-green-products/biobased-and-biopreferred-products

The following recommendations put forward in *An Economic Impact Analysis of the U.S. Biobased Products Industry*[136] can make this achievable:

- Improve the ability of the Federal Government, including the General Services Administration and other acquisition departments of federal agencies, to track the purchase of biobased products in acquisition systems. Currently, there is not a singular way of doing so, and it is difficult to accurately determine the increases in the use of biobased products by the Federal Government.

- Expand marketing and consumer education of the BioPreferred Program's USDA Certified Biobased Product label. Currently, many consumers are confused or are unaware of what a biobased product is, and they do not recognize or understand the label. While there are certainly benefits to having products labelled as USDA Certified Biobased, increased market recognition would help the biobased products industry grow and encourage more companies to pursue certification.

- Leverage the similar goals between the USDA and the DOE to cooperate on increasing the purchase of biobased products. Both agencies have similar objectives in terms of growth and less reliance on nonrenewable resources, and research supported by both agencies can provide greater power and increased success.

**Demonstrate Sustainability**

Developing carbon markets are not only beneficial to incentivizing producers to sequester carbon in the soil, but can bring greater value to sustainable fuels, biobased products, and food and feed applications. These markets allow the manufacturers of biobased chemicals, plastics, food, animal feed, and everyday materials to reliably demonstrate their true environmental benefit, from farm to consumer.

Additional mechanisms should be developed to better enable producers to showcase the benefits of these technologies.

**Trade**

An effective U.S. government trade policy is critically necessary to address tariff and non-tariff barriers that affect the trade of, and innovation in, biotech products globally. In particular, the U.S. bioeconomy needs a proactive trade agenda focused on enhancing IP protection abroad, a harmonized and science-based regulatory environment, fair and equitable technology transfer policies, and access and enforcement policies that appropriately value American innovation and are governed by the rule of law. We applaud that the United States is actively negotiating agreements with key trading partners such as China to address systemic trade practices such as forced technology transfer and IP theft that threatens biotechnology ecosystem across sectors.

With respect to agricultural biotechnology, U.S. leadership is essential to ensure that U.S. agriculture can benefit from advances in science that reduce its environmental footprint while improving crop production. Many U.S. trading partners, including China and Europe, maintain unjustified, non-science barriers that delay the approval of new plant biotech products. To reduce the potential for trade disruption, biotech companies will often delay

[136] https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2018.pdf

commercialization of new products in the United States until China and Europe have approved the same products. Such delays impact U.S. competitiveness and cost our economy dearly. A recent study estimates Chinese delays between 2011 and 2016 reduced farm income by $5 billion and U.S. GDP by $7 billion.[137]

For new innovations like gene editing, the global regulatory landscape is unclear, and there is a risk that genome-edited products will be brought under outdated, discriminatory, and highly burdensome regulatory frameworks previously adopted for transgenic ag-biotech products, even though many of the newer products being developed using gene editing do not contain DNA from outside the plants gene pool. This creates the potential for enormous barriers to entry for this emerging industry, potentially limiting the use of this game-changing technology to only a handful of companies and in only large-scale crops. The United States currently is working with like-minded governments to chart a more reasonable path forward for new innovations in biotechnology like gene editing. The U.S. government also has joined many governments from across the Americas, Africa, and Asia to support agricultural applications of precision biotechnology.[138] This international effort is a clear signal to the world that innovations in precision biotechnology, like genome editing, should not face arbitrary and unjustified treatment by regulatory authorities. We applaud these efforts and encourage renewed urgency in their implementation.

## Conclusion

BIO applauds USDA for taking a proactive approach and seeking information about facilitating the transformative breakthroughs for agriculture to meet the challenges of the 21st Century and increase agricultural production by 40 percent while cutting the environmental footprint by 50 percent.

Achieving this goal and addressing the challenges of climate change and inequality in society, will require the rapid development and deployment of biology-based technologies throughout the agricultural supply chain. It will require USDA and the federal government to establish supportive policies and regulations, provide robust funding for research and development, modernize infrastructure, support all farmers and ranchers, and build public support of new technologies.

We urge the Administration to seize the opportunity to expand on this American leadership, by acting and supporting the pro-innovation technologies and policies we outlined in our comments. We look forward to our continued partnership in this critical endeavor.

[137] https://www.bio.org/press-release/new-report-shows-substantial-economic-costs-chinese-delays-ag-biotech-approvals
[138] https://www.usda.gov/media/press-releases/2018/11/02/wto-members-support-policy-approaches-enable-innovation-agriculture

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/10/2021 4:35:54 AM
**To**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]
**Subject**: Re: References for Thursday discussion

OK. Thanks, Tomas.'

Sent from my iPhone

On Mar 9, 2021, at 11:29 PM, Carbonell, Tomas <Carbonell.Tomas@epa.gov> wrote:

Hi Joe,

Purely for your reference, I wanted to share the background documents and briefing material for the issues I was hoping we could discuss on Thursday (pending Region 4 actions, O3 NAAQS area designations, and WY regional haze) – I am happy to walk through the highlights, so please don't feel a need to wade through all of these before our call. Thanks,

Tomás
<TN I&M Issue Paper_OAR Briefing.docx>
<R4 Multi State Issue Paper_OAR Briefing.docx>
<O3D Remand_OAR Briefing.docx>
<WY EGU 2.3.pdf>
<Wyodak Briefing Paper re Settlement Agreement Finalization_2021_0225.docx>
<PacifiCorp Jim Bridger Regional Haze Hot Issue Paper_2021_0225.docx>

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/10/2021 12:34:23 AM
**To**: Campbell, Ann [Campbell.Ann@epa.gov]; Rakosnik, Delaney [rakosnik.delaney@epa.gov]
**Subject**: FW: API and Air Issues

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** McKeon, Brian M. <bmckeon@bhfs.com>
**Sent:** Tuesday, February 9, 2021 10:46 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Subject:** API and Air Issues

Hi Joe,

I hope this email finds you well, excited to see you and so many other great former colleagues and friends (especially so many Boxerland alums) joining the Administration!

I'm reaching out to see if you'd be able to share who on your team would be best for a touch-base call with API on things that are primarily air-related: Methane, Ozone and PM NAAQS, Social Cost of Carbon, and Benefit-Cost Analysis. API is hoping to connect, share some high-level thoughts, and ask a few process questions.

Obviously if you have the bandwidth they'd welcome a conversation with you, but acknowledge you're likely being pulled in a million different directions right now so thought there might be someone on your team that would be good for a quick touch-base conversation.

Thanks for anything you can share,

Brian

Brian McKeon
Brownstein Hyatt Farber Schreck
202-734-0289
bmckeon@bhfs.com

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Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/26/2021 1:45:26 PM
**To**: Nishida, Jane21 [ActAdmJ21Nishida@epa.gov]; Cassady, Alison [Cassady.Alison@epa.gov]
**Subject**: FW: IPC Deliverable for Monday?
**Attachments**: Leaders' Summit Delieverables.xlsx; NSC SOC IPC on Leaders' Summit.pdf

Further to our brief discussion just now. Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** Shoaff, John <Shoaff.John@epa.gov>
**Sent:** Friday, February 26, 2021 8:44 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Subject:** RE: IPC Deliverable for Monday?

Joe,

**Ex. 5 Deliberative Process (DP)**

to come. Thanks!

John

**JOHN SHOAFF** | DIRECTOR
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**From:** Goffman, Joseph <Goffman.Joseph@epa.gov>
**Sent:** Friday, February 26, 2021 8:37 AM
**To:** Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Shoaff, John <Shoaff.John@epa.gov>
**Subject:** IPC Deliverable for Monday?

Please remind me what it is. I can't find the relevant email in my inbox and Jane just brought up a reference to it at the AM Check-in. Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/17/2021 8:47:21 PM
**To**: Lance, Kathleen [Lance.Kathleen@epa.gov]
**Subject**: FW: NYT--New E.P.A. Head Says Agency Has Climate Regulations Underway

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** Millett, John <Millett.John@epa.gov>
**Sent:** Wednesday, March 17, 2021 9:15 AM
**To:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Nunez, Alejandra <Nunez.Alejandra@epa.gov>; Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Shaw, Betsy <Shaw.Betsy@epa.gov>; Shoaff, John <Shoaff.John@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>; DeLuca, Isabel <DeLuca.Isabel@epa.gov>; Kim, Eun <Kim.Eun@epa.gov>
**Subject:** NYT--New E.P.A. Head Says Agency Has Climate Regulations Underway

# *New E.P.A. Head Says Agency Has Climate Regulations Underway*

Michael Regan says the E.P.A. is already working on new rules to control planet-warming emissions from cars and power plants.

E.P.A. administrator Michael S. Regan said his immediate priorities for the agency are restoring the role of science in developing rules and rebuilding morale.Credit...Pool photo by Caroline Brehman

By Lisa Friedman

- March 15, 2021

WASHINGTON — Michael S. Regan, the new administrator of the Environmental Protection Agency, confirmed on Monday that the agency is preparing new regulations on the electricity sector in an effort to meet President Biden's aggressive climate change goals.

Mr. Regan said his immediate priorities for the E.P.A. are "rebuilding the morale" at the agency, restoring the role of science — and scientists — in developing air and water rules, and ensuring new environmental policies do not further hurt communities already disproportionately affected by toxic sites.

He was not specific on the precise new policies E.P.A. will undertake to rein in planet-warming carbon dioxide emissions, or when they will be made public. But, Mr. Regan said, the agency will "absolutely" develop new rules for power plants and automobiles and that E.P.A. staff is currently working on those plans.

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"We'll be hearing from staff very soon about the particulars," Mr. Regan said.

Reducing carbon emissions from power plants and vehicles, which are the largest sources of planet-warming pollution in the United States, is critical to meeting Mr. Biden's goal of no net carbon emissions by 2050.

Unless Congress passes legislation — an unlikely scenario — it will be up to the E.P.A. to create new regulations for both sectors. The Obama administration sought to reshape the electric power sector by pushing utilities away from coal and toward electricity generated by natural gas, solar, wind and other lower or no-carbon sources. That rule, the Clean Power Plan, was halted by the Supreme Court.

But the Trump administration's efforts ran into trouble as well. The Clean Power Plan replacement — a far weaker rule that only asked utilities to make modest efficiency modifications at individual power plants — was struck down entirely by a federal court earlier this year.

That decision, by the U.S. Court of Appeals for the District of Columbia, affirmed that the E.P.A. has the authority to regulate carbon dioxide from the power sector. Mr. Regan said he intends to take advantage of that.

"We're starting with a clean slate but we're not starting from scratch," he said. In addition, Mr. Regan noted, market forces have changed. Coal-burning power plants already are retiring at a rapid pace, and according to the International Energy Agency, renewables could surpass coal as the world's largest source of power by 2025.

"We're not looking backward; we're looking forward, and I'm really excited about that," he said.

Republicans from fossil fuel states have indicated they are ready to fight any broad regulations that target coal. Senator Shelley Moore Capito of West Virginia, who opposed Mr. Regan's confirmation, said she did so because "he did not commit to a different policy agenda than that of the Obama administration" — which, she said, "absolutely devastated my state and other energy-producing states."

The agency is under time pressure. President Biden has scheduled a global climate change summit for April 22, where the United States will announce a new national emissions target. Foreign leaders also will be expecting the administration to prove to the world how it plans to meet the goals it lays out.

Mr. Regan said it was too soon to promise there will be proposed regulations released by the time of the summit. But, he said, "I do believe that we will have the scientific credibility to support the direction the president wants to go."

For now, Mr. Regan said, he is focused on staff morale that suffered under a Trump administration that often ignored career scientists and scientific findings. He pointed specifically to the Trump administration's approach to climate change as well as per- and polyfluoroalkyl substances, or PFAS, a toxic family of substances found in common household products.

"Morale is not where we want it to be, not nearly where we want it to be. We're going to spend some time there," he said.

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- 
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- Today, 1 percent of the world is too hot for humans to live. By 2070, that may increase to 19 percent. What will happen to the billions of people who currently live in those areas?
- Want to go even deeper? Maybe it's time to pick up a book about climate change. We can help you find the right one.
- Also, find out how much hotter your hometown has become. The engineering and land management that enabled California's tremendous growth have left it more vulnerable to climate shocks, which are getting worse.

He also said he intends to appoint an environmental justice adviser to revamp the agency's approach to civil rights and help develop deeper relationships with communities that most closely experience the burdens of pollution and impacts of climate change. "That's going to be a significant priority," he said.

Mr. Regan had kind words for his immediate predecessor, Andrew Wheeler, and said that Mr. Wheeler left "a very kind letter" on his desk in the administrator's office.

Mr. Regan, who was sworn in on Friday, said he's still learning his way around the building. One place he said he's not likely to have much use for, though, is the soundproof phone booth that Scott Pruitt, President Donald J. Trump's first E.P.A. administrator, had installed at a taxpayer cost of $43,000.

"I don't even know where it is or what it looks like. I guess the first thing I should do is take a look at it," Mr. Regan said, adding, "I've been using the phone on my desk."

**A New Chief at E.P.A.**

Michael S. Regan vows to rebuild after a difficult four years.

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Dec. 17, 2020

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Feb. 2, 2021

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March 10, 2021

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John Millett
Director, OAR Communications
Desk: 202-564-2903
Cell: 202-510-1822
~~~~~~~~~~~~~~~~~~

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/4/2021 3:15:14 AM
**To**: Culligan, Kevin [Culligan.Kevin@epa.gov]
**CC**: Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]
**Subject**: FW: WH Briefing -- USE THIS VERSION
**Attachments**: EGU strategy - v4.pptx

Again, thank you and the team for an excellent job on this.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

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**From:** Goffman, Joseph
**Sent:** Wednesday, February 3, 2021 8:20 PM
**To:** Utech, Dan <Utech.Dan@epa.gov>
**Cc:** Campbell, Ann <Campbell.Ann@epa.gov>; Carbonell, Tomas <Carbonell.Tomas@epa.gov>
**Subject:** WH Briefing -- USE THIS VERSION

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/1/2021 1:23:35 PM
**To**: Ann Campbell (Campbell.Ann@epa.gov) [Campbell.Ann@epa.gov]
**Subject**: Two Controls from Friday afternoon
**Attachments**: Multi org_Fullmer Cline_Reconsider Resp_02-22-21.docx SIGNED.docx; AX-21-000-1866_Ukeiley.docx SIGNED.docx

I used the "draw" function to sign the Word letters and send them back for letter head to be added. Otherwise, I can't quite find the step in the CMS links to reply in CMS to confirm my approval. Sorry to generate all this work, but it seems as if my idiocy is incurable. Thanks.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

Ms. Rachel Fullmer Cline
Environmental Defense Fund
2060 Broadway, Suite 300
Boulder, CO 80302

Dear Ms. Fullmer Cline:

Thank you for your letter of February 15, 2021, to the U.S. Environmental Protection Agency Acting Administrator Jane Nishida, petitioning for reconsideration, on behalf of the American Lung Association, Clean Air Task Force, Chesapeake Bay Foundation, Earthjustice, Environment America, Environmental Defense Fund, Environmental Law & Policy Center, National Parks Conservation Association, Natural Resources Defense Council, Sierra Club, and Union of Concerned Scientists, of the final action on the Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM), published in the Federal Register at 85 FR 82864 (December 18, 2020). The Acting Administrator asked that I respond on her behalf.

On January 20, 2021, President Biden issued an "Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" which directed review of certain Agency actions taken from January 17, 2017, until January 20, 2021. An accompanying fact sheet provides a non-exclusive list of Agency actions that Agency heads will review in accordance with that order, including the PM NAAQS decision. In addition to that review, the EPA is reviewing your petition and upon completion of the review will determine whether to grant or deny your request.

If you have any questions, please contact Erika Sasser, Division Director, Health and Environmental Impacts Division, EPA's Office of Air Quality Planning and Standards at (919) 541-3889.

Again, thank you for your letter. I appreciate the opportunity to be of service and trust the information provided is helpful.

Sincerely,

Joseph Goffman
Acting Assistant Administrator

Mr. Robert Ukeiley
Center for Biological Diversity
1536 Wynkoop Street, Suite 421
Denver, CO 80202

Dear Mr. Ukeiley:

Thank you for your letter of February 9, 2021, to the U.S. Environmental Protection Agency Acting Administrator Jane Nishida, petitioning for reconsideration, on behalf of the Center for Biological Diversity, of the final action on the Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM), published in the Federal Register at 85 FR 82864 (December 18, 2020). The Acting Administrator asked that I respond on her behalf.

On January 20, 2021, President Biden issued an "Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" which directed review of certain Agency actions taken from January 17, 2017, until January 20, 2021. An accompanying fact sheet provides a non-exclusive list of Agency actions that Agency heads will review in accordance with that order, including the PM NAAQS decision. In addition to that review, EPA is reviewing your petition and upon completion of the review will determine whether to grant or deny your request.

If you have any questions, please contact Erika Sasser, Division Director, Health and Environmental Impacts Division at (919) 541-3889.

Again, thank you for your letter. I appreciate the opportunity to be of service and trust the information provided is helpful.

Sincerely,

Joseph Goffman
Acting Assistant Administrator

Appointment

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/9/2021 5:02:18 PM
**To**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]

**Subject**: Accepted: 2015 Ozone Transport: Clean Air Act Authorities and Analytic Options
**Location**: Microsoft Teams Meeting

**Start**: 3/11/2021 4:00:00 PM
**End**: 3/11/2021 5:00:00 PM

**Recurrence**: (none)

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/3/2021 4:16:03 AM
**To**: Dunham, Sarah [Dunham.Sarah@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]
**Subject**: Feb 2 2021 Light-duty Vehicle Options Paper_ revised8pm.docx - JG comments
**Attachments**: Feb 2 2021 Light-duty Vehicle Options Paper_ revised8pm.docx

This is quite good. I've added some marginal comments and questions, with merely quick-reaction, but my no means deep or truly reflective, thoughts. Feel free to dismiss once you've looked at them. Thanks.

March 1, 2021

Acting Administrator Jane Nishida
U.S. Environmental Protection Agency
Mail Code 1101A
1200 Pennsylvania Ave., NW
Washington, D.C. 20460
Nishida.Jane@epa.gov

BY FIRST CLASS MAIL AND EMAIL

**Re: PETITION FOR RECONSIDERATION OF EPA'S *NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE,* 85 FED. REG. 87,256 (DEC. 31, 2020) – EPA-HQ-OAR-2018-0279**

Dear Acting Administrator Nishida,

The Environmental Protection Agency published its review of the National Ambient Air Quality Standards for Ozone, otherwise known as the "Ozone NAAQS," on December 31, 2020. 85 Fed. Reg. 87,256 (Dec. 31, 2020).

American Academy of Pediatrics, American Lung Association, American Public Health Association, Appalachian Mountain Club, Clean Air Task Force, Chesapeake Bay Foundation, Earthjustice, Environment America, Environmental Defense Fund, Environmental Law & Policy Center, National Parks Conservation Association, Natural Resources Defense Council, and Sierra Club respectfully petition EPA to convene a proceeding for reconsideration of these standards under Section 307(d) of the Clean Air Act, 42 U.S.C. § 7607(d), and in light of President Biden's recent Executive Orders, because the 2020 review failed to rationally engage with the body of evidence that mandated strengthening the standard, did not set standards at the levels the statute's directive demands, and is the result of a truncated process that resulted in ultimately arbitrary conclusions.

The undersigned organizations represent millions of members and supporters across the country who are deeply concerned about the health, environmental, and economic impacts of air pollution and support setting strong, science-based National Ambient Air Quality Standards ("NAAQS") that ensure public health and the environment are protected.

## I. Introduction

The rulemaking docket leaves no doubt: Ozone is one of the most dangerous and persistent forms of air pollution in the United States today. Scientists link ozone, the principal component of smog, to premature deaths, thousands of emergency room visits, and tens of thousands of asthma attacks each year. It is especially dangerous for small children who are uniquely vulnerable because they breathe more air for their body weight than adults and their lungs are still developing from infancy through adolescence, people with asthma, and senior citizens, who are often warned to stay indoors on polluted days. Ozone pollution disproportionately impacts low-income communities and communities of color. Across the nation, people of color are consistently overrepresented in areas with higher ozone levels and that are in nonattainment of ozone NAAQS. Furthermore, the asthma burden of people of color—particularly among Black people—is far higher than that of white people. Also, as well as being a greenhouse gas, ozone pollution can severely damage forests and plants, stunting their growth, increasing the risk of tree die-off from disease, and causing harms that affect whole ecosystems. Hundreds of counties throughout the nation, home to hundreds of millions of people and many treasured natural places, suffer from unsafe ozone levels.

The enactment of the Clean Air Act and its amendments "carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health." 116 Cong. Rec. 42,329, 42,381 (Dec. 18, 1970) (remarks of Sen. Muskie). Its purpose is to "protect and enhance" air quality, 42 U.S.C. § 7401(b), and mitigate the "mounting dangers to the public health and welfare" caused by air pollution. *Id.* § 7401(a)(2). To that end, the Clean Air Act establishes both primary and secondary "National Ambient Air Quality Standards," or NAAQS, for some of the most common "criteria" pollutants in the "ambient air." *Id.* § 7409; *see also* 40 C.F.R. part 50.

Primary NAAQS must be "requisite to protect the public health" with "an adequate margin of safety," to prevent not only any known or anticipated health-related effects from polluted air, but also those that are scientifically uncertain or that research has not yet uncovered. 42 U.S.C. § 7409(b)(1). Further, the statute makes clear that there are significant limitations on the discretion granted to EPA in setting the NAAQS. In exercising its judgment, EPA must err on the side of protecting public health, and "taking account of the 'preventative' and 'precautionary' nature of the act… the Administrator must then decide what margin of safety will protect the public health from the pollutant's adverse effects – not just known adverse effects, but those of scientific uncertainty or that 'research has not yet uncovered.'" *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *see also Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 464–71 (2001).

Importantly, the NAAQS must not only be adequate to protect the average member of the population, but must also protect against adverse effects in vulnerable subpopulations, such as children, pregnant people, the elderly, the socially disadvantaged, and people with heart and lung

disease. The D.C. Circuit has repeatedly found that if a certain level of a pollutant "adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *Am. Lung Ass'n*, 134 F.3d at 389 (citation omitted); *see also Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010); *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 524 (D.C. Cir. 2009). EPA must also build into the NAAQS an adequate margin of safety for these sensitive subpopulations. *See Am. Farm Bureau Fed'n*, 559 F.3d at 526.

The Clean Air Act requires that secondary NAAQS "specify a level of air quality the attainment and maintenance of which . . . is requisite to protect the public welfare from any known or anticipated adverse effects." 42 U.S.C. § 7409(b)(2); *Am. Farm Bureau Fed'n*, 559 F.3d at 530. Effects on welfare include impacts on "soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants." 42 U.S.C. § 7602(h). Senator Muskie, one of the prime architects of the Act, in speaking about the amendments for public welfare during the Senate debates, noted that the protections for public welfare "are especially important because some pollutants may have serious effects on the environment at levels below those where health effects may occur" and will be set to be "protective against any known or anticipated adverse environmental effects." Legislative History of Clean Air Act Amendments of 1970 at 227 (Senate Debate on S. 4358, Sept. 21, 1970). The congressionally mandated "ongoing, periodic review and revision process set up by Congress . . . ensure[s] that regulatory guidelines and standards which protect human safety and welfare are kept abreast of rapid scientific and technological developments," *Am. Lung Ass'n v. Browner*, 884 F. Supp. 345, 347 (D. Ariz. 1994), and that "as the contours and texture of scientific knowledge change . . . EPA's NAAQS review necessarily changes as well," *Mississippi v. EPA*, 744 F.3d 1334, 1344 (D.C. Cir. 2013).

a. 2020 Ozone NAAQS Review

Prior to the 2020 review, EPA last updated the annual ozone standard in 2015, when the Obama administration completed its statutory 5-year review of the 2008 ozone standard, and slightly strengthened the health standard to 70 ppb (from 75 ppb) in October of 2015. 80 Fed. Reg. 65,292 (Oct. 26, 2015). This modest strengthening was less than what the record would have supported. In its 2014 review of the science leading up to the 2015 review, EPA's Clean Air Scientific Advisory Committee (CASAC) concluded that the 2008 standard of 75 ppb was insufficient to protect public health. The scientific panel recommended a lower standard, in the range between 60 and 70 ppb, explaining that "[a]t 70 ppb, there is substantial scientific evidence of adverse effects… including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation," and that a 70 ppb standard "may not meet the statutory

requirement to protect public health with an adequate margin of safety."[1] Most importantly, the panel's policy advice was "to set the level of the standard *lower than 70 ppb* within a range down to 60 ppb." *Id.* (emphasis added). Despite this recommendation, EPA proposed a range only between 65 to 70 ppb for the 2015 review, and ultimately finalized a standard of 70 ppb, despite CASAC's recommendations. 79 Fed. Reg. 75,234 (Dec. 17, 2014); 80 Fed. Reg. 65,292 (Oct. 26, 2015).

In the leadup to the 2020 ozone NAAQS review, then-EPA Administrator Pruitt announced a so-called "back to basics" policy for the NAAQS in 2018 that truncated scientific review processes and stripped review boards of independent scientists who had legitimately relevant expertise.[2] The Trump Administration proposed to maintain the 2015 standard of 70 ppb in July of 2020, and finalized the standard on December 23, making the rule effective immediately on publication in the Federal Register. *Review of the National Ambient Air Quality Standards for Ozone*, 85 Fed. Reg. 49,830 (Aug. 14, 2020) ("Proposed Rule"); *National Ambient Air Quality Standards for Ozone*, 85 Fed. Reg. 87,256 (Dec. 31, 2020) ("Final Rule").

b. Authority for Reconsideration

Because the Agency's final decision meets the test under Section 307(d) of the Clean Air Act, 42 U.S.C. § 7607(d), EPA must immediately undertake a reconsideration proceeding of the 2020 ozone standards. Under Section 307(d), the Administrator must grant a petition for reconsideration if a petitioner "can demonstrate to the Administrator that it was" either (1) "impracticable" to raise an objection or (2) "if the grounds for such objection arose after the period for public comment." In addition, the objection must be "of central relevance to the outcome of the rule." *Id.* § 7607(d)(7)(B). "The first element's impracticability prong – rather than the 'arising after' prong – is met 'when the final rule was not a logical outgrowth of the proposed rule.'" *Chesapeake Climate Action Network v. EPA*, 952 F.3d 310, 319 (D.C. Cir. 2020) (internal citation omitted). "A final rule is the 'logical outgrowth' of a proposed rule if 'interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period.'" *Clean Air Council v. Pruitt*, 862 F.3d 1, 10 (D.C. Cir. 2017) (internal citation omitted); *see also Portland Cement Ass'n v. EPA*, 665 F.3d 177, 185–86 (D.C. Cir. 2011). An objection is of central relevance if it "provides substantial support for the argument that the regulation should be revised." *Coal. for Responsible Regul. v. EPA*, 684 F.3d 102, 125 (D.C. Cir. 2012), *aff'd in*

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[1] Letter to Hon. Gina McCarthy from Clean Air Scientific Advisory Committee, "CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards," at 2 (June 26, 2014) (EPA-CASAC-14-004) ("2014 CASAC Letter").

[2] Memorandum from E. Scott Pruitt, Former Administrator, U.S. Environmental Protection Agency, on Back to Basics for Reviewing the National Ambient Air Quality Standards to EPA Assistant Administrators at 3 (May 9, 2018) ("2018 Pruitt NAAQS Memo"), available at https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf

*part, rev'd in part on other grounds sub. nom. Util. Air Regul. Grp. v. EPA*, 573 U.S. 302 (2014); *see also* 42 U.S.C. § 7607(d)(7)(B). When a petitioner meets these elements, EPA must convene a reconsideration proceeding. A reconsideration proceeding provides members of the public with an opportunity to comment on aspects of a final rule that they were not given adequate notice of previously.

As this Petition explains, the 2020 ozone standards violate EPA's core duty to protect public health and welfare in carrying out obligations in the Clean Air Act, and in setting the NAAQS with an adequate margin of safety. The Final Rule's rationale also differs significantly from the proposal in ways that do not represent a logical outgrowth of the Proposed Rule, making it impracticable to have raised objections to certain issues prior to issuance of the Final Rule. The Administrator must therefore "convene a proceeding for reconsideration of the rule" in accordance with the requirements of the Act. 42 U.S.C. § 7607(d)(7)(B). But not all aspects of the rule are necessarily subject to mandatory reconsideration, and, because of the seriousness of the harms ozone causes and the urgency of action to address those harms, Petitioners reserve their right to pursue litigation even without EPA action on this petition.

Further, the Biden Administration has pledged an ambitious, broad-based, "whole-of-government" approach to addressing environmental injustices. As EPA renews its commitment to environmental justice and civil rights, EPA must thus reconsider its decision to maintain outdated standards for ozone that disproportionately harm Black and brown communities.[3] Section 2 of Executive Order 13990 mandates that

> [t]he heads of all agencies shall immediately review all existing regulations, orders, guidance documents, policies, and any other similar agency actions (agency actions) promulgated, issued, or adopted between January 20, 2017, and January 20, 2021, that are or may be inconsistent with, or present obstacles to, the policy set forth in section 1 of this order. For any such actions identified by the agencies, the heads of agencies shall, as appropriate and consistent with applicable law, consider suspending, revising, or rescinding the agency actions.[4]

These executive orders affirm that a reconsideration of EPA's 2020 ozone standards decision is necessary.

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[3] Exec. Order No. 13990, *Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis*, 86 Fed. Reg. 7037 (Jan. 20, 2021); Exec. Order No. 12898, 59 Fed. Reg. 7629 (1994); *20th Anniversary of Executive Order 12898 on Environmental Justice*, Proclamation No. 9082 of Feb. 10, 2014, 79 Fed. Reg. 8819 (Feb. 13, 2014), *available at* https://obamawhitehouse.archives.gov/the-press-office/2014/02/10/presidential-proclamation-20th-anniversary-executive-order-12898-environ.

[4] Exec. Order No. 13990, 86 Fed. Reg. 7037 (Jan. 20, 2021).

## II. Grounds for objection regarding the primary standard

a. Overwhelming scientific evidence shows ozone harms human health, including at levels the current standard allows.

The scientific evidence—including controlled human exposure studies, animal toxicology, and epidemiology described in the Integrated Science Assessment for Ozone and Related Petrochemical Oxidants ("ISA") and in studies raised by commenters—demonstrates that significant harms to human health occur at ozone levels allowable under the current 70 ppb standard.

EPA's failure to rationally consider certain studies and failure to rationally explain its reliance on studies of healthy individuals when selecting the level necessary to protect vulnerable populations warrant reconsideration. First, these issues are of central relevance to both whether the 70 ppb standard "accurately reflect[s] the latest scientific knowledge," 42 U.S.C. § 7408(a)(2), and whether it is "requisite to protect the public health" with "an adequate margin of safety," *id.* § 7409(b)(1), taking into account sensitive populations. Second, it would have been impracticable for the public to comment on these issues at the proposal stage.

EPA also failed to rationally consider "new" studies raised by commenters that demonstrate health harms below the level of the current standard. The Agency did not rationally consider American Thoracic Society ("ATS") Guidelines and lung inflammation studies that relate to what constitutes an adverse effect in people with asthma. EPA additionally did not rationally explain how its reliance on studies that mostly include only healthy adults, where children and others are known to be more vulnerable, can lead to a final rule that provides the legally-required level of protection for vulnerable populations.

i. EPA fails to rationally consider new studies and wrongly dismissed them on the ground that they purportedly did not materially change the broad scientific conclusions of the ISA.

EPA failed to rationally consider new studies identified by commenters and arbitrarily and capriciously dismissed these studies after having "provisionally considered" them, on the grounds that they "do not materially change the broad conclusions of the ISA." 85 Fed. Reg. 87,289. EPA states that the provisional consideration of these new studies was not intended to "provide the kind of in-depth critical review" that was given to the studies included in the ISA, but "was focused on determining whether they warranted reopening the review of the air quality criteria to enable the EPA, the CASAC and the public to consider them further." *Id.* at 87,262. This provisional consideration is really no consideration at all, as EPA makes clear by stating:

> Accordingly, the EPA is basing the final decisions in this review on the studies and related information included in the $O_3$ air quality criteria that have undergone rigorous review by the EPA, the CASAC and the public. The EPA will consider these "new" studies for inclusion in the air quality criteria for the next $O_3$ NAAQS review . . . .

*Id.* at 87,263. EPA determined that reopening the review was not warranted because "the 'new' information and findings do not materially change any of the broad scientific conclusions regarding the health and welfare effects of $O_3$ in ambient air made in the air quality criteria." *Id.* at 87,262-63.

The studies introduced by commenters provide important evidence about health effects that occur at ozone levels allowed in areas meeting the current primary standard, and therefore EPA's decision on whether to consider them as part of this NAAQS review is of central relevance to its decision to retain the existing standard. Because EPA's proposal did not include any indication that it would apply this "provisional consideration" to new studies raised by commenters, or consider them only in the context of "reopening review of the air quality criteria," objections to EPA's treatment of the new studies raised by commenters were impracticable to raise during the comment period. Additionally, EPA's rationale for putting off consideration of the "new" studies until a future round of ozone NAAQS review was arbitrary and capricious. EPA arbitrarily does not explain what it means by "materially" and "broad" in stating that these provisionally-considered studies "do not materially change any of the broad scientific conclusions regarding the health and welfare effects" of ozone. Even if the new studies do not change unspecified "broad" conclusions, they can still have important implications for individual scientific conclusions, such as whether particular levels of ozone cause specific health effects, a point centrally relevant to the outcome of EPA's review of the ozone standard.

In the Final Rule, EPA indicates that it "will consider these 'new' studies for inclusion in the air quality criteria for the next $O_3$ NAAQS review, which the EPA expects to begin soon after the conclusion of this review and which will provide the opportunity to fully assess these studies through a more rigorous review process involving the EPA, the CASAC, and the public." *Id.* at 87,263. But in doing so, EPA did not engage with the findings of studies published after March 2018 and did not explain why certain studies, including several that identify health harms at currently permissible levels, were excluded from the final ISA in April 2020 or a provisional science assessment.

At the very least, EPA should have considered all studies published as of December 3, 2018, the final date for accepting comments on the ISA, or as of April 2020, when the ISA was finalized. As an example of past practice, on December 14, 2012, EPA published its *Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure*, a detailed, analytical document. EPA noted at the time that the report "presents the findings of EPA's survey and provisional assessment of [studies published since the completion of the 2009 PM ISA]. EPA has screened and surveyed the recent literature and developed a provisional assessment that places those studies of potentially greatest relevance to the current PM NAAQS review in the context of the findings of the 2009 PM ISA."[5] Unlike before, EPA did not conduct a thorough provisional assessment of recently published peer-reviewed studies for the April 2020 $O_3$ Integrated Science Assessment prior to finalizing the $O_3$ NAAQS proposal. These recent studies include a 2019 study analyzing air pollution concentrations (including ozone) and asthma

[5] EPA, Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure at vii (Dec. 2012)

incidence in children[6] that identified reduced asthma incidence as ozone concentrations fell over time.

A sample of additional important recent studies the Agency failed to adequately consider in its Final Rule include:

**Fuller, Christina H., Jordan W. Jones, and Douglas W. Roblin. "Evaluating Changes in Ambient Ozone and Respiratory-Related Healthcare Utilization in the Washington, DC Metropolitan Area."** ***Environmental Research*** **186 (July 2020): 109603. https://doi.org/10.1016/j.envres.2020.109603.**

Authors estimated the association between changes in ambient ozone (exposure windows of current day, 1-day lag and 3-day moving average) and changes in healthcare utilization using linear regression controlling for census tract-level socioeconomic indicators and temperature. Increases in ozone were associated with increases in three of the four utilization event types. A 10 ppb increase in 1-day ozone was associated with a 2.95% (95% CI: 1.93%, 3.96%) increase in hospital calls/emails, a 1.56% (95% CI: 0.38%, 2.74%) increase in emergency department/urgent care visits and a 1.10% (95% CI: 0.48%, 1.73%) increase in provider visits. The mean ozone concentration during the study period was 46.1 ppb.

**Gao, Hui, Kan Wang, William W. Au, Wensui Zhao, and Zhao-lin Xia. "A Systematic Review and Meta-Analysis of Short-Term Ambient Ozone Exposure and COPD Hospitalizations."** ***International Journal of Environmental Research and Public Health*** **17, no. 6 (Mar. 23, 2020): 2130. https://doi.org/10.3390/ijerph17062130.**

Authors used random effect models to derive overall excess risk estimates between short-term ambient-level $O_3$ exposure and COPD hospitalizations. Based on the results from 26 eligible studies, analyses showed that a 5 ppb increase in maximum 8-h ozone concentration was associated with a 0.84% (95% CI: 0.09%, 1.59%) higher rate COPD hospitalizations.

**Mendoza, Daniel L, Cheryl S Pirozzi, Erik T Crosman, Theodore G Liou, Yue Zhang, Jessica J Cleeves, Stephen C Bannister, William R L Anderegg, and Paine III Robert. "Impact of Low-Level Fine Particulate Matter and Ozone Exposure on Absences in K-12 Students and Economic Consequences."** ***Environmental Research Letters*** **15, no. 11 (Nov. 18, 2020): 114052. https://doi.org/10.1088/1748-9326/abbf7a.**

Authors modeled $PM_{2.5}$ and annual average $O_3$ concentrations at 36 schools from July 2015 to June 2018 using data from a dense, research grade regulatory sensor network and determined exposures and daily absences at each school to estimate lost school revenue, productivity, and family economic burden. Pollution exposure was associated with a rate ratio as high as 1.02 absences per $\mu g\ m^{-3}$ and 1.01 per ppb increase for $PM_{2.5}$ and ozone, respectively. $PM_{2.5}$ and ozone exposures below the air quality index breakpoints for good air quality (<12.1 $\mu g\ m^{-3}$ and

[6] Garcia, Erika, et al., "Association of Changes in Air Quality with Incident Asthma in Children in California, 1993-2014." *JAMA* 321, no. 19 (May 21, 2019), https://doi.org/10.1001/jama.2019.5357

<55 ppb, respectively) was associated with positive rate ratios of absences: 1.04 per $\mu g\ m^{-3}$ and 1.01 per ppb increase, respectively. Annual mean $O_3$ exposure level across all of the schools was about 28 ppb.

**Seltzer, Karl M., Drew T. Shindell, Prasad Kasibhatla, and Christopher S. Malley. "Magnitude, Trends, and Impacts of Ambient Long-Term Ozone Exposure in the United States from 2000 to 2015."** ***Atmospheric Chemistry and Physics*** **20, no. 3 (Feb. 14, 2020): 1757–75. https://doi.org/10.5194/acp-20-1757-2020.**

Authors modeled long-term $O_3$ exposure over the continental United States from 2000 to 2015 and generated a measurement-based assessment of impacts on human-health and crop yields. Overall, these results provide a measurement-based estimate of long-term $O_3$ exposure over the United States and quantify the historical trends of such exposure. Authors estimated net estimated premature deaths attributable to long-term $O_3$ exposure (at levels peaking at 55.9 ppb) ranged from 14,500 to 37,600 between 2000 and 2015.

**Wagner, James G., Christina E. Barkauskas, Aaron Vose, Ryan P. Lewandowski, Jack R. Harkema, and Robert M. Tighe. "Repetitive Ozone Exposures and Evaluation of Pulmonary Inflammation and Remodeling in Diabetic Mouse Strains."** ***Environmental Health Perspectives*** **128, no. 11 (Nov. 2020): 117009. https://doi.org/10.1289/EHP7255.**

Researchers assessed whether pulmonary responses to repetitive ozone exposures are exacerbated in murine strains that are hyperglycemic and insulin resistant. Results demonstrate that in diabetic animal strains repetitive ambient ozone exposure led to early and exaggerated pulmonary inflammation. The work provides a biological mechanistic framework to support the emerging epidemiological associations among air pollution, diabetes, and lung disease.

**Dimakopoulou, Konstantina, John Douros, Evangelia Samoli, Anna Karakatsani, Sophia Rodopoulou, Despina Papakosta, Georgios Grivas, et al. "Long-Term Exposure to Ozone and Children's Respiratory Health: Results from the RESPOZE Study."** ***Environmental Research*** **182 (March 2020): 109002.** https://doi.org/10.1016/j.envres.2019.109002.

Investigators quantified the effects of long-term exposure to $O_3$ on respiratory health outcomes in 10-11-year old children. A 10 $\mu g/m^3$ (5 ppb) increase in long-term $O_3$ exposure was associated with lower forced vital capacity (FVC) and Forced Expiratory Volume at 1 second ($FEV_1$) by 17mL (95% Confidence Interval: 5-28) and 13mL (95% CI: 3-21) respectively, and small decreases in lung growth: 0.008% (95% CI: 0.002-0.014%) for FVC and 0.006% (95% CI: 0.000-0.012%) in $FEV_1$. The study provides evidence that long-term ozone exposure is associated with reduced lung volumes and growth.

ii. EPA also fails to rationally consider new ATS Guidelines and lung inflammation studies.

Because the standard must be set at a level that protects sensitive populations, EPA's consideration of the following is of central relevance to the decision to retain the 2015 primary standard: (1) whether certain lung function decrements constitute adverse effects in people with asthma, a question where ATS Guidelines are especially important, and (2) whether inflammation from a single exposure is an adverse event. In the Final Rule, however, EPA provides new rationales, not included in the Proposed Rule; so it would have been impracticable for the public to comment on those rationales during the comment period.

Though the Final Rule states that commenters were incorrect that EPA had failed to rationally consider the ATS Guidelines, the Final Rule still fails to rationally explain how EPA took the Guidelines into account in coming to its decision to retain the 2015 primary standard. Notably, EPA seems to misconstrue the Guidelines' statement about the adversity of lung function changes, an error that renders EPA's consideration of the Guidelines irrational. EPA characterizes the new Guidelines as "giv[ing] weight to findings of such lung function changes in the absence of respiratory symptoms in individual with pre-existing compromised function." 85 Fed. Reg. 87,292/3. In reality, the new Guidelines are stronger than that, saying such effects "*should* be considered adverse." Guidelines at 7, EPA-HQ-OAR-2018-0279-0126 (emphasis added).

In response to comments about how the proposal failed to consider 10% $FEV_1$ decrement in assessing the results of the chamber studies, EPA says that it "present[ed]" results regarding such decrements in the risk assessment. 85 Fed. Reg. 87,293/1 n.118. EPA's response entirely misses the point of the comments: whether EPA considered how many participants in chamber studies experienced at least 10% decrement, rather than 15% (as it focused on in the proposal). Comments 35-36, EPA-HQ-OAR-2018-0279-0444.[7] That EPA "present[ed]" the result of the risk assessment addressing 10% decrement is entirely unresponsive to that point. Notably in any event, EPA writes off the risk assessment pretty much entirely. *See, e.g.*, 85 Fed. Reg. 87,303/2-06/1 (explaining the basis for its final decision, EPA exclusively discusses the exposure assessment's results without even mentioning the risk assessment's result). EPA also says that it alluded in the Policy Assessment ("PA") to 10% decrement as "a focus" that "may be appropriate." *Id.* at 87,293/1. This response also fails entirely to address the core concern of the comment: without considering the number of study participants who experienced 10% $FEV_1$ decrement, EPA hasn't rationally shown how the current standard provides requisite protection for the sensitive populations for whom such decrement is likely an adverse health effect.

Further, in response to comments indicating that the proposal did not rationally consider studies showing lung inflammation at exposures as low as 60 ppb, the Final Rule asserts that commenters are wrong because EPA gave them "significant consideration." *Id.* at 87,294. At the same time, however, EPA also seems to assert that it need not have given weight to lung inflammation because "the inflammatory response observed following the single exposure to 60 ppb in the study by Kim et al. (2011) of largely healthy subjects is not necessarily an adverse

[7] We attach and incorporate these comments into this petition, as well.

response." *Id.* Stating that something is "not necessarily" an adverse response does not rationally consider the likelihood that it is an adverse response, at least in more vulnerable populations. EPA also gives an explanation for discounting this study that was not given in the Proposed Rule:

> the potential for effects reported from 6.6-hour exposures to 60 ppb $O_3$, during quasi-continuous exercise, including the inflammation reported by Kim et al. (2011) to contribute to adverse health effects is uncertain. Newly available evidence in this review does not reduce this uncertainty or provide a contradiction to conclusion regarding the implications of inflammation induced by single or isolated exposures. . . .

*Id.* at 87,294 n.121. EPA acknowledges that people with asthma likely experience adverse effects as a result of this inflammation, and thus its generic reliance on uncertainty in particular studies that don't include people with asthma is inconsistent with the Act, as the D.C. Circuit's controlling interpretation makes clear. The D.C. Circuit has held that the Act's mandate requires that in considering uncertainty EPA "must err on the side of caution" in terms of protecting human health and welfare: "The Act requires EPA to promulgate protective primary NAAQS even where … the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree.'" *E.g.*, *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 369, 378 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38,652, 38,653 (July 18, 1997)); *see also* Comments at 11-12.

Similarly, EPA states: "not every occurrence of an exposure considered to have the potential to increase airway inflammation will result in such an adverse effect. We find it important to note, however, that continued acute inflammation can contribute to a chronic inflammatory state, with the potential to affect the structure and function of the lung." 85 Fed. Reg. 87,294. Saying that "not every" exposure to certain levels will result in harmful lung inflammation is not the same thing as rationally considering the exposures that *do* lead to such adverse effects. And, given the acknowledged potential for chronic lung inflammation to be harmful, EPA's dismissal of lung inflammation is arbitrary and capricious. EPA's further reliance on its exposure assessment is arbitrary, as explained in comments and below.

EPA also provides a rationale for discounting other lung inflammation studies that was not present in the Proposed Rule:

> One commenter contends that inflammation is apparent from short-term $O_3$ exposures ranging from 12 to 35 ppb, based on air quality metrics reported in some epidemiologic studies, such as mean 24-hour averages or monthly averages of 8- hour concentrations (ISA, Table 4–28). The commenter implies that such values for these metrics are lower than the level of the standard (70 ppb) means that exposures allowed by the standard are causing outcomes analyzed in the study. However, none of the metrics for which values are cited by the commenter are in terms of design values for the current standard, such that a direct comparison of the values is not meaningful.

*Id.* at 87,294 n.120. Regardless, EPA has not addressed whether the values in those studies are ozone concentrations and exposures that would be expected to occur in areas with design values complying with the current standard.

iii. EPA fails to rationally explain how its approach of reliance on studies that feature healthy adults provides requisite protection to more vulnerable populations.

EPA does not rationally explain how reliance on studies involving mostly healthy adult subjects enables it to set a standard that provides an "adequate margin of safety" that takes into account sensitive populations including adults and children with asthma. EPA's judgments about whether the standard adequately protects these sensitive populations are centrally relevant to the question of whether EPA has fulfilled its statutory mission under the Clean Air Act.

EPA acknowledges multiple times in the Final Rule that the majority of the studies on which it relies include only healthy adults. *See, e.g.*, *id.* at 87,269 ("Within the evidence base from controlled human exposure studies, the majority of studies involve healthy adult subjects (generally 18 to 35 years), although there are studies involving subjects with asthma… ."); *id.* at 87,293–94 ("We recognize that this evidence and the evidence represented by the three benchmark concentrations used in the exposure/risk analyses (60, 70 and 80 ppb) is for largely healthy adults and does not include data for people with asthma."). The Final Rule also acknowledges that "[w]hile the evidence regarding the susceptibility of people with asthma to the effects of $O_3$ is robust, our understanding of the exposures at which various effects (of varying severity) would be elicited is less defined." *Id.* at 87,293.

The Final Rule states that controlled human exposures studies have indicated "similar magnitude of $O_3$-related $FEV_1$ decrements for people with as for people without asthma" and that, for other respiratory effects, "the evidence has also found the observed responses to generally not differ due to the presence of asthma, although the evidence base is more limited with regard to study subjects with asthma." *Id.* at 87,293. As pointed out in comments, EPA's seeming assumption that the level of lung function impairment is similar for people with asthma is unfounded. Comments at 40. EPA then states that due to the uncertainty regarding the exposures eliciting effects in people with asthma and the severity of those effects, "other aspects of the evidence are informative to the necessary judgments," and states that EPA therefore relies on the ATS Guidelines and advice from CASAC in determining whether the standard is protective of people with asthma. 85 Fed. Reg. 87,293. As already discussed above, EPA fails to rationally consider the ATS Guidelines, and does not rationally consider lung inflammation, a respiratory effect of particular concern for people with asthma. The Clean Air Act requires EPA to set a precautionary NAAQS that will be protective of human health, including the health of sensitive populations, such as children, particularly during vulnerable developmental windows. Children are not little adults, and these differences are in kind rather than degree. EPA's failure to rationally explain how its reliance on studies of healthy adults leads it to a standard that protects vulnerable populations is therefore inconsistent with the Clean Air Act and arbitrary.

b. EPA's failure to adopt a long-term exposure standard is arbitrary and capricious, and its explanation is new.

For the first time, EPA addresses the need for a long-term ozone standard to protect public health. Long-term exposure is particularly relevant for the susceptible population of children, especially as pertains to lung growth and capacity. EPA's rejection of such a standard is arbitrary.

EPA notes in the Final Rule that a long-term $O_3$ exposure is "likely" to cause respiratory effects and contends that recent studies "are generally consistent with the evidence assessed in the ISA, and, arbitrarily, as explained above, that they do not materially change the broad conclusions in the ISA regarding the scientific evidence." 85 Fed. Reg. 87,299-300. In doing so, EPA takes issue with commenters citing studies of adverse health effects linked to long-term exposure levels below the current NAAQS and argues that a short-term standard helps to reduce long-term exposure levels: "we note that the impact of standards with short averaging times, such as eight hours, is not limited to reducing short-term exposures." *Id.* at 87,300.

EPA thus acknowledges (in accordance with the scientific evidence) that long-term exposure levels far below 70 ppb pose a serious risk to public health but seeks to indirectly address long-term exposures through its consideration of revisions to the short-term standard. EPA argues that the short-term standard limits "the magnitude of concentrations to which a population is exposed in eight hour periods, [and] also limits the frequency to which the population is exposed to such concentrations over the long term," *id.*, but EPA does not make any effort to analyze the existing literature or conduct its own analysis within the Policy Assessment to determine the extent to which long-term concentrations are affected by the short-term standard and what the resulting public health impacts of changes to long-term exposure levels might be.

EPA also makes no effort to disentangle what it acknowledges to be the complex effects of combined short- and long-term exposure levels and instead argues that the entirety of health effects linked to chronic pollution exposures can be addressed through consideration of the short-term standard. Contrary to the scientific evidence described here, EPA contends that "the current standard provides control of exposures to such concentrations over both the short and long term" without quantifying the "control" that the current standard supposedly provides over long-term exposure levels. *Id.*

In dismissing long-term exposure studies, EPA takes issue with the fact that short-term $O_3$ levels in multiple studies "did not meet the current standard in all locations and time periods analyzed in these three multicity studies." *Id.* Yet the metric of interest in these studies—the long-term exposure level—in all cases fell far below the currently permissible short-term level. EPA conflates short- and long-term exposure levels in an attempt to ignore the independent evidence that clearly demonstrates the need for EPA to adopt a long-term standard.

In the Final Rule, EPA addresses only a sample of recent studies cited by commenters relevant to the importance of adopting a long-term exposure standard to protect public health. Importantly, it does not address the fact that multiple studies document adverse health impacts

linked to long-term exposure levels well below the current standard and argues without scientific evidence or its own analysis that the existing standard is sufficiently protective of long-term exposure levels.

As noted by Nassikas et al. (2020),[8] the meteorological conditions that determine ozone levels are projected to be more favorable to ozone formation over much of the United States due to continued climate change, even as emissions of anthropogenic ozone precursors are expected to decrease by 2050. In particular, as noted by Archer et al. (2019),[9] in the mid-Atlantic region of the United States, warmer temperatures caused by climate change threaten to heighten long-term ozone levels and chronic exposures to ozone.

The Final Rule does not rationally address the scientific finding that a number of studies published after March 2018, the cut-off period for study consideration in the current ozone ISA, confirm statistically significant health harms from long-term exposures to ozone.[10,11,12] EPA cannot rationally reject these conclusions based on these studies simply because the studies did not evaluate health effects associated with air quality under the current standard.

For example, while there were no epidemiologic studies examining the association between long-term exposure to ozone and COPD available for inclusion in the 2013 Ozone ISA, a study by Paulin et al. (2019) of smokers with or at-risk for COPD found that long-term exposure is associated with worse respiratory outcomes. As noted in Limaye and Knowlton (2019),[13] the adverse respiratory health outcomes identified in this study were found to be potentially independent of smoking intensity or exposures to air pollution on the job, underscoring the health risks that ozone air pollution poses to tens of millions of individuals who currently smoke or formerly smoked. The median $O_3$ exposure level in the study was 25.1 ppb, demonstrating the risks of chronic ozone exposure at levels far below the current short-term standard.

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[8] Nassikas, Nicholas, Keith Spangler, Neal Fann, Christopher G. Nolte, Patrick Dolwick, Tanya L. Spero, Perry Sheffield, and Gregory A. Wellenius. "Ozone-Related Asthma Emergency Department Visits in the US in a Warming Climate." *Environmental Research* 183 (Apr. 2020): 109206. https://doi.org/10.1016/j.envres.2020.109206.

[9] Archer, Cristina L., Joseph F. Brodie, and Sara A. Rauscher. "Global Warming Will Aggravate Ozone Pollution in the U.S. Mid-Atlantic." *Journal of Applied Meteorology and Climatology* 58, no. 6 (June 2019): 1267–78. https://doi.org/10.1175/JAMC-D-18-0263.1.

[10] Dominici, Francesca, Joel Schwartz, Qian Di, Danielle Braun, Christine Choirat, and Antonella Zanobetti. "Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1." *Research Reports: Health Effects Institute 2019* (Nov. 1, 2019): 200. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7300216/.

[11] Seltzer, Karl M., Drew T. Shindell, Prasad Kasibhatla, and Christopher S. Malley. "Magnitude, Trends, and Impacts of Ambient Long-Term Ozone Exposure in the United States from 2000 to 2015." *Atmospheric Chemistry and Physics* 20, no. 3 (Feb. 14, 2020): 1757–75. https://doi.org/10.5194/acp-20-1757-2020.

[12] Dedoussi, Irene C., Sebastian D. Eastham, Erwan Monier, and Steven R. H. Barrett. "Premature Mortality Related to United States Cross-State Air Pollution." *Nature* 578, no. 7794 (Feb. 2020): 261–65. https://doi.org/10.1038/s41586-020-1983-8.

[13] Limaye, Vijay S., and Kim Knowlton. "Shining New Light on Long-Term Ozone Harms." *JAMA Internal Medicine*, 2019, 2. https://doi.org/10.1001/jamainternmed.2019.5967.

Additional studies published after March 2018, including what EPA acknowledges in the Final Rule to be a high-quality study, demonstrate causal links between long-term exposures and adverse health outcomes. Lim et al. (2019)[14] quantified associations of long-term (annual or warm season average of daily 8-h maximum concentrations) exposure with all-cause and cause-specific mortality in the NIH-AARP Diet and Health Study, a large prospective cohort of U.S. adults with 17 years of follow-up from 1995 to 2011. Long-term exposure levels ranged from 26.8 ppb to 56.3 ppb. That study found that long-term annual average exposure was significantly associated with deaths caused by cardiovascular disease (per 10 ppb; hazard ratio [HR], 1.03; 95% CI, 1.01–1.06), ischemic heart disease (HR, 1.06; 95% CI, 1.02–1.09), respiratory disease (HR, 1.04; 95% CI, 1.00–1.09), and chronic obstructive pulmonary disease (HR, 1.09; 95% CI, 1.03–1.15) in single-pollutant models. The results were robust to alternative models and adjustment for co-pollutants (fine particulate matter and nitrogen dioxide).

Another large study by Rhee et al. (2019)[15] analyzed air pollution exposures at the ZIP code level in the U.S. and hospital admissions with acute respiratory distress syndrome (ARDS) among nearly 1.2 million Medicare beneficiaries aged >65 years from 2000 to 2012 and found that an increase of 1 ppb in annual average ozone was associated with statistically significant increases in annual hospital admission rates for ARDS of 0.72% (95% CI, 0.62–0.82) and 0.15% (95% CI, 0.08–0.22), respectively in areas with a median $O_3$ concentration of 39.1 (interquartile range: 36.7 to 41.6 ppb). Importantly, this effect remained in low-pollution regions (annual average $PM_{2.5}$ level < 12 $\mu g/m^3$ and annual average ozone level < 45 ppb). In those areas, the 1 ppb annual increase in ozone concentration was associated with a significant increase in annual hospital admission rates for ARDS of 0.27% (95% CI, 0.16–0.38).

Strosnider et al. (2019)[16] conducted an analysis of respiratory emergency department visits in 894 counties, the largest U.S. multicity study of impacts among all ages. The 869 county-specific interquartile range for daily 8-hour maximum ozone varied from 8.0 to 34.0 ppb with a mean interquartile range of 16.54 ppb. Linking daily respiratory emergency department visits with estimated ozone concentrations during the week before the date of the visit, per 20-ppb increase in ozone, rate ratios were statistically significant at 1.017 (95% CI, 1.011–1.023) among children, 1.051 (95% CI, 1.046–1.056) among adults younger than 65, and 1.033 (95% CI, 1.026–1.040) among adults 65 and older.

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[14] Lim, Chris C., Richard B. Hayes, Jiyoung Ahn, Yongzhao Shao, Debra T. Silverman, Rena R. Jones, Cynthia Garcia, Michelle L. Bell, and George D. Thurston. "Long-Term Exposure to Ozone and Cause-Specific Mortality Risk in the United States." *American Journal of Respiratory and Critical Care Medicine* 200, no. 8 (May 3, 2019): 1022–31. https://doi.org/10.1164/rccm.201806-1161OC.

[15] Rhee, Jongeun, Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Yun Wang, Qian Di, John Balmes, and David C. Christiani. "Impact of Long-Term Exposures to Ambient PM2.5 and Ozone on ARDS Risk for Older Adults in the United States." *Chest* 156, no. 1 (July 2019): 71–79. https://doi.org/10.1016/j.chest.2019.03.017.

[16] Strosnider, Heather M., Howard H. Chang, Lyndsey A. Darrow, Yang Liu, Ambarish Vaidyanathan, and Matthew J. Strickland. "Age-Specific Associations of Ozone and Fine Particulate Matter with Respiratory Emergency Department Visits in the United States." *American Journal of Respiratory and Critical Care Medicine* 199, no. 7 (Apr. 2019): 882–90. https://doi.org/10.1164/rccm.201806-1147OC.

Another recent study[17] analyzing the health effects of long-term exposure to ozone restricted to areas meeting the current standard demonstrates that dangerous health effects are still observed in these areas. Yazdi et al. (2021) analyzed 63 million Medicare patients for ozone-related hospital admissions for four cardiovascular and respiratory outcomes (myocardial infarction, ischemic stroke, atrial fibrillation and flutter, and pneumonia) between 2000 and 2016. The study found that long-term ozone exposure was associated with an increased risk of hospital admission for pneumonia by 0.00413% (95% CI, 0.00376– 0.00447) for each 1 ppb increase in long-term exposure. The maximum 8-hour ozone exposure level considered in the study was 65.09 ppb, and at lower concentrations ozone exposure increased the probability of hospital admission with larger effect estimates than the primary results This study deployed a doubly robust additive model and adjusted for co-pollutant exposures and many potentially confounding variables including age, race, sex, region, distance to hospital, income, education, BMI, and smoking status.

In the Final Rule, EPA contends that "the $O_3$ concentrations most likely to contribute to health effects are the higher concentrations" yet these recent studies show that long-term exposures at levels well below 70 ppb contribute to widespread population health harms. 85 Fed. Reg. 87,300. The recent studies build upon the existing body of evidence and coherently demonstrate significant causal links between long-term exposure to ozone and adverse health outcomes. In its Final Rule, EPA arbitrarily did not establish a long-term exposure standard despite robust evidence that doing so would benefit human health.

c. EPA does not purport to comply with the Clean Air Act because it does not ensure the absence of adverse effects on sensitive individuals.

In the Final Rule, the Administrator highlights "the populations for which the evidence indicates increased risk" as including "people with asthma, children and outdoor workers, among other groups." *Id.* at 87,290. He concludes that the current primary standard "provides the requisite protection of the public health with an adequate margin of safety, including for at-risk populations," *id.* at 87,300, and the current exposure and risk analysis results describe "appropriately strong protection of at-risk populations from exposures associated with $O_3$-related health effects." *Id.* at 87,306. This does not even claim to meet the Act's requirements: "NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children, and if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *Coal. of Battery Recyclers Ass'n*, 604 F.3d at 618; *accord Am. Lung Ass'n*, 134 F.3d at 389 ("NAAQS 'must be set at a level at which there is "an absence of adverse effect" on [] sensitive individuals'" (alteration in original; quoting *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980)). Whatever constitutes "appropriately strong protection" is not the same as assuring the "absence of adverse effect," as required. *Id.*

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[17] Danesh Yazdi, Mahdieh, Yan Wang, Qian Di, Yaguang Wei, Weeberb J. Requia, Liuhua Shi, Matthew Benjamin Sabath, et al. "Long-Term Association of Air Pollution and Hospital Admissions Among Medicare Participants Using a Doubly Robust Additive Model." *Circulation* CIRCULATIONAHA.120.050252 (Feb. 22, 2021). https://doi.org/10.1161/CIRCULATIONAHA.120.050252.

The 1970 Clean Air Act Amendments made clear that the millions of Americans with respiratory ailments are just as entitled to the protection of the NAAQS as those without respiratory conditions: "Included among those persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment." S. Rep. No. 91-1196, at 10 (1970). As the D.C. Circuit has explained:

> In its effort to reduce air pollution, Congress defined public health broadly. NAAQS must protect not only average healthy individuals, but also "sensitive citizens" – children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution.

*Am. Lung Ass'n,* 134 F.3d at 389 (citations omitted); *Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA*, 686 F.3d 803, 810 (D.C. Cir. 2012). NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals." *Lead Indus. Ass'n*, 647 F.2d at 1153.

EPA must also build into the NAAQS an adequate margin of safety for these sensitive subpopulations. *See Am. Farm Bureau Fed'n*, 559 F.3d at 526. The Administrator must also rationally explain (as he has not in the Final Rule) how the standard provides requisite protection for sensitive populations. *Am. Lung Ass'n*, 134 F.3d at 392–93.

In its Proposed Rule, response to comments, and Final Rule, the Agency has refused to directly confront the coherent body of science, both from the 2020 and the 2015 review, that mandates a standard set below 70 ppb. The Agency fails to address its own analysis showing that a lower standard would significantly reduce exposures of concern for sensitive groups, much less the same information in the Comments. Even if this failure was itself not arbitrary, EPA fails to articulate a rational basis for rejecting lower standards, which substantially reduce and nearly eliminate exposures of concern for children and children with asthma—two important sensitive groups.[18] For the reasons given above, EPA's decision not to strengthen the standards is arbitrary and must be reconsidered. Further, given the evidence available to the Agency, its decision is unlawful under the Clean Air Act and further merits reconsideration.

d. EPA's exposure and risk analysis is arbitrary.

EPA provides new arguments in an attempt to bolster its fatally flawed reliance on the exposure and risk assessment. These arguments are meritless.

Comments explained various ways in which the exposure and risk assessment arbitrarily failed to rationally consider the harms EPA predicted various standard levels would allow on

[18] And by association, outdoor workers, for whom the Agency acknowledges that it uses the exposure of children as an imperfect substitute. *See, e.g.*, 85 Fed. Reg. 87,298 n.134 ("while as recognized in multiple reviews, outdoor workers are also at risk, the EPA has focused, in past reviews as in the current one, on children, the population group for which the analysis estimates in terms of percentage of population are greatest (PA, section 3.4.2). Accordingly, providing protection for this population group will provide protection for other at-risk populations as well.")

sensitive populations, like outdoor workers and children at summer camps. Comments at 46-51. Importantly, these populations spend time outside day after day. In the Final Rule, EPA now offers irrational excuses for how it examined these populations. For outdoor workers, EPA claims "uncertainties" and "data limitations"—which didn't prevent it from providing some analysis for this sensitive population in 2014—now purportedly led it to do no new analysis, but instead to "expect[]" its 2014 results "might" still hold. 85 Fed. Reg. 87,276/2 n.81, 87,298/1-2. EPA cannot rationally rely on generic uncertainties. Further, elsewhere, EPA touts the improvements in this health risk and exposure assessment compared with the 2014 version. *E.g.*, *id.* at 87,278/1-2. EPA's wan "expect[ation]" of perhaps similar results thus lacks rational basis. Thus, EPA's failure to analyze ozone's impacts on the important, acknowledged sensitive population of outdoor workers is arbitrary.

As for children at summer camps, EPA does not claim it actually gave that population any consideration at all. Instead, it says "to the extent that the behaviors of such children…are represented in the [consolidated human activity database ("CHAD")], they are represented among the at-risk populations of children and children with asthma that were simulated in the exposure/risk analyses." *Id.* at 87,298/1 n.133. EPA thus leaves unanswered the key questions of <u>whether</u> such behaviors are actually represented in the CHAD and, to the extent they are not, what EPA did to rationally fill the gap. Further, even if these behaviors are represented in the CHAD, EPA fails to explain how protecting such children by protecting a less sensitive population provides requisite protection to the more sensitive population. *See id.*; *see also id.* at 87,298/1 n.132 (EPA makes similar argument about "athletes, hikers and others who exercise outdoors, using their full lung capacity," as it does about children at summer camps).

Finally, EPA's new approach to the impact of averting behavior, where people respond to harmful ambient levels of ozone by avoiding outdoor activities, is unlawful and irrational. First, EPA appears to contend that standards need not protect people who are "refraining from normal activity or resorting to medical interventions to ward off adverse effects of poor air quality." Response to Comments at 14 (quoting S. Rep. No. 91-1196, at 10 (1970)), EPA-HQ-OAR-2018-0279-0572. EPA's claim has no valid basis in law. As explained in more detail above and in comments, the Act's entire premise is that the air must be clean enough to breathe safely, so that people—even people who are more vulnerable to air pollution's harmful effects than a healthy young adult—can engage in their ordinary activities. *See, e.g.*, *Am. Lung Ass'n*, 134 F.3d at 388-89. Going against its own mandate, EPA misconstrues a snippet of legislative history. But far from supporting EPA, that legislative history confirms EPA's error. The legislative history makes clear that standards must protect "particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment," but not necessarily "patients in intensive care units or newborn infants in nurseries," who, for other reasons, are not going outside. S. Rep. No. 91-1196, at 10. EPA's redefining "the normal course of daily activity" to exclude periods when the ambient air is dangerously dirty fundamentally undermines the standards and thus the Act. EPA must abandon this illegal position.

Second, EPA points briefly to its "very limited" 2014 analysis of averting behavior and presumes, based on that analysis and unspecified other "available information," that averting behavior "will likely have little effect on the range of exposures generated from the APEX

simulations." Response to Comments at 14-15. Similar to the irrationality of its response to its failure to consider outdoor workers, EPA's explanation here lacks any rational basis: it is unclear what EPA's conclusion rests on, apart from a six-year-old sensitivity analysis carried out with different data and assumptions that EPA acknowledges is itself "very limited."

## III. Grounds for objection regarding the secondary standard

a. EPA unlawfully changed its justification for a 3-year average standard after the close of the public comment period.

Between the Proposed Rule and the Final Rule, EPA unlawfully changed its justification for using a 3-year average for the secondary standard instead of the 2014 expert CASAC's recommendation of a W126 single-year average. In the Proposed Rule, EPA asserted that a "3-year average was identified for considering the seasonal W126 index based on the recognition that there was year-to-year variability" in environmental factors that contribute "uncertainties" in the "projections of the potential for harm to public welfare." 85 Fed. Reg. 49,900. This 3-year average was based on EPA's claim in the PA that "the evidence that allows for specific evaluation of the predictability of growth impacts from single-year versus multiple-year average exposure estimates is quite limited." *Id.* at 49,901. Based on this purported uncertainty, the Administrator stated that the available evidence supported "a conclusion that it is reasonable to use a seasonal RBL averaged over multiple years, such as a 3-year average." *Id.* at 49,910.

But in the Final Rule, EPA added an additional justification for the use of a 3-year average metric: protection against what EPA newly deems "unusually damaging years." *Id.* at 87,325. Underlying this criterion is an EPA staff memo by Benjamin Wells, "Additional Analyses of Ozone Metrics Related to Consideration of the Ozone Secondary Standard," dated December 16, 2020, and uploaded to the docket on December 31, 2020, the same day EPA released its Final Rule. EPA used the memo—which analyzes various ambient air monitoring data "relat[ed] to the form and averaging time of the current secondary standard"[19]—to conclude that "the form and averaging time of the current standard is effective in controlling peak hourly concentrations and that a W126 index based standard would be much less effective in providing the needed protection against years with such elevated and potentially damaging hourly concentrations." 85 Fed. Reg. 87,340. The public has had no opportunity to challenge or analyze this conclusion, which forms a core basis for EPA's use of a 3-year average form. Petitioners object to EPA's conclusion and the use of the Wells memo without exposing them to public comment.

EPA's "last-minute addition to the record of a study which constituted [a] basis for the final secondary standard is disturbing," and requires reconsideration under 42 U.S.C. § 7607(d)(7)(B). *Am. Petroleum Inst. v. Costle,* 665 F.2d 1176, 1190 (D.C. Cir. 1981). As stated above, under § 7607(d)(7)(B), the Administrator must grant a petition for reconsideration if a petitioner "can demonstrate to the Administrator that it was" either (1) "impracticable" to raise

[19] Memorandum from Benjamin Wells, EPA, on Additional Analyses of Ozone Metrics Related to Consideration of the Ozone Secondary Standard to Ozone NAAQS Review Docket (EPA-HQ-OAR-2018-0279) at 2 (Dec. 16, 2020) ("Wells memo").

an objection or (2) "if the grounds for such objection arose after the period for public comment." In addition, the objection must be "of central relevance to the outcome of the rule." 42 U.S.C. § 7607(d)(7)(B).

Here, Petitioners meet both procedural prongs of § 7607(d)(7)(B), and their objection is centrally relevant to the outcome of the rule. First, it was impracticable for Petitioners to raise an objection to EPA's new analysis or the conclusion of the Wells memo, because, as discussed below, its conclusion was not a logical outgrowth of the data analyzed in the Proposed Rule. *See Portland Cement Ass'n*, 665 F.3d at 188 ("when an agency is simultaneously in control of both defining the universe of relevant data and of applying that data to a given rulemaking, it cannot allow itself to do the latter without having already done the former."). And Petitioners could not have anticipated that EPA's rejection of the W126 standard would be based on an analysis of "peak concentrations that may contribute to 'unusually damaging years' for vegetation," 85 Fed. Reg. 87,340, when the Proposed Rule was explicit that the decision was based on perceived uncertainty with other data. 85 Fed. Reg. 49,910–11 (justifying the 3-year average based on uncertainty, imprecision, or inexactitude without reference to "unusually damaging years"); *see, e.g.*, *Chesapeake Climate Action Network*, 952 F.3d at 320–21 ("EPA gave no notice that it would analyze any best performing stringency requirements, so EPA cannot now claim that Petitioners were on notice of how EPA would ultimately analyze such issues.") Second, Petitioners' objection to EPA's new analysis and the Wells memo arose after the public comment period had already been closed for two months. 42 U.S.C. § 7607(d)(7)(B). Indeed, EPA placed the memo on the docket on the same day that it announced the Final Rule. And, as stated above, EPA used its new analysis and the Wells memo to avoid basing its decision to use the 3-year average on uncertainty alone, making them centrally relevant to its decision to maintain the current standard. Considering this procedural failing, EPA must reconsider the Final Rule.

Furthermore, EPA's changed rationale and use of the Wells memo was prejudicial and unlawfully violates fundamental notice and comment requirements. As explained below, EPA critically changed the justification for the metric used to measure the protection of vegetation from ozone's effects in violation of basic notice-and-comment requirements. *See Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 201 (D.C. Cir. 2007) ("[T]he failure to provide an opportunity for comment on [a] model's methodology… constitutes a violation of the APA's notice-and-comment requirements.").

Nor are EPA's new rationale and the Wells memo themselves rational, as explained below. EPA's new claim that "unusually damaging years" are somehow distinct from the biologically relevant W126 metric has no rational basis in the expert CASAC's recommendations that the D.C. Circuit held in *Murray Energy* that EPA flouted. Even if that EPA claim were not meritless, the N100 metric analysis EPA uses to justify retaining the current standard was itself not exposed to public comment and is also arbitrary. Further, there are significant issues with EPA's assertions about the E-R functions as justification for 3-year averaging. For these reasons, among others, EPA must grant this petition for reconsideration.

i. EPA newly misconstrues the W126 standard and how it captures cumulative seasonal exposure impacts.

EPA has bifurcated the advice from CASAC on protecting vegetation from "unusually damaging years" from the context it was given, which is explicitly linked to the W126 metric, which directly addresses the cumulative effects of ozone exposure on vegetation. EPA's failure does not satisfy EPA's requirements under the *Murray Energy* remand. *See Murray Energy Corp. v. EPA*, 936 F.3d 597, 617 (D.C. Cir. 2019) ("EPA has not demonstrated how its chosen benchmark protects against 'unusually damaging years that will be obscured in the average.'"). The 2014 CASAC Letter, cited in n.1 above, that articulated the need for a stronger W126 standard if EPA chose to use a 3-year average rather than the scientifically justified 1-year value was based on a form of standard that is cumulative. As the Letter shows, CASAC clearly prefaced this advice with their opposition to the 3-year averaging and their scientific justification for the biologically relevant 1-year standard based on extensive data analysis and evaluation of W126 forms and levels and the impact on vegetation.

ii. The Wells memo is based on a flawed analysis that cannot withstand scientific rigor.

The Wells memo and data analysis are flawed and cannot be rationally used to justify a 3-year averaging form for the secondary standard. First, Wells's analysis focuses on the use of N100, which neither EPA nor even the current CASAC discuss as a metric in the Policy Assessment or proposal. The ISA reports only one study's use of the N100 metric in terms of foliar injury and only in combination with the SUM60 cumulative standard. *See* ISA tbl.8-4. Instead, past reviews have focused on a cumulative standard form as necessary to reflect the impacts to vegetation, citing the W126 metric by itself as an appropriate form of standard to protect against ozone impacts. *See* PA (2014) at ES-9, 5-73, EPA-HQ-OAR-2018-0279-0058. Second, the Wells memo introduces a new metric, D100, as the number of days with one or more hours at or above 100 ppb. Wells memo at 4. This D100 metric has never been evaluated in the scientific literature or past reviews. EPA's attempt to introduce this metric through the Wells memo is arbitrary; and therefore, the D100 metric should not be considered until a rigorous scientific review has been conducted on its utility.

Furthermore, based on the description of the N100 metric on page 4 of the memo, it is unclear what hours of the day are included in its calculation. Wells states that "the N100 metric was calculated as the maximum number of hours with an hourly $O_3$ concentration of 100 ppb or greater in the three consecutive calendar months yielding the highest number in a given year." The reason why it is important to note which hours of a day are included in a metric is because at some mountain and downwind sites, the transport of ozone and precursors can result in late evening or overnight maximums. But the Wells memo leaves this critical data point of the N100 metric undefined, and so commentators cannot know if the metric was calculated using all hours of the day, was restricted to the 17 hours used for the 8-hr primary standard, or was restricted to the 12 hours used for the W126 calculations that approximate daylight hours. This specificity would also illuminate the comparisons with other metrics if indeed they were appropriate. The N100 metric in the memo is also limited to three consecutive months, diminishing its utility to appropriately reflect peak ozone conditions throughout the growing season. The National Park

Service reports N100 hours across the full 7-month growing season in combination with W126.[20] At the very least, the N100 summing window should match the metric that it is being compared against; yet as discussed below some of the comparisons made in the memo are also nonsensical.

The Wells memo lays out a goal to describe the relationships between metrics including N100 compared to the W126 and the annual 4th highest daily maximum 8-hour $O_3$ concentration, averaged over 3 consecutive years, known as the "4th max metric." Comparing N100 to W126 has no scientific basis, as the two metrics were never meant to be singular but only to complement each other.[21] And of course, a metric that looks at maximum 8-hour average daily values would be more similar to a metric based on maximum hourly values than to one that is cumulative. Even if we were to assume that it is appropriate to examine how the N100 compares to the 4th max metric, then we must also consider that the N100 is limited to a 3-month period while the 4th max is not. Finally, the analysis provides little justification for the 4th max metric alone—even if a good proxy for N100—being sufficient to protect vegetation, as it disregards the need for a metric that protects against cumulative impacts of ozone. Indeed, another fundamental flaw in EPA's analysis—which applies not just to this issue of averaging period but also to all other vegetation-related aspects of the secondary standard—is that it pretends the choice here is between the 4th max metric alone and a W126 cumulative standard (over whatever averaging period); in reality, it is between the 4th max metric alone and the 4th max metric in addition to a W126 cumulative standard. It is thus irrational for EPA to use the 4th max metric to justify rejecting the W126 standard when both could be in place.

iii. EPA's analysis that a 3-year average for the standard is compatible with the E-R functions is irrational.

In addition to the irrationality of relying on the Wells memo, EPA's analysis of the E-R curves does not justify using a 3-year average for the secondary standard. For example, EPA argues that the E-R function methodologies supports its 3-year averaging approach because E-R functions themselves were based on exposures that spanned multiple years. 85 Fed. Reg. 87,326. These composites were originated by Lee and Hogsett (1996) from Weibull curves from 51 seedling cases, which included 11 tree species, and had a mix of exposure durations. PA app.4A. Of the 51 cases, none spanned 3 years, 22 spanned over 2 years, while 29 were conducted within 1 year. Actual exposure days for 2-year experiments ranged from 75–555 days, with 11 out of the 22 cases having exposures less than 120 days, which implies that the exposure within a year could be 60 days or less. In order to calculate composites across experiments for the same species (or across all cases) the curves were standardized to a 92-day W126. This standardization

[20] Kohut, Robert J., National Park Service, "Field Surveys to Assess Foliar Ozone Injury on Plants in National Parks and Monuments on the Colorado Plateau," *Natural Resource Report* (May 2020). It is worth noting that the National Park Service (NPS) also reports EPA derived 3-month W126 metric alone in addition to the 7-month W126 plus N100 combination. The thresholds for these two sets of metrics differ greatly based on previous literature. NPS cites EPA 2010 proposed W126 3-month standard thresholds in the range of 7–15 ppm-hours to protect vegetation and 5–9 ppm-hours for foliar injury.

[21] Lefohn, Allen S. et al, "Effect of Surface Ozone Exposures on Vegetation Grown in the Southern Appalachian Mountains: Identification of Possible Areas of Concern." *Atmospheric Environment*, no. 31, (Mar. 1997): 1695-1708.

is not an averaging process but instead is a simple linear prorating approach to adjust to a standard exposure window. Predicted relative biomass loss as a function of W126 was calculated and then the species median response at different W126 levels used to fit the final curve for each species. EPA fails to rationally explain how the normalization step and data reduction procedure justifies averaging a W126 metric across 3 years, nor has EPA rationally explained how it justifies selecting the current standard level and form. E-R functions that are composite median values already reduce the variance within the datasets and are only one piece of evidence to be considered in setting a standard form and level.

b. EPA's reliance on its own Aspen analysis is flawed.

Commenters provided a detailed critique of EPA's analysis in the PA that applied the Aspen E-R curves to varying W126 levels based on the impacts found in King et al (2005). EPA claims that the analysis that compared E-R derived relative biomass loss (RBL) for Aspen to actual observation from King et al. (2005) in the 2013 and 2020 ISAs supports their 3-year averaging form of the standard. EPA's assertion that a 3-year average is compatible with the E-R methodology because it is normalized across multiple seasons is irrational because it does not even apply to the Aspen data. All of the 14 E-R curves for Aspen that were used in the composite spanned only one season ranging from 82-114 day exposure durations. *See* ISA tbl.8-23. Therefore, the Aspen E-R curves do not support EPA's claim that E-R functions themselves based on multiple years justify a 3-year averaging form.

EPA itself notes that the yearly approach taken in 2020 analysis, shown in Figure 8-17 on page 8-193 of ISA 2020 "indicat[es] a somewhat less tight fit to the experimental observations," compared to the cumulative approach presented in ISA 2013 shown in Figure 9-20 of that document. This implies that the cumulative approach that accounts for yearly variation or higher years and carry over, is a better approach than assuming there is no such impact.

Each species' E-R curves, even as species composites, have different shapes and may differ from the Aspen example. PA app.4A at 4A-3 to -9. Therefore, the exposure level represented and derived RBL in the Aspen example may play out differently for different species within a season or cumulatively across seasons. This one species provides one piece of evidence but should not dictate the form of the standard.

c. EPA failed to remedy the issues from the *Murray Energy* remand with regard to visible leaf damage and other areas where EPA finds there to be uncertainty.

While EPA found that its data indicated that the "risk of [visible foliar] injury. . . to be higher at the highest W126 index values," it nevertheless concluded that there was "uncertainty" with this data that precluded it from issuing an "appropriate metric (or metrics) for quantifying $O_3$ exposures." 85 Fed. Reg. 87,315. This conclusion fails to remedy EPA's error from the *Murray Energy* court's remand.

In *Murray Energy*, the D.C. Circuit held that EPA's decision not to set a target level to protect against visible leaf damage during the 2015 review was arbitrary and capricious. 936

F.3d at 620. CASAC had advised EPA of its "scientific judgment" that "a level of 10 ppm-hrs is required to reduce foliar injury." *Id.* at 618 (quoting CASAC). But EPA rejected this advice in the final rule, and instead EPA concluded that there were too many "uncertainties and complexities" in the evidence to specify a level of air quality to protect against foliar injury. 80 Fed. Reg. 65,407-08. The court rejected EPA's reasoning, holding: (1) that EPA must explain what evidence is available and rationally explain how it reached the conclusion that this evidence leaves EPA "unable to choose a level at all"; and (2) that "[w]here CASAC has 'reached a scientific conclusion that adverse [welfare] effects [are] likely to occur,' EPA must, 'explain why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it.'" *Murray Energy*, 936 F.3d at 619 (quoting *Mississippi*, 744 F.3d at 1357).

Petitioners' comments explained how EPA continues to violate the Clean Air Act when it fails to exercise its judgment about what level of air quality is requisite to protect the public welfare. *See* Comments at 74–80. But in the Final Rule, EPA unlawfully and arbitrarily persists in failing to identify a level at which ozone's effects on visible leaf damage would be adverse—as required by the court in *Murray Energy*. 85 Fed. Reg. 87,344.

Furthermore, EPA states that its decision to not set a standard is also based on perceived uncertainties on soil moisture. *See* 85 Fed. Reg. 87,314/1. But soil moisture is just a risk factor that may or may not make a site and its plants at risk, not a determinant in the threshold. Soil moisture status does not cause the injury: ozone does. Even if soil moisture could be considered causal also, the mere fact that air pollution is one of many causes of an adverse impact does not relieve EPA of its obligation to protect the public welfare against adverse effects from air pollution. *See, e.g.*, 42 U.S.C. § 7408(a)(2)(A). Given the robust data EPA has on foliar injury, the contribution of soil moisture does not prevent EPA from specifying a level of protection. Thus, EPA's decision to decline to specify a secondary standard protective against foliar injury based on soil moisture is unlawful and arbitrary.

d. EPA failed to rationally consider the climate impacts of the secondary NAAQS.

In the Final Rule, EPA arbitrarily relies on supposed uncertainty to avoid setting the secondary NAAQS at a protective level consistent with the need to address global climate change. See 85 Fed. Reg. 87,337. ("[T]he significant limitations and uncertainties summarized here together preclude identification of an $O_3$ standard that could be judged to provide requisite protection of the public welfare from adverse effects linked to $O_3$ influence on radiative forcing, and related climate effects.")

But the important facts about ozone's climate impacts are known. First, it is clear that ozone has a strong warming impact, especially in Northern mid-latitudes (where the United States is) and in the Arctic. Second, whatever its exact radiative forcing, ozone is the third strongest greenhouse gas. Third, it is well-established that ozone formation is reduced through decreases in emissions of methane, nitrogen oxides, carbon monoxide and VOCs. As EPA

acknowledges, reducing these precursors would significantly benefit public health as well as climate. Finally, ozone's harmful effects on vegetation growth negatively affects carbon sequestration, thus further exacerbating climate change. Consequently, EPA must consider the direct as well as indirect climate impacts of ozone when it makes judgment about reconsidering the secondary standard.

## IV. Conclusion

For the foregoing reasons, Petitioners respectfully request that the Administrator expeditiously reconsider the Final Rule.

Sincerely,

**American Academy of Pediatrics**
**American Lung Association**
**American Public Health Association**
**Appalachian Mountain Club**
**Clean Air Task Force**
**Chesapeake Bay Foundation**
**Earthjustice**
**Environment America**
**Environmental Defense Fund**
**Environmental Law & Policy Center**
**National Parks Conservation Association**
**Natural Resources Defense Council**
**Sierra Club**

# Attachments

## Attachments

1. Comments, EPA-HQ-OAR-2018-0279-0444

2. Letter to Hon. Gina McCarthy from Clean Air Scientific Advisory Committee, "CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards," (June 26, 2014) (EPA-CASAC-14-004)

3. Index of Scientific Studies Included in Footnote Citations

# Attachment 1

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

| Review of the National Ambient Air Quality Standards for Ozone, 85 Fed. Reg. 49,830 | Docket ID No. EPA–HQ–OAR–2018–0279 Submitted via Regulations.gov, Oct. 1, 2020 |
|---|---|

Appalachian Mountain Club, Clean Air Task Force, Earthjustice, Environmental Defense Fund, Environmental Law and Policy Center, Natural Resources Defense Council, National Parks Conservation Association, and Sierra Club ("NGO Commenters") respectfully submit the following comments on the Environmental Protection Agency's ("EPA") "Review of the Ozone National Ambient Air Quality Standards," 85 Fed. Reg. 49,830 (Aug. 14, 2020). Our organizations represent millions of members and supporters across the country who are deeply concerned about the health, environmental, and economic impacts of air pollution and support implementation of strong, science-based National Ambient Air Quality Standards ("NAAQS") that ensure public health and the environment are protected. As the undersigned organizations explain, EPA must revise its Proposal for both the primary and secondary ozone standard to no higher than 60 ppb and 7 ppm-hrs (single-year W126 metric), respectively, propose a primary standard that directly addresses long-term ozone exposure, and then reopen the comment period.

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## I. INTRODUCTION

Ozone, the principal component of smog, is one of the most dangerous and persistent forms of air pollution in the United States today. Scientists link ozone to premature deaths, thousands of emergency room visits, and tens of thousands of asthma attacks each year. Ozone is especially dangerous to small children, people with asthma and senior citizens, who are often warned to stay indoors on polluted days. Also, as well as being a greenhouse gas, smog pollution can severely damage forests and plants, stunting their growth, increasing the risk of tree die-off from disease, and causing harms that affect whole ecosystems. Hundreds of counties throughout the nation suffer from unsafe ozone levels.

The Clean Air Act requires the U.S. Environmental Protection Agency to set primary National Ambient Air Quality Standard (NAAQS) for ozone pollution at a level that protects public health with an adequate margin of safety, and it requires the nation to then achieve compliance with that level of air pollution. EPA's review of the NAAQS must "accurately reflect the latest scientific knowledge." 42 U.S.C. § 7408(a)(2). The review must be "thorough." *Id.* § 7409(d)(1). EPA's Proposal to retain the current standard of 70 ppb, set in 2015, does not reflect this knowledge and is not requisite to protect public health with an adequate margin of safety.

Just as it was true in 2015 that an extensive body of scientific literature unequivocally documented the need for a standard set below 70 ppb, so too does the literature continue to reflect that need today. Despite the fact this body of evidence has only grown since the last review, EPA's Proposal declines to set the standard at the level the statute's directive demands. It fails to meaningfully engage with the body of evidence that mandates strengthening the standard, provides no margin of safety, and is the result of a review process rife with flaws.

Though we identify numerous technical flaws in EPA's Proposal, just as importantly, EPA's proposed standard cannot be squared with the mandates of the Clean Air Act simply because it in essence requires people—especially sensitive populations such as children—to stay indoors to avoid exposures to levels of air quality that the scientific literature has repeatedly shown to be unhealthful. This is all the more problematic because some people do not have an option to limit outdoor activity, such as the nearly 9 million workers whose jobs require them to be out of doors all day.

In addition, a weak ozone standard poses a unique injustice to low-income communities and communities of color. Across the nation, people of color are consistently overrepresented in areas with higher ozone levels and that are in nonattainment of ozone NAAQS. Furthermore, across the nation the asthma burden of people of color—particularly among Blacks—is far higher than that of whites. The Proposal acknowledges as much. EPA must adopt a 60 ppb standard if it is to protect these communities. This mandate has never been more urgent, as we also know that communities of color currently face a disproportionately high risk from COVID-19. Doubly burdening these communities in the midst of a respiratory pandemic is unconscionable, and further counsels for strengthening the standard.

Ultimately, the Clean Air Act promises Americans that anyone can go outside whenever they want, for as long as they want, and where air quality is attaining the NAAQS it will be safe for them to breathe. EPA must adopt a level no higher than 60 ppb if EPA is to fulfill this promise. EPA must also adopt a standard that directly targets long-term ozone exposure, which the science shows adversely affects public health and which the 8-hour standard does not control.

As for the secondary, welfare-protective, standard, EPA's attempt to once again reverse engineer the secondary standard to precisely match the primary is unlawful and arbitrary. Rather than once again try to twist the science about how ozone harms plants—over the course of a multi-month season—so that it fits with the science about how EPA acknowledges ozone harms people—through short-term exposures, measuring in hours—EPA must set a standard that is scientifically justified. The only Clean Air Scientific Advisory Committee (CASAC) panels with relevant expertise to review the secondary standard concluded that such a standard must be of the W126 form. Nothing has changed to undermine that conclusion. Accordingly, to protect plants against a range of harms that include growth loss, loss of carbon sequestration capacity, crop yield loss, and visible leaf damage, that W126 standard must be no higher than 7 ppm-hours, measured as a 3-month average.

## II. EPA'S LEGAL OBLIGATIONS IN SETTING AND REVIEWING THE NAAQS

### A. Overview of the Clean Air Act's requirements for primary NAAQS

The Clean Air Act Amendments of 1970 first introduced the requirement to establish enforceable NAAQS. The amendments were intended to be "a drastic remedy to what was perceived as a serious and otherwise uncheckable problem of air pollution." *Union Electric Co. v. EPA*, 427 U.S. 246, 256 (1976). The 1970 amendments "carrie[d] the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health." 116 Cong. Rec. 42,329, 42,381 (Dec. 18, 1970) (remarks of Sen. Muskie).

The NAAQS drive the Clean Air Act's requirements for controlling emissions of conventional air pollutants. Once EPA establishes NAAQS, states and EPA identify those geographic areas that fail to meet the standards. 42 U.S.C. § 7407(d). Each state must prepare an "implementation plan" designed to control pollutant emissions in order to reduce the ambient concentrations of the pollutant to below the level of the NAAQS and maintain that improved air quality. *Id.* § 7410.

The Clean Air Act provides a clear process for establishing the NAAQS. The first step involves identifying those pollutants, the "emissions of which, in [EPA's] judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," and "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources." *Id.* § 7408(a)(1)(A), (B). Once EPA identifies a pollutant, it must select a

NAAQS that is based on air quality criteria that "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." *Id.* § 7408(a)(2).

Primary NAAQS must be set at a level "requisite to protect the public health" with "an adequate margin of safety." *Id.* § 7409(b)(1). To ensure that the NAAQS keep pace with scientific understanding and continue to provide the necessary protection, EPA must review and revise as appropriate the underlying air quality criteria and the NAAQS themselves at least every five years. *Id.* § 7409(d)(1). Any primary NAAQS that EPA promulgates under these provisions must be adequate to protect public health and provide an adequate margin of safety, in order to prevent not only any known or anticipated health-related effects from polluted air, but also those that are scientifically uncertain or that research has not yet uncovered. Further, the statute makes clear that there are significant limitations on the discretion granted to EPA in selecting a level for the NAAQS. In exercising its judgment, EPA must err on the side of protecting public health, and may not consider cost or feasibility in connection with establishing the level of the NAAQS and its other elements (e.g., indicator, the form of the standard, and averaging time). The D.C. Circuit summed up EPA's mandate succinctly:

> Based on these comprehensive [air quality] criteria and taking account of the "preventative" and "precautionary" nature of the act, … the Administrator must then decide what margin of safety will protect the public health from the pollutant's adverse effects – not just known adverse effects, but those of scientific uncertainty or that "research has not yet uncovered." … Then, and without reference to cost or technological feasibility, the Administrator must promulgate national standards that limit emissions sufficiently to establish that margin of safety.

*Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *see also Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 464–71 (2001). Each of these requirements is discussed in more detail below. Unless otherwise indicated, we discuss legal requirements for secondary standards in the section addressing those standards.

### B. EPA's prior implementation of the primary ozone NAAQS

One of the first pollutants for which EPA adopted NAAQS was ozone, a principal component of urban smog, and a severe lung irritant even to healthy adults. *See* 66 Fed. Reg. 5,002, 5,012–13 (Jan. 18, 2001). The first predecessor to the current primary ozone NAAQS was promulgated in 1971 at 0.08 ppm, averaged over one hour. 36 Fed. Reg. 8,187 (April 30, 1971). *See Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1182 (D.C. Cir. 1981) (though the 1971 standard was nominally addressed to photochemical oxidants, compliance was gauged by

measuring only ozone). In 1979, EPA relaxed this standard to 0.12 ppm, also averaged over one hour. 44 Fed. Reg. 8,220 (Feb. 8, 1979).

Subsequently, a growing body of peer-reviewed scientific evidence emerged, documenting the inadequacy of the 1979 standard to protect public health with an adequate margin of safety. However, despite the Act's express mandate to review and (as appropriate) revise NAAQS at intervals of no greater than five years, 42 U.S.C. § 7409(d)(1), EPA failed to consider the new evidence, or to revise the NAAQS to reflect it. 58 Fed. Reg. 13,008, 13,013 (Mar. 9, 1993) (EPA "missed both the 1985 and 1990 deadlines for completion of [ozone NAAQS] review cycles under section 109(d)"). Even after being sued by the American Lung Association and ordered to complete a review of the NAAQS, EPA issued a final decision that still refused to consider the new evidence—and declined to revise the NAAQS. 58 Fed. Reg. at 13,008, 13,013–14, 13,016. When that decision was challenged in the D.C. Circuit, EPA sought and received a voluntary remand to consider the new science. Order of June 27, 1994 in *American Lung Association v. Browner*, D.C. Cir. No. 93-1305.

EPA completed a NAAQS review considering that evidence in 1997, many years after the scientific understanding developing in the early 1980s had coalesced. That review produced the 1997 eight-hour NAAQS, at 80 ppb (equivalent to 84 ppb under standard rounding conventions[1]). 62 Fed. Reg. 38,856 (July 18, 1997). After several years of litigation, the D.C. Circuit upheld the standard against industry challenge. *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355 (D.C. Cir. 2002); *see also Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027 (D.C. Cir. 1999), *reh'g granted in part and denied in part*, 195 F.3d 4 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001).

In 2002, EPA failed again to timely review and revise the 1997 NAAQS, leading to another suit forcing it to carry out its mandatory duty under 42 U.S.C. § 7409(d). *Am. Lung Ass'n v. Whitman*, No. 03-CV-778 (D.D.C.). In the review process, CASAC, the expert body charged with reviewing the air quality criteria and NAAQS and making scientific recommendations on them, unanimously found that the primary NAAQS should be revised to a level between 60 and 70 ppb. In 2008, EPA disagreed with CASAC's recommendations and set the primary standard at 75 ppb. 73 Fed. Reg. 16,436 (Mar. 27, 2008).

Soon thereafter, EPA itself raised concerns about whether its 2008 standards complied with the Act and began a reconsideration of the NAAQS. In early 2010, based solely on the information already before it, EPA proposed to strengthen the primary NAAQS to somewhere within the CASAC-recommended range of 60–70 ppb. 75 Fed. Reg. 2938 (Jan. 19, 2010). The Proposal stated that the Administrator "judge[d] that a standard level of 0.075 ppm is not sufficient to provide [health] protection with an adequate margin of safety." *Id.* at 2996. Then-Administrator Lisa Jackson proposed a standard set at 65 ppb, based on the advice of CASAC.

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[1] *Mississippi v. EPA*, 744 F.3d 1334, 1344 (D.C. Cir. 2013).

The White House declined to finalize that proposed reconsideration, instead assuring the D.C. Circuit that it would address the reconsideration when it completed its next review and revision of the ozone NAAQS. *See Mississippi v. EPA*, 744 F.3d 1334, 1341–42 (D.C. Cir. 2013). Ultimately, the D.C. Circuit upheld the 2008 standard. *Id.* at 1342.

The 2008 standard was due for review and revision in 2013. Because EPA again missed its deadline, American Lung Association, Sierra Club, and others sued EPA and obtained an order requiring EPA to complete its review by October 1, 2015. Order, *Sierra Club v. EPA*, No. 13-CV-2809 (N.D. Cal. Apr. 30, 2014).

In its 2014 review of the science, the CASAC again concluded that the 2008 standard of 75 ppb was insufficient to protect public health. The panel again recommended a lower standard, in the range between 60 and 70 ppb. Further, it concluded that

> based on the scientific evidence, a level of 70 ppb provides little margin of safety for the protection of public health, particularly for sensitive subpopulations… At 70 ppb, there is substantial scientific evidence of adverse effects as detailed in the charge question responses, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard, it may not meet the statutory requirement to protect public health with an adequate margin of safety.2

Most importantly, the panel's policy advice was "to set the level of the standard *lower than 70 ppb* within a range down to 60 ppb." *Id.* (emphasis added). Despite this recommendation, EPA proposed a range only between 65 to 70 ppb. 79 Fed. Reg. 75,234 (Dec. 17, 2014). By its own estimates, a standard set at 65 ppb instead of 70 ppb would have avoided almost 3000 deaths, and 640,000 asthma attacks in children, per year.[3] Despite these overwhelming benefits, the Obama administration completed the 5-year review of the 2008 standard, and strengthened the ozone health standard, to 70 ppb, in October of 2015. 80 Fed. Reg. 65,292 (Oct. 26, 2015).

Various industry groups, states, and environmental groups sued over the 2015 standards. *Murray Energy Corp. v. EPA*, 936 F.3d 597 (D.C. Cir. 2019). Industry petitioners argued that EPA failed to take into account the impact of "background" ozone levels—namely, ozone concentrations that come from sources other than anthropogenic U.S. sources, i.e., from natural sources and from sources in other countries. They also argued that EPA failed to consider economic, social, and energy impacts from lowering the NAAQS. After briefing was complete, the case was held in abeyance for more than a year as the new administration considered whether

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[2] Letter to Hon. Gina McCarthy from Clean Air Scientific Advisory Committee, "CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards" June 26, 2014, pg. 2.

[3] U.S. EPA, Regulatory Impact Analysis of the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone, EPA-452/P-14-006, Nov. 2014, Table ES-7.

to revisit the standard. In 2019, a three-judge panel unanimously upheld the primary standard and rejected the industry arguments. In rejecting those argument, the Court held that the Clean Air Act prohibits EPA from considering the impact of background ozone on attainability of the updated primary and secondary standards, and it also forbids the Agency from considering costs—which industry sought to rename "adverse impacts"—from the revised NAAQS under *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001). The panel also rejected the renewed argument that the Clean Air Act was somehow an unconstitutional delegation of lawmaking authority to EPA. But, as we discuss in depth in a subsequent section, the Court rejected as arbitrary EPA's secondary standard and remanded it, granting environmental groups' petition.

As well as drastically (and arbitrarily) altering the CASAC, as discussed below, then-Administrator Pruitt issued a memo in 2018 that initiated this review and committed the Agency to completing its review of the ozone standard by October of this year.

### C. EPA must issue air quality criteria that accurately reflect the latest scientific knowledge, and the primary NAAQS must protect public health with an adequate margin of safety based on the criteria.

In setting or revising a primary NAAQS, section 109 of the Clean Air Act requires that EPA assure the protection of public health with an adequate margin of safety. This mandate "carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health," 116 Cong. Rec. 42,329, 42,381 (Dec. 18, 1970) (remarks of Senator Muskie).

Standards must be based on an air quality level requisite to protect public health and not on an estimate of how many persons will intersect given concentration levels.[4] EPA interprets the Clean Air Act as providing all people in the United States—including sensitive groups—the opportunity to pursue their normal activities in a healthy environment. 44 Fed. Reg. 8,202, 8,210 (Feb. 8, 1979). Thus, as EPA has acknowledged, it cannot deny protection from the effects of air pollution by claiming that the people experiencing those effects are insufficiently numerous, or that levels that are likely to cause adverse health effects occur only in areas that are infrequently visited.[5] Nor can EPA deny protection against adverse health and welfare effects merely because

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[4] *See* 116 Cong. Rec. 32,821, 32,901 (Sept. 21, 1970) (remarks of Sen. Muskie) ("This bill states that all Americans in all parts of the Nation should have clean air to breathe, air that will have no adverse effects on their health.").

[5] *See* 116 Cong. Rec. 32,981, 33,114 (Sept. 22, 1970) (remarks of Sen. Nelson) ("This bill before us is a firm congressional statement that all Americans in all parts of the Nation should have clean air to breathe, air which does not attack their health."); *see also id.* at 33,116 (remarks of Sen. Cooper) ("The committee modified the President's proposal somewhat so that the national ambient air quality standard for any pollution agent represents the level of air quality necessary to protect the health of persons."); 116 Cong. Rec. 42,329, 42,392 (Dec. 18, 1970) (remarks of Sen. Randolph) ("[W]e have to insure the protection of the health of the citizens of this Nation, and we have to protect against environmental insults—for when the health of the Nation is endangered, so is our welfare, and so is our economic prosperity"); *id.* at 42,523 (remarks of Rep. Vanik) ("Human health and comfort has been placed in the priority in which it belongs—first place.").

those effects are confined to subgroups of the population or to persons especially sensitive to air pollution. *See, e.g.*, *Nat'l Envtl. Ass'n's Clean Air Project v. EPA*, 686 F.3d 803, 810 (D.C. Cir. 2012).

Further, where scientific evidence confirms that, at levels allowed by current NAAQS, adverse effects occur year after year in numerous individuals, risks are by definition "significant" enough to require protection under the Act's protective and precautionary approach. *See* H.R. Rep. No. 95-294, 1st Sess., at 43–51 (1977); *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976) (en banc). That is all the more true where the effects involved include highly serious ones like hospitalization and death. *See Ethyl Corp.*, 541 F.2d at 18 ("the public health may properly be found endangered … by a lesser risk of a greater harm").

**1. EPA is required to establish NAAQS that protect vulnerable subpopulations.**

Importantly, the NAAQS must be set at levels that are not simply adequate to protect the average member of the population, but must also protect against adverse effects in vulnerable subpopulations, such as children, the elderly, socially disadvantaged, those working and exercising outdoors, and people with heart and lung disease. The D.C. Circuit has repeatedly found that if a pollutant's concentration in the ambient air "adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *Am. Lung Ass'n*, 134 F.3d at 390 (citation omitted); *see also Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010); *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 524 (D.C. Cir. 2009). EPA must also build into the NAAQS an adequate margin of safety for these sensitive subpopulations. *See Am. Farm Bureau Fed'n*, 559 F.3d at 526.

The drafters of the 1970 Clean Air Act Amendments made clear that the millions of people in the United States subject to respiratory ailments are entitled to the protection of the NAAQS: "Included among those persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment." S. Rep. No. 91-1196, at 10 (1970). As the D.C. Circuit has explained:

> In its effort to reduce air pollution, Congress defined public health broadly. NAAQS must protect not only average healthy individuals, but also "sensitive citizens" – children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution.

*Am. Lung Ass'n*, 134 F.3d at 390 (citations omitted); *Nat'l Envtl. Dev. Ass'n's Clean Air Project*, 686 F.3d at 810. NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals." *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980).

**2. The adequate margin of safety requirements addresses uncertainties in the scientific information, and EPA must err on the side of protecting public health when there is scientific uncertainty.**

The D.C. Circuit has characterized the NAAQS as "preventive in nature." *E.g.*, *Ethyl Corp.*, 541 F.2d at 15; *see also* H.R. Rep. No. 95-294, at 49-51 (explaining amendments designed *inter alia* "[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs"). The Act's mandate requires that in considering uncertainty EPA "must err on the side of caution" in terms of protecting human health and welfare: "The Act requires EPA to promulgate protective primary NAAQS even where … the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree.'" *E.g.*, *Am. Trucking Ass'ns v. EPA* (*ATA III*), 283 F.3d 355, 369, 378 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38,652, 38,653 (July 18, 1997)).

Thus, in keeping with the precautionary and preventive nature of the NAAQS, EPA must set standards that protect against potential adverse health effects—not just those impacts that have been well-established by science. *See id.* at 369 (citing 1997 Ozone NAAQS, 62 Fed. Reg. 38, 856, 38,857 (July 18, 1997)) (section 109(b)(1)'s "margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information ... as well as to provide a reasonable degree of protection against hazards that research has not yet identified"); *see also Am. Petroleum Inst. v. EPA*, 684 F.3d 1342, 1352 (D.C. Cir. 2012).

In an early seminal case on setting the NAAQS, the D.C. Circuit found that Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." *Lead Indus. Ass'n*, 647 F.2d at 1154. Limited data is not an excuse for establishing a standard that permits adverse effects. To the contrary, "Congress' directive to the Administrator to allow an 'adequate margin of safety' alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful." *Id.* at 1154–55 (quoting H.R. Rep. No. 95-294, at 520 (1977), as reprinted in 1977 U.S.C.C.A.N. 1077, 1480)).

In another case dealing with this same "margin of safety" requirement, the D.C. Circuit rejected industry's argument that EPA was required to document "proof of actual harm" as a prerequisite to regulation, instead upholding EPA's conclusion that the Act contemplates regulation where there is "a significant risk of harm." *Ethyl Corp.*, 541 F.2d at 12–13. The court found that:

> Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, "reasonable medical concerns" and theory long precede certainty. Yet the statutes and commonsense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

*Id.* at 25; *accord Indus. Union Dep't v. Am. Petroleum Inst.*, 448 U.S. 607, 655–56 (1980) (agency need not support finding of significant risk "with anything approaching scientific certainty," but rather must have "some leeway where its findings must be made on the frontiers of scientific knowledge," and may "risk[] error on the side of overprotection rather than underprotection"). As discussed above, EPA must act in the face of "inevitable" scientific uncertainty, *Lead Indus. Ass'n*, 647 F. 2d at 1154, and set standards with a protective and precautionary approach that errs on the side of caution—*i.e.*, in favor of protecting human health—in interpreting uncertainty.

### 3. The only lawful consideration in setting NAAQS is the effect of the pollutant in the ambient air on health and welfare.

It is well-established that the Act requires EPA to set health- and welfare-protective NAAQS for a pollutant based solely on the health and welfare effects caused by that pollutant in the ambient air, without regard to the sources of the pollutant or any costs of implementing the standards. *E.g.*, *Whitman*, 531 U.S. at 465, 469; *Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1040-41 (D.C. Cir. 1999), *reh'g granted in other part and denied in part*, 195 F.3d 4 (D.C. Cir. 1999) *aff'd in relevant part sub nom. Whitman,* 531 U.S. 457 (2001); *Nat. Res. Def. Council* v. *EPA*, 902 F.2d 962, 972-73 (D.C. Cir. 1990), *vacated in unrelated part by* 921 F.2d 326 (D.C. Cir. 1991); *Nat. Res. Def. Council v. EPA*, 824 F.2d 1146, 1157, 1159 (D.C. Cir. 1987) (en banc); *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); *Lead Indus. Ass'n*, 647 F.2d at 1148-50 & n.39.[6] This principle was reaffirmed last year in *Murray Energy Corp.*, 936 F.3d at 622-24, where the Court held that EPA must set the primary NAAQS based exclusively on public-health considerations, without regard to "background" levels of the pollutant. Costs, however named, and "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of [NAAQS]." *Id.* at 621-24 (citation omitted).

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[6] The briefing in *Whitman* further shows that, in rejecting consideration of "costs," the Whitman Court rejected consideration of "overall adverse … impacts" in NAAQS reviews. Industry parties themselves said in Whitman that they were there arguing that EPA must consider precisely those types of impacts: "Congress intended that EPA exercise its public health risk management judgment based on consideration of the overall impact of its decision on society." Appalachian Power Co. Resp. Br. ("Power Co. Whitman Resp.") 34, *Whitman v. Am. Trucking Ass'ns*, No. 99-1257 (U.S.). Indeed, various parties argued to the Supreme Court that EPA must consider broad impacts beyond just the "costs of implementation." The Court found that the "text of § [74]09(b), interpreted in its statutory and historical context and with appreciation for its importance to the [Act] as a whole," foreclosed all these arguments about costs. *Whitman*, 531 U.S. at 471.The D.C. Circuit later explained, "[i]t is only health effects relating to pollutants in the air that EPA may consider." *Nat. Res. Def. Council*, 902 F.2d at 973 (emphasis in original); *see also Murray Energy v. EPA*, 936 F.3d 597, 621-22 (D.C. Cir. 2019) (making it again clear that costs—"however denominated"—cannot play any lawful role in standard-setting).

## III. THE PROCESS FOR REVIEWING THESE NAAQS IS UNLAWFUL AND ARBITRARY, RENDERING THE PROPOSAL UNLAWFUL AND ARBITRARY.

The process for scientific review that provides the foundation for this Proposal has been marred by critical process flaws. Due to these process flaws, the Proposal is not based on the latest scientific knowledge, as the Act requires, and is arbitrary, capricious, and an abuse of discretion. EPA should reopen the review process to ensure that the Agency satisfies its statutory obligations to base its decision on the latest scientific knowledge in order to protect public health with an adequate margin of safety.

The numerous problems with the process for developing this Proposal include that EPA unreasonably relied on recommendations from a CASAC that was constituted illegally, undercut the necessary expertise and support for scientific review, conflated steps for scientific assessment and policy determinations, failed to conduct a thorough assessment of the most recent studies on the health and welfare harms of ozone pollution, and dramatically accelerated the entire review process, leaving insufficient time for public comment and scientific review.

These process flaws occurred due to an array of unprecedented, *ad hoc* changes that radically departed from the longstanding practice of prior reviews. For decades of prior reviews, EPA has utilized an organized, sequential review process, first drafting an integrated review plan ("IRP"), followed by a review of the science in the form of an Integrated Science Assessment ("ISA"), a Risk and Exposure Assessment ("REA"), and then a review of policy issues in its Policy Assessment ("PA"). Prior reviews conducted this process with the advice of a CASAC supported by pollutant-specific review panels.

We concur with the former members of CASAC who participated in the 2009–2015 review of the ozone NAAQS—including two former chairs and ten former members of the chartered CASAC—who unanimously wrote to the current CASAC that these "myriad unwarranted changes … are collectively harmful to the quality, credibility, and integrity of EPA's scientific review process and to CASAC as an advisory body."[7]

These deficiencies have led to an arbitrary and capricious Proposal to retain the current inadequate standards that fails to comply with the Clean Air Act's requirements for a sound scientific foundation and an adequate margin of safety.

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[7] H. Christopher Frey et al., Advice from the former U.S. EPA Clean Air Scientific Advisory Committee Ozone Review Panel on EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019), and EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019) (Dec. 2, 2019), pg. 2, *available at* https://yosemite.epa.gov/sab/sabproduct nsf//B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf. [hereinafter "Former CASAC Advice Letter"].

### A. EPA cannot proceed with this rulemaking without recommendations from a lawfully-constituted CASAC.

In October of 2017, former EPA Administrator Scott Pruitt announced a new CASAC appointments policy that broke with decades of Agency practice.[8] Administrator Pruitt simply announced by memorandum that EPA would no longer allow scientists who had received grants from the Agency to serve on its scientific committees. EPA grants are awarded through a competitive process and, therefore, researchers who receive those grants are often leading experts in their fields.

Following the issuance of this directive, EPA began to replace the members of CASAC, replacing all seven members of CASAC by October 2018. Two suits were filed by environmental and health organizations, along with scientists removed from the committee. EPA lost both. The Southern District of New York declared that EPA's exclusion of these experts was arbitrary and capricious, finding that EPA failed to explain "why an outright ban on EPA grant recipients would improve the existing policies that required demanding and continuous conflict of interest reviews[.]" *Nat. Res. Def. Council v. EPA*, 438 F. Supp. 3d 220, 232 (S.D.N.Y. 2020). In the D.C. Circuit, the court faulted EPA because the agency "nowhere confront[ed] the possibility that excluding grant recipients—that is, individuals who EPA has independently deemed qualified enough to receive competitive funding—from advisory committees might exclude" those candidates who are "'the most qualified, knowledgeable, and experienced[.]'" *Physicians for Soc. Responsibility v. Wheeler*, 956 F.3d 634, 647 (D.C. Cir. 2020). The Southern District issued an order vacating the Pruitt directive on April 15, 2020, pronouncing these flaws "serious." *Nat. Res. Def. Council v. EPA*, No. 19-cv-05174, 2020 WL 2769491 (S.D.N.Y. Apr. 15, 2020). EPA has chosen not to appeal.[9] Thus, the Pruitt directive is void.

As the D.C. Circuit recognized, this directive represented "a major break from the agency's prior policy, under which grantees regularly served on advisory committees." *Physicians for Soc. Responsibility*, 956 F.3d at 645. Had the Agency adhered to its longstanding practice, the pool of potential CASAC members would have included researchers with decades of expertise and experience with CASAC reviews. As the D.C. Circuit noted, the Pruitt directive failed to address past practices for addressing conflicts, the failure of which "is especially glaring given that the prior regime existed, in part, for the very purpose of facilitating the critical role played by EPA's scientific advisory committees." *Physicians for Soc. Responsibility*, 956 F.3d at 647. Instead, the decision criteria relied upon in the Pruitt directive were arbitrary, unlawful, and

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[8] EPA, "Strengthening and Improving Membership on EPA Federal Advisory Committees," (Oct. 31, 2017) [hereinafter "Pruitt directive"].

[9] Press Release, U.S. EPA, *EPA Will Not Appeal Adverse SDNY Decision Regarding October 31, 2017 Federal Advisory Committee Directive* (June 24, 2020), https://www.epa.gov/newsreleases/epa-will-not-appeal-adverse-sdny-decision-regarding-october-31-2017-federal-advisory.

unrelated to expertise. In contrast, the directive expressed no concerns about committee members who work for or are funded by industries or government entities subject to EPA regulation. Indeed, members from industry or government comprised the majority of the CASAC's membership during this review.

The CASAC has not been reconstituted in response to these decisions. Instead, EPA has continued to rely on CASAC's advice, despite the arbitrary exclusion of the most qualified, knowledgeable, and experienced members. The exclusion of qualified experts has had grave implications for the review. The Clean Air Act requires EPA to engage with an advisory board capable of providing "independent scientific review," and to explain any departure from its recommendations.[10] EPA must conduct this engagement with a CASAC that is constituted lawfully, and that is capable of providing the necessary independence and scientific expertise.

Because the advisory panel was inadequately and unlawfully constituted, any reliance on its advice, absent independent support for that reliance, is arbitrary, capricious, and an abuse of the Agency's discretion. Before finalizing this Proposal, EPA must re-assess CASAC membership and allow a lawfully-constituted committee to conduct the required scientific review.[11]

### B. CASAC lacked critical expertise and support in the development of this Proposal.

Congress established the CASAC to be an independent body providing expert scientific advice to EPA on NAAQS decisions, and EPA's decisions regarding the NAAQS must be based on the best available science. 42 U.S.C. § 7409(d). However, changes to the membership of and support provided by CASAC during this review left EPA without the necessary expertise for a proper evaluation of the science. Because CASAC lacked the expertise and support to consider the full breadth and diversity of the evidence regarding the health and welfare impacts of ambient ozone, EPA's reliance on its advice for this Proposal is arbitrary, capricious, and an abuse of discretion. CASAC was simply not equipped to provide expert advice to the Administrator on the key scientific and technical issues, and therefore its advice warranted no deference from the Administrator.

#### 1. The members of CASAC lacked critical expertise due to turnover under EPA's arbitrary policy.

Between 2017 and 2018, due to the now-voided Pruitt directive described above, there was a complete turnover of CASAC membership such that by October 2018, no member of

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[10] 42 U.S.C. §§ 7409, 7607(d)(3). .

[11] *See Bullock v. United States BLM*, 2020 U.S. Dist. LEXIS 177029, *35-36 (D. Mont. September 25, 2020) (stating improperly appointed officials' actions are unlawful under the Administrative Procedure Act as not issued "in accordance with law.").

CASAC had served on the committee for more than one year. This turnover resulted in a loss of institutional memory, a lack of experience with NAAQS reviews, and a lack of necessary technical expertise on the committee.

While Administrator Wheeler emphasized the representation of five panelists who work in state, local, or federal environmental agencies when he announced the CASAC membership,[12] the members lack diversity and breadth in expertise. The unbalanced composition of CASAC for this review included only two academic research scientists, and most members lacked prior experience with NAAQS reviews. CASAC itself highlighted this lack of adequate epidemiological expertise in an April 2019 letter to Administrator Wheeler during the review for the particulate matter NAAQS, noting that "the breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals."[13] Former ozone panel members concurred, noting that "the current CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields to a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state and local government, rather than scientific expertise first and foremost."[14]

As the D.C. Circuit notes, EPA's new approach goes against Congress's intent for the function and purpose of CASAC:

> Congress expected that CASAC's central role would be one of scientific analysis, explaining that CASAC's "main function" was "to assess the health and environmental effects of ambient air pollution." … CASAC would "provide an outside mechanism for evaluating whether any pollutant may reasonably be anticipated to endanger public health or environment, for evaluating the scientific and medical data which might bear on this question, and for reviewing gaps in the available data and recommending additional needs for research." … Given these functions, Congress expected that CASAC members would "be selected on the basis of their special expertise" in fields such as "environmental toxicology, epidemiology and/or clinical medicine."[15]

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[12] Press Release, EPA, "*Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process* (Oct. 10, 2018) *available at* https://archive.epa.gov/epa/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee.html.

[13] Anthony Cox et al., "CASAC Review of the EPA's *Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)*," at 1 (Apr. 11, 2019), https://yosemite.epa.gov/sab/sabproduct nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/%24File/EPA-CASAC-19-002+.pdf. Though this letter came as part of the review of the PM NAAQS, this particular CASAC comment holds for the ozone review as well, for the scientific issues and evidence for the ozone NAAQS are at least similar in depth and breadth as those for the PM NAAQS.

[14] *See* Former CASAC Advice Letter, *supra* n. 7, at 3.

[15] *Mississippi v. EPA*, 744 F.3d 1334, 1354 (D.C. Cir. 2013) (citations omitted).

Thus, scientific expertise must be the primary consideration in the selection of CASAC members. The unbalanced composition of the CASAC and the dearth of academic research scientists hindered the committee's ability to conduct the "thorough" review mandated by the Act. 42 U.S.C. § 7409(d)(1). For these reasons, the Administrator's reliance on CASAC members' recommendations in the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.

### 2. EPA lacked critical expertise because it failed to form a truly expert review panel.

For four decades, the chartered seven-member CASAC has augmented its ranks with additional experts to allow the breadth, depth, and diversity of expertise needed to review multidisciplinary scientific issues relevant to each of the criteria pollutants regulated under the NAAQS.[16] That expanded expert panel has been in place to fulfill the statute's requirement that the NAAQS reflect the latest scientific knowledge. EPA's abandonment of that process was arbitrary and capricious, and lead to inadequate scientific review.

In July 2018, EPA issued a request for experts for the ozone review panel. In October, EPA announced that it would not form an expert ozone review panel, providing no rationale for this change. Likewise, this Proposal provides no rationale for that "modification" to the CASAC review process.[17] EPA's decision not to form an expert ozone panel left CASAC without needed supplemental expertise. As former CASAC members have put it, a specialized expert panel is needed to "augment[] CASAC with the expertise it needs via qualified review panels that deliberate, interactively, with members of the chartered CASAC."[18]

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[16] CASAC's charter provides it with the authority to convene such expert panels. That charter states: "EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter." Of course, the panel is not CASAC, and does not itself make recommendations to the agency. As the CASAC charter states, "[s]uch subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the chartered CASAC for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee, nor can they report directly to the EPA." United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, June 5, 2019 (date of filing with Congress), https://yosemite.epa.gov/sab/sabproduct nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf. Additional experts have been appointed to review panels that interact with members of the chartered CASAC for all reviews since the late 1970s. Over time, the chartered CASAC has typically been augmented with 12 or more additional experts in a given review cycle for a given criteria pollutant. The average number of experts among 20 such panels for which membership data is available is 14, and the average size of the review panels is 20 members, inclusive of participating CASAC members.

[17] *See* 85 Fed. Reg. at 49,836.

[18] *See supra,* n. 7, Former CASAC Advice Letter.

Administrator Wheeler has implied that this departure from past practice is justified because deliberations with an expert panel could slow the process down.[19] But former members of the ozone review panel explain that this rationale does not hold water:

> Contrary to implications of statements made by the Administrator to justify why the PM Review Panel was disbanded and why an ozone review panel was not formed, panels do not slow down or in any way hamper CASAC's role in the NAAQS review process because they work collaboratively and in parallel with the chartered CASAC. Moreover, engagement of panels is essential to CASAC having the breadth, depth, and diversity of expertise and experience needed for these complex scientific reviews. Therefore, failure to form an ozone review panel fatally undermines the ability of CASAC to complete a thorough, detailed review of the PA rooted in the best available science without providing any advantages to process efficiency.[20]

The failure to form an ozone review panel also contributes to EPA's violation of Section 108's requirement for the NAAQS to "accurately reflect the latest scientific knowledge" because its absence limits EPA's ability to learn of and evaluate new scientific information. 42 U.S.C. § 7408(a)(2).

The Administrator's late appointment of a "pool" of experts, nominally available to answer specific questions from CASAC members submitted in writing, five months after CASAC requested additional help,[21] does not rectify these failings. Appointment by the Administrator, rather than via the customary review process with SAB vetting and public participation, is an inadequate process and leads to at least the appearance of bias. Further, due to the now-voided Pruitt directive, eminent scientists were illegally barred from consideration for inclusion in the pool.[22]

There are several crucial differences between the pool of consultants available to CASAC and a traditional supplemental expert panel. First, this pool was not selected specifically for the review of the ozone NAAQS—the same consultants were involved in the particulate matter NAAQS review—and therefore lacks the expertise to provide CASAC the comprehensive support necessary for the ozone review. Additionally, no member of the consultant pool had

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[19] EPA asserts that the new approach is "focused, efficient, and transparent" without addressing whether this change actually improves the efficacy of the NAAQS review process. 85 Fed. Reg. at 49,836.

[20] *See* Former CASAC Advice Letter *supra* n. 7, at 4.

[21] Anthony Cox et al., "CASAC Review of the EPA's *Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)*," (Apr. 11, 2019), https://yosemite.epa.gov/sab/sabproduct nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/%24File/EPA-CASAC-19-002+.pdf.

[22] *See* Compilation of EPA Grant Information regarding Nominees to CASAC and Administrator Wheeler's Expert Pool (attached) (documenting the ineligibility of five expert-pool nominees—Peter DeCarlo, David Eaton, Joel Kaufman, Armistead Russell, and Ivan Rusyn—as a result of their EPA grants and the directive).

served on the ozone expert panel in the 2009–2015 review of the ozone NAAQS, suggesting that crucial relevant expertise is missing from the pool.

Despite the Administrator's claims to the contrary,[23] the pool of experts that Administrator Wheeler selected to answer directed questions from CASAC did not adequately address CASAC's request for additional expertise. According to a report quoting one of CASAC's members in the wake of the Administrator's announcement, no person named to the pool had "'sufficient expertise and experience' in epidemiology"—an area in which CASAC needed significant help.[24] For example, though an EPA roster identified Dr. Frederick Lipfert as an expert on "air quality" and "epidemiology," a press report later quoted him as saying: "'I'm an amateur epidemiologist at best[.]'"[25] Another member of the pool, Dr. David Parrish, repeatedly stated in his responses to CASAC's questions that he had "no relevant expertise in evaluating exposure and risk," "no relevant expertise in evaluating public health implications," "no relevant epidemiological expertise," and "no relevant health effects expertise[.]"[26] The Administrator's decision to appoint pool members lacking relevant expertise was arbitrary and unlawful, particularly given the fact that candidates with relevant expertise had been included on the list of nominees.[27]

Six of the pool's twelve original members, moreover, were reportedly nominated by or affiliated with groups that have opposed strengthening the NAAQS in the past.[28] As a report on the pool's members explained:

> Two of Wheeler's … picks work for well-known industry consulting firms that are representing clients with a stake in the reviews. … [B]oth were nominated by the National Rural Electric Cooperative Association, which opposed EPA's 2015 cut to the national ground-level ozone standard[.] … Another two—one of whom has since quit—were endorsed by the National Cattlemen's Beef Association,

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[23] *Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts*, EPA (Sept. 13, 2019), https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts#:~:text=Administrator%20Wheeler%20Announces%20New%20CASAC%20Member%2C%20Pool%20of%20NAAQS%20Subject%20Matter%20Experts,-09%2F13%2F2019&text=WASHINGTON%20(September%2013%2C%202019),Committee%20(CASAC)%2C%20Dr. (attached).

[24] Sean Reilly, *Documents Expose Ties Among EPA Panel's Experts*, E&E News (Feb. 7, 2020), https://www.eenews.net/stories/1062289617 (attached) [hereinafter, "Expert Panel Article"].

[25] *Id.* (noting that Dr. Lipfert had nominated himself for the expert pool, and that his "educational background, which includes a doctorate, is in engineering and environmental studies"); List of Nominees for CASAC PM and Ozone Consultants (Aug. 2019) (attached).

[26] Responses to CASAC Questions on the Ozone PA from Consultant Dr. David Parrish at 5-6, 9-10 (attached); *see* Expert Panel Article *supra* n. 24.

[27] *See* Expert Panel Article *supra* n. 24 (noting that the EPA's own "roster shows that Wheeler passed over … academic specialists in epidemiology in appointing the experts"); List of Nominees for CASAC PM and Ozone Consultants (Aug. 2019).

[28] *See* Expert Panel Article, *supra* n. 24.

> which unsuccessfully fought EPA's 2012 tightening of the annual limit on soot concentrations. … Yet another, the self-described amateur epidemiologist, is also on the advisory board of a conservative group known as the American Council on Science and Health. In comments to CASAC last fall, a trustee for the council disputed the long-established connection between soot exposure and early death. … [And] [a]nother expert working with the committee is … an independent consultant nominated by the Chicago-based Truck and Engine Manufacturers Association, which also opposed EPA's 2015 decision to trim the ozone threshold.[29]

This report raises questions about whether a number of the members of the pool could be relied upon to provide wholly objective scientific advice.

Critically, this process differs from the usual expert panel review process. This panel of consultants was directed to only interact with CASAC in writing, rather than to respond in real-time and deliberate with the committee. This undermines the mechanisms of peer review central to a strong evaluation of science-based information. Even if Administrator Wheeler had populated his pool with the experts CASAC needed to complete its review, the limitations he placed on the pool's members would have made it difficult for them to offer meaningful contributions to the process. While members of review panels typically participate in CASAC's public meetings, Administrator Wheeler's pool was not allowed to join the committee's meetings or to deliberate with the committee's members.[30] As one of CASAC's members has said, the Administrator's requirement that the pool's members only communicate with the committee in writing "'adversely affect[ed]' CASAC's ability to advise EPA[.]"[31] The Administrator's expedited process further prevented the pool's members from offering useful comments. As a professor at Texas A&M University explained after resigning from the pool, "'I simply did not have as much time to devote to the tasks as the tasks would have required[.]'"[32]

All told, the pool of consultants selected by Administrator Wheeler failed to remedy the arbitrary and unlawful deficiencies in CASAC's expertise as applied to this NAAQS review. Instead, the pool made the Administrator's reliance on CASAC's advice all the more arbitrary, for even with the consultants, CASAC lacked the necessary expertise to comment on the standards.

EPA has failed to recognize and consider the impact of these arbitrary decisions on the CASAC's ability to perform its duties and on the quality of the recommendations produced by

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[29] *See* Expert Panel Article, *supra* n. 24.
[30] Former CASAC Advice Letter, *supra* n. 7, at 4. Members of the public are regularly invited to join CASAC meetings and speak to CASAC members directly. *See, e.g.,* Notification of a Public Meeting of the Chartered Clean Air Scientific Advisory Committee (CASAC), 84 Fed. Reg. 58,713 (Nov. 1, 2019) (public notice of hearing on CASAC Draft Report on Policy Assessment for Ozone, inviting public comment and participation).
[31] *See* Expert Panel Article, *supra* n. 24.
[32] *Id.* (quoting Professor Brent Auvermann).

the CASAC. Rushing through the external review process, without the typical subject matter experts and a shorthanded CASAC, was particularly egregious and undermined the CASAC's ability to conduct the required review, make recommendations, and advise the Administrator, as required by the Clean Air Act. The above factors and "exceptional nature" of this NAAQS review indicate that the current CASAC was simply unable to fulfill its role in this process under these challenging circumstances, and the Administrator's reliance on this broken process is arbitrary and unlawful.[33]

### C. The development of the Proposal conflated science and policy assessment steps.

Not only did EPA lack the necessary expertise for the review process underlying this Proposal, that review process was also flawed because of the simultaneous assessment of both science and policy issues. EPA has collapsed what has normally been three sequential stages of review for this Proposal—the ISA, REA, and PA—into a single review, with overlapping comment periods. This is contrary to four decades of past practice for NAAQS reviews, wherein EPA has first completed its review of the latest scientific assessment, and only after that, drafted its policy assessment. This process allows for the most recent, relevant science to provide the basis for policy decisions. By drafting and reviewing the ISA and the PA concurrently, the necessary clarity in available science is not available for the PA. As former members of CASAC describe, this "risks commingling policy issues prematurely before the science issues are adequately vetted and settled, which in turn creates the potential for policy choices to be made irrespective of the science" and harms the integrity of the process.[34] As the Independent Particulate Matter Review Panel noted, "the integrity of the process is harmed when policy issues are addressed before the science issues are adequately settled." As the IRP explained, the PA is "intended to 'bridge the gap' between EPA's scientific assessments and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS."[35] But here, that bridge was built for the purpose of connecting to a pre-determined result, without setting an adequate foundation to support that result.

The ISA was finalized on April 1, 2020, months after the comment period for the draft PA closed in December of 2019.[36] This contrasts with the prior review, for which a full review period for the PA was completed after the final ISA was published. For this review, now that the

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[33] Clean Air Scientific Advisory Committee, *CASAC Review of the EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Ozone (External Review Draft – October 2019)* (EPA-CASAC-20-003), at 1-2 (Dec. 16, 2019), https://yosemite.epa.gov/sab/sabproduct nsf/LookupWebProjectsCurrentCASAC/4713D217BC07103485258515006359BA/$File/EPA-CASAC-20-003.pdf [hereinafter, "CASAC review of PA"]

[34] Former CASAC Advice Letter, at 5.

[35] U.S. Environmental Protection Agency, "Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards." August 2019. Accessed at: https://www.epa.gov/sites/production/files/2019-08/documents/o3-irp-aug27-2019_final.pdf, at 6-1.

[36] *See* 84 Fed. Reg. 58,711 (noting end of comment period on December 16, 2019).

ISA is finalized, EPA must re-open the PA for the opportunity for review by CASAC and the public. This will help to prevent the conflation of science and policy and ensure that the findings in the PA are based on the best available science.

### D. EPA failed to consider the "latest scientific knowledge" as required by section 108.

Section 108 requires that the NAAQS "accurately reflect the latest scientific knowledge" on public health and welfare.[37] In prior NAAQS reviews, EPA has properly considered a reassessment of studies past the initial ISA cutoff date to be necessary. But EPA has not conducted any such assessment for this review, nor established any other procedure for ensuring more recent studies have been taken into account.

Instead, EPA has only committed to considering studies published through March 30, 2018. This early cutoff date was six months before the first draft of the ISA was available, and more than a year before the final ISA was completed. Without a post-ISA assessment of more recent studies, EPA has failed to ensure the proposed standard accurately reflects the latest scientific knowledge.

Here, EPA states that later-published studies were considered only "if they were submitted in response to the Call for Information or identified in subsequent phases of ISA development[.]"[38] However, the Clean Air Act charges the Administrator to conduct a thorough review of the latest science.[39] It is EPA's job, with support of expert staff, to evaluate the science. This early cutoff date for EPA review unreasonably and unlawfully shifts the burden to the public to identify and evaluate relevant studies. We cite numerous examples of such studies in section IV.B of these comments.

EPA's failure to analyze more recent studies through a post-ISA assessment is arbitrary. Additionally, given the longstanding prior policy, EPA's failure to acknowledge or explain this change in approach is also arbitrary.[40]

At the very least, EPA should have considered all studies published as of December 3, 2018, the final date for accepting comments on the ISA,[41] or as of April 2020, when the ISA was finalized, before beginning the review period for the PA.

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[37] 42 U.S.C. § 7408(a)(2).
[38] 85 Fed. Reg. at 49,838 n.17.
[39] 42 U.S.C. §§ 7409(d)(1), 7408(a)(2).
[40] *See, e.g.*, *Physicians for Soc. Responsibility*, 956 F.3d at 644 ("Reasoned decision-making requires that when departing from precedents or practices, an agency must offer a reason to distinguish them or explain its apparent rejection of their approach.").
[41] Release of Draft Integrated Review Plan for the Ozone National Ambient Air Quality Standards, 83 Fed. Reg. 55,163 (Nov. 2, 2018).

### E. The review process left inadequate time and opportunity for scientific review and public participation.

Both the process for the scientific review that underlies this Proposal and the comment period for this rulemaking have been dramatically and arbitrarily accelerated compared to prior NAAQS reviews, leaving insufficient time for adequate scientific review and public participation.

The Clean Air Act requires EPA to review, and if necessary, revise, the NAAQS every five years in light of the latest scientific knowledge. 42 U.S.C. §§ 7408, 7409. It is possible to meet those statutory deadlines without sacrificing the integrity of the scientific review process outlined by the statute. Though the 2018 Pruitt NAAQS Memo was purportedly driven by this desire to adhere to the statutory deadline of October 2020, the memo only announced this desire after years of Agency inaction and delay with respect to the standards.[42] In order to complete a review that meets its statutory obligations, the Agency review is required to be "thorough", and "accurately reflect the latest scientific knowledge."[43]

EPA's professed concern about meeting statutory deadlines for this rulemaking are belied by the other national standards that are much further behind in reviews—for carbon monoxide, nitrogen oxides, and sulfur dioxide—but about which EPA has done nothing. Rather, the evidence points to a process designed to arrive at a pre-determined result, delaying any increase in stringency of the standard. This process has all the hallmarks of being driven by the desired outcome to maintain the current standard, and forego the proper evaluation of scientific advancements in the name of public health protections.

#### 1. The scientific review process was arbitrarily accelerated.

In the IRP, EPA initially anticipated review of two drafts of the ISA,[44] but only provided one. This departs from the past practice for multiple ISA drafts; e.g., the three drafts of the ozone ISA for the 2009–2015 review, each with at least a 60-day comment period.[45] The ISA for this review was especially rushed because, as described above, the ISA review period overlapped with the review period for the PA. The draft PA was released just two months after the IRP was finalized, compared to over a year and a half during the previous ozone review.

Significant prior experience shows that these complex and technical documents often require substantial revisions. Failing to issue second drafts of these documents severely undermines the opportunities for CASAC, public, and other expert comment on EPA's scientific and policy analyses, which are foundational to subsequent regulatory processes. Moreover, and

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[42] 80 Fed. Reg. 65,291 (Oct. 26, 2015).
[43] 42 U.S.C. §§ 7409(d)(1), 7408(a)(2).
[44] *See* IRP, *supra* n. 35, at 4-3.
[45] 76 Fed. Reg. 10,893 (Feb. 28, 2011); 76 Fed. Reg. 60,820 (Sep. 30, 2011); 77 Fed. Reg. 36,534 (June 19, 2012).

critically, a second draft ISA (as contemplated by the IRP) would have allowed for consideration and inclusion of important additional studies, in keeping with the directives in Clean Air Act sections 108(a)(2) and 109(d)(1) to consider the "latest" "useful" science, as part of the "thorough review" of the air quality criteria and existing standards.[46] The truncated review undertaken by EPA, coupled with selective inclusion of some post-ISA studies but the exclusion of others without adequate explanation (see section IV.B) has led to a record that does not fully satisfy these requirements. Even without the improperly excluded studies, the record compels revision of the primary standards. In all these respects, the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.

Comment deadlines throughout the review have prevented the public from meaningfully engaging in the review process. The ozone PA was released on November 1, 2019 with a 45-day comment period. Within this same period, comments on the particulate matter PA and ozone ISA were also due (on November 12 and December 2, respectively). This 45-day comment period is remarkably short given both the simultaneous review of two other major NAAQS review documents, as well as the broad scope of the draft PA, which covered the same scope as three assessment documents—the policy assessment, the welfare risk and exposure assessment, and the health risk and exposure assessment—that were reviewed separately in the prior review cycle. The 45-day comment period on the PA did not leave enough time for a thorough review of this extensive and technical document. In comparison, the 2015 review had two drafts of the PA, each with a longer comment period than that provided during this review.[47]

The shortened drafting period for these review documents placed extreme pressure on EPA staff, which has led to some critical omissions simply due to time constraints. For example, the PA failed to consider the health effects of ozone on outdoor workers, a particularly at-risk group.[48] CASAC's review of the PA also criticized EPA's failure to simulate impacts on outdoor workers.[49]

Former ozone expert panel members agree that this process "did not provide sufficient time to complete the 'thorough review' of the 'latest scientific information' of the 'kind and extent' of 'all identifiable effects' mandated by the Clean Air Act for the review of NAAQS," adding that "[t]his would be true even if the committee were supported by a robust panel of experts in the multiple disciplines involved."[50]

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[46] 42 U.S.C. §§ 7408(a)(2),7409(d)(1).
[47] 77 Fed. Reg. 42,495 (July 19, 2012) (first draft notice of availability); 77 Fed. Reg. 51,798 (Aug. 27, 2012) (extending comment period); 79 Fed. Reg. 4,694 (Jan. 29, 2014) (second draft notice of availability).
[48] Comment made by EPA staff during the EPA Presentation - Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, December 5, 2019 at the Clean Air Scientific Advisory Committee meeting; *see also Am. Trucking Ass'ns*, 283 F.3d at 375 (citing EPA's discussion of ozone exposure risks for outdoor workers and children in setting the 1997 ozone standard at 62 Fed. Reg. 38,856, 38,60).
[49] *See* CASAC Review of PA, *supra,* n. 33, at A-5 (comments of Dr. James Boylan).
[50] *See* Former CASAC Advice Letter, *supra,* n. 7, at 2, 5.

These flaws underscore that the requirements of section 108 have not been met in this review. EPA's rushed process may well have deprived even a lawfully constituted CASAC of adequate time to provide expert advice. To be certain, the inexpert CASAC, even assisted by the ad hoc consultant pool, failed to remedy these issues. Individually and in combination, the process flaws resulted in a Proposal that cannot be lawfully finalized without major revisions to the review process.

**2. This Proposal has been arbitrarily accelerated.**

Like the process for reviewing the foundational documents for this Proposal, the current comment period has also been arbitrarily accelerated. The 48 days that EPA has provided, in total, for public comment on the Proposal is a remarkably short comment period for such a consequential and scientifically complex rulemaking. EPA routinely provides longer comment periods on nationwide rules of this importance, including a 90-day comment period on the proposed ground-level ozone NAAQS in 2014.[51] Here, EPA offers no reason for why a comment period of about half that length would be sufficient. Even EPA's recent—and significantly shorter—Proposal regarding the particulate matter NAAQS afforded commenters 60 days. It is irrational to provide a shorter comment period for a longer Proposal of similar complexity.

And the mere 18-day lead time for public hearings also burdened the public by not providing them adequate opportunity to prepare to testify or to make arrangements that would allow them to testify, if, for example, they had work, school, or care-giving responsibilities that precluded their participation during a weekday. Limiting public participation in hearings is not consistent with the Act and is thus also arbitrary. *See* 42 U.S.C. § 7607(h) (EPA "shall ensure a reasonable period for public participation" in rulemaking).

The unreasonably short time period EPA has provided is all the more egregious due to the current public health crisis. The ozone review is being finalized during a global pandemic caused by a respiratory virus, meaning that the very respiratory health experts who are most relevant and best situated to provide detailed comments are necessarily preoccupied with the COVID-19 crisis. The 48-day public comment period would be a remarkably short comment period for such a consequential, highly technical and scientific rulemaking notwithstanding the extent of the current crisis. But the pandemic exacerbates barriers to public participation, with the closure of the docket room, and the closure of public reading areas—like libraries and schools that afford internet access to those who do not have it at home—coupled with the requirement that comments be submitted electronically. Although some changes may be warranted by the pandemic, they restrict opportunities for public input and may silence important feedback, particularly from the most vulnerable individuals in the population. Pushing through this incredibly important review despite the current circumstances and changes to the process

[51] 79 Fed. Reg. 75,234 (Dec. 17, 2014).

that further restrict public input is unacceptable, and must be remedied before the rule is finalized.

Without any explanation at all, EPA denied our organizations' request for an extension of the comment deadline expressing the above concerns.[52] These factors raise serious concerns about the adequacy of the opportunity for public comment and other issues with statutory requirements under the Clean Air Act. Given the current public health crisis, and the lack of expert panel support for CASAC, the public should have far more than the customary 90-day comment period, not substantially less.

## IV. THE ADMINISTRATOR'S PROPOSED DECISION TO RETAIN THE PRIMARY STANDARD FOR OZONE IS UNLAWFUL AND ARBITRARY ON ITS MERITS.

The Administrator's proposed decision to retain the primary standard for ozone at 70 ppb is fundamentally at odds with the Clean Air Act's essential purpose and requirements. Ignoring precedent and the statutory directive to set standards at a precautionary level—one "allowing an adequate margin of safety"—the Administrator proposes to leave the primary standard unrevised because he contends that the "currently available evidence does not substantially differ from that which was available in the 2015 review when the current standard was established." 85 Fed. Reg. 49,830, 49,869 (Aug. 14, 2020). As noted at length in our comments both here and on the 2015 standards, a level of 70 ppb was then, and remains now, insufficiently protective of public health. The Administrator's decision to retain the standard is arbitrary, capricious and an abuse of discretion.

### A. Overwhelming scientific evidence shows ozone harms human health, including at levels the current standard allows

The scientific evidence described in the ISA shows that ozone harms human health and that significant harms occur at levels lower than what the current standard allows. Scientific evidence across various lines of evidence—including controlled human exposure studies, animal toxicology, and epidemiology—confirm these harms and coherence of adverse health effects. Importantly, the ISA identifies new health harms, including links to metabolic disease, that are linked to ozone exposures.

The epidemiology literature synthesis presented in the ISA indicates that a stronger standard (below 70 ppb) is merited, given robust evidence of health harms at lower exposure

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[52] Environmental Defense Fund, Earthjustice, Clean Air Task Force, National Parks Conservation Association, Moms Clean Air Force, Appalachian Mountain Club, Sierra Club, Natural Resources Defense Council, and Physicians for Social Responsibility, "Request to Extend Public Comment Deadline for *Review of Ozone National Ambient Air Quality Standards*, 85 Fed. Reg. 49,830" (August 14, 2020), regulations.gov ID EPA-HQ-OAR-2018-0279-0321.

levels. At an 8-hour maximum level of 60 ppb, the ISA finds evidence of lung function impairments, pulmonary inflammation, injury, oxidative stress and other respiratory symptoms in children and adults exposed to ozone concentrations at that level or lower. Controlled human exposure studies showed ozone-induced decreases in lung function and inflammation in exercising adults at levels as low as 60 ppb. Risks of hospital admissions, emergency department visits, and physician visits for respiratory ailments were found to be elevated at 8-hour maximum levels of 31-55 ppb, with the lower threshold of those findings at a concentration that is less than half of the current standard. Collectively, these findings are coherent in their determinations of adverse health effects well below the level of the current standard. EPA must consider a more stringent primary NAAQS for ozone given the body of studies examining short-term ozone exposure and respiratory effects.

### B. A long-term exposure ozone standard is necessary, and EPA arbitrarily fails to consider establishing one

EPA agrees long-term ozone exposure likely causes harms and notes in the ISA that within epidemiology studies of long-term exposure risks "it is much more common for the association to be underestimated because near-road ozone scavenging can result in greater spatial variability due to a reduction in ozone concentration compared with ambient ozone measured at a fixed-site monitor." ISA at 3-1; 2-1.

Within the final ISA, EPA has arbitrarily included a small number of studies published after March 2018 and not explained why certain studies, including several that identify health harms at currently permissible levels, were excluded from the final ISA. These include a 2019 study analyzing air pollution concentrations (including ozone) and asthma incidence in children.[53] While that study identified reduced asthma incidence as ozone concentrations fell over time (IRR for asthma was 0.85 (95% CI, 0.71–1.02) for a median reduction of 8.9 parts per billion, with an absolute incidence rate decrease of 0.78 cases per 100 person-years), the effect was not statistically significant. A number of studies published after March 2018, the cut-off period for study consideration in the current ozone ISA, confirm statistically significant health harms from both short- and long-term exposures to ozone.[54,55,56] For example, while there were

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[53] Erika Garcia et al., *Association of Changes in Air Quality with Incident Asthma in Children in California, 1993-2014,* JAMA 321, no. 19 (May 21, 2019), https://doi.org/10.1001/jama.2019.5357.

[54] Dominici, Francesca, Joel Schwartz, Qian Di, Danielle Braun, Christine Choirat, and Antonella Zanobetti. "Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1." Research Reports: Health Effects Institute 2019 (November 1, 2019). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7300216/.

[55] Seltzer, Karl M., Drew T. Shindell, Prasad Kasibhatla, and Christopher S. Malley. "Magnitude, Trends, and Impacts of Ambient Long-Term Ozone Exposure in the United States from 2000 to 2015." *Atmospheric Chemistry and Physics* 20, no. 3 (February 14, 2020): 1757–75. https://doi.org/10.5194/acp-20-1757-2020.

[56] Dedoussi, Irene C., Sebastian D. Eastham, Erwan Monier, and Steven R. H. Barrett. "Premature Mortality Related to United States Cross-State Air Pollution." Nature 578, no. 7794 (February 2020): 261–65. https://doi.org/10.1038/s41586-020-1983-8.

no epidemiologic studies examining the association between long-term exposure to ozone and COPD available for inclusion in the 2013 Ozone ISA, a recent study by Paulin et al. (2019) of smokers with or at-risk for COPD found that long-term exposure is associated with worse respiratory outcomes and increased emphysema and gas trapping. As noted in Limaye and Knowlton (2019),[57] the adverse respiratory health outcomes identified in this study were found to be potentially independent of smoking intensity or exposures to air pollution on the job, underscoring the health risks that ozone air pollution poses to tens of millions of individuals who currently smoke or formerly smoked. Additional studies published after March 2018 demonstrate causal links between long-term exposures and adverse health outcomes. Lim et al. (2019)[58] investigated associations of long-term (annual or warm season average of daily 8-h maximum concentrations) exposure with all-cause and cause-specific mortality in the NIH-AARP Diet and Health Study, a large prospective cohort of U.S. adults with 17 years of follow-up from 1995 to 2011. That study found that long-term annual average exposure was significantly associated with deaths caused by cardiovascular disease (per 10 ppb; hazard ratio [HR], 1.03; 95% confidence interval [CI], 1.01–1.06), ischemic heart disease (HR, 1.06; 95% CI, 1.02–1.09), respiratory disease (HR, 1.04; 95% CI, 1.00–1.09), and chronic obstructive pulmonary disease (HR, 1.09; 95% CI, 1.03–1.15) in single-pollutant models. The results were robust to alternative models and adjustment for co-pollutants (fine particulate matter and nitrogen dioxide).

Rhee et al. (2019)[59] analyzed air pollution exposures at the ZIP code level in the U.S. and hospital admissions with acute respiratory distress syndrome (ARDS) among nearly 1.2 million Medicare beneficiaries aged >65 years from 2000 to 2012 and found that an increase of 1 ppb in annual average ozone was associated with statistically significant increases in annual hospital admission rates for ARDS of 0.72% (95% CI, 0.62–0.82) and 0.15% (95% CI, 0.08–0.22), respectively. Importantly, this effect remained in low-pollution regions meeting the current NAAQS (annual average PM2.5 level < 12 $\mu g/m^3$ and annual average ozone level < 45 ppb). In those areas, the 1 ppb annual increase in ozone was associated with an increase in annual hospital admission rates for ARDS of 0.27% (95% CI, 0.16–0.38).

As noted by Nassikas et al. (2020),[60] the meteorological conditions that govern ozone concentration are projected to be more favorable to ozone formation over much of the United

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[57] Limaye, Vijay S, and Kim Knowlton. "Shining New Light on Long-Term Ozone Harms." JAMA Internal Medicine, 2019, 2. https://doi.org/10.1001/jamainternmed.2019.5967.

[58] Lim, Chris C., Richard B. Hayes, Jiyoung Ahn, Yongzhao Shao, Debra T. Silverman, Rena R. Jones, Cynthia Garcia, Michelle L. Bell, and George D. Thurston. "Long-Term Exposure to Ozone and Cause-Specific Mortality Risk in the United States." American Journal of Respiratory and Critical Care Medicine 200, no. 8 (May 3, 2019): 1022–31. https://doi.org/10.1164/rccm.201806-1161OC.

[59] Rhee, Jongeun, Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Yun Wang, Qian Di, John Balmes, and David C. Christiani. "Impact of Long-Term Exposures to Ambient PM2.5 and Ozone on ARDS Risk for Older Adults in the United States." Chest 156, no. 1 (July 2019): 71–79. https://doi.org/10.1016/j.chest.2019.03.017.

[60] Nassikas, Nicholas, Keith Spangler, Neal Fann, Christopher G. Nolte, Patrick Dolwick, Tanya L. Spero, Perry Sheffield, and Gregory A. Wellenius. "Ozone-Related Asthma Emergency Department Visits in the U.S. in a

States due to continued climate change, even as emissions of anthropogenic ozone precursors are expected to decrease by 2050. In particular, as noted by Archer et al. (2019),[61] in the mid-Atlantic region of the United States, warmer temperatures caused by climate change threaten to heighten long-term ozone levels and chronic exposures to ozone.

Strosnider et al. (2019)[62] conducted an analysis of respiratory emergency department visits in 894 counties, the largest U.S. multicity study of impacts among all ages. Linking daily respiratory emergency department visits with estimated ozone concentrations during the week before the date of the visit, per 20-ppb increase in ozone, rate ratios were statistically significant at 1.017 (1.011–1.023) among children, 1.051 (1.046–1.056) among adults younger than 65, and 1.033 (1.026–1.040) among adults 65 and older.

Collectively, these studies build upon the existing body of evidence and coherently demonstrate significant causal links between long-term exposure to ozone and adverse health outcomes. Moreover, they show that long-term exposures at levels well below 70 ppb contribute to widespread population health harms. EPA has not considered establishing a long-term exposure standard despite robust evidence that doing so would benefit human health. EPA's failure to so consider is arbitrary, capricious and an abuse of discretion, for it allows unquestionably adverse effects—like death, hospitalization, emergency room visits, and disease worsening or incidence—to persist, contrary to the Clean Air Act.

In so failing, EPA also departs without explanation from CASAC's recommendation. As CASAC recognized, there's a mismatch between the short-term averaging period of the current standard and the long-term exposures that also cause harms: lowering the short-term peaks doesn't necessarily lower the long-term levels that harm people.[63] At most, the PA includes a footnote about how the 2014 HREA found that reductions to meet an 8-hour standard "would be expected to reduce $O_3$ concentrations in terms of the metrics reported in epidemiologic studies to be associated with respiratory mortality and morbidity,"[64] but "expected" is different from reality, and CASAC's comments were about reality. The Proposal is silent. Even if EPA's buried speculation in the PA were enough to constitute addressing CASAC's recommendation, it does so without rational explanation.

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Warming Climate." Environmental Research 183 (April 2020): 109206. https://doi.org/10.1016/j.envres.2020.109206.

[61] Archer, Cristina L., Joseph F. Brodie, and Sara A. Rauscher. "Global Warming Will Aggravate Ozone Pollution in the U.S. Mid-Atlantic." Journal of Applied Meteorology and Climatology 58, no. 6 (June 2019): 1267–78. https://doi.org/10.1175/JAMC-D-18-0263.1.

[62] Strosnider, Heather M., Howard H. Chang, Lyndsey A. Darrow, Yang Liu, Ambarish Vaidyanathan, and Matthew J. Strickland. "Age-Specific Associations of Ozone and Fine Particulate Matter with Respiratory Emergency Department Visits in the United States." American Journal of Respiratory and Critical Care Medicine 199, no. 7 (April 2019): 882–90. https://doi.org/10.1164/rccm.201806-1147OC.

[63] *See* CASAC review of PA, *supra* n. 33, at 4-5.

[64] U.S. EPA, Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, External Review Draft, EPA-452/P-19-002 (October 2019), at 3-12 n.18. [hereinafter "2020 Policy Assessment"]

### C. EPA cannot rely on claimed "uncertainties" and other impermissible factors to avoid strengthening the standard

EPA must set standards to protect public health even if there are scientific uncertainties, as stated by the Clean Air Act and reaffirmed by the federal courts.[65] The Administrator's proposed decision to retain the primary ozone standard is fundamentally at odds with the Clean Air Act's essential purpose and requirements. Ignoring precedent and the statutory directive to set standards at a precautionary level—one "allowing an adequate margin of safety"—the Administrator proposes not to revise the primary standard based on purported "uncertainties" in the science – even though there is coherent and powerful evidence of serious harm, including hospitalization; and more than ample epidemiological evidence of dire harm, at human exposure levels well below those allowed by the current NAAQS; corroborating clinical evidence showing the biological plausibility of those effects; and accountability and similar related studies showing reductions in health effects when ozone levels are reduced.

EPA also proposes to arbitrarily rely on purportedly similar evidence regarding the level of protection EPA projects here and what it projected in the 2015 standard as a basis for retaining the current standard. *See, e.g.*, 85 Fed. Reg. at 49,860/2, 49,866/1; *see also id.* at 49,869/1-2 (similar, regarding "overall health effects evidence base" and conclusions drawn therefrom), 49,870/1-2 (similar, regarding chamber and epidemiologic studies and relevant exposure levels), 49,871/2-3 (proposing to "consider the exposure and risk analyses for this review" "similarly" to how EPA considered them in the 2015 review, and claiming "the current analyses update and improve upon" the prior ones), 49,873/1-3 (similar, regarding proposed conclusions regarding exposure analysis results); *see also id.* at 49,870/2 ("the Administrator notes that the evidence base in this review does not include new evidence of respiratory effects associated with appreciably different exposure circumstances than the evidence available in the last review, including particularly any circumstances that would also be expected to be associated with air quality conditions likely to occur under the current standard."). Even if that were true, and even if it were permissible and rational to rely on the exposure assessment as EPA proposes to, the purported similarities just aren't relevant. The D.C. Circuit firmly rejected the notion that "the initial assessment is sacrosanct and remains the governing standard until every aspect of it is undermined." *Mississippi*, 744 F.3d at 1343 ("It would … make no sense to give prior NAAQS the sort of presumptive validity Mississippi insists upon."). The analytical similarities do not support retaining the standard, for privileging EPA's prior approach "would bind EPA to potential deficiencies in past reviews because discrepancies between past and current judgments as easily reflect problems in the past as in the present." *Id.* And, to the extent the evidence

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[65] Comments of Christopher Frey. Regarding the CASAC's Review of the U.S. EPA's External Review Draft of the PA for Ozone (2019). December 5, 2019. Pg. 27-28. *Available at* https://yosemite.epa.gov/sab/sabproduct.nsf/9FB1491880D2E312852584C70060F33D/$File/Written+Statement+H+Christopher+Frey+CASAC+O3+Draft+PA+191205+Submitted.pdf [hereinafter "Frey PA Comments"].

regarding ozone's harms has grown stronger—as it has—that supports a stronger standard, for evidence that bolsters prior conclusions can justify a stronger standard. *Id.* at 1344 ("additional certainty about what was merely a thesis might very well support a determination that the line marked by the term 'requisite' has shifted.").

### D. The proposed decision to retain the current NAAQS does not even purport to comply with the Act's requirements

The Administrator proposes to conclude only that the current standard "provides a strong degree of protection to at-risk populations such as children with asthma" or "a high level of protection, including for at-risk populations, from $O_3$-related effects of exposures that might be expected with air quality conditions that just meet the current standard." 85 Fed. Reg. at 49,873/1. This does not even claim to meet the Act's requirements: "NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children, and if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *Coal. of Ass'n of Battery Recyclers*, 604 F.3d at 618 (cleaned up); *accord American Lung*, 134 F.3d at 389 ("NAAQS 'must be set at a level at which there is "an absence of adverse effect" on [] sensitive individuals'" (alteration in original; quoting *Lead Indus.*, 647 F.2d at 1153). Whatever "a strong degree of protection" or "a high level of protection" mean, it is not the same as assuring the "absence of adverse effect," as required.

### E. EPA arbitrarily fails to consider ozone's impacts on important populations of concern

Exposure to ozone poses risks to the health of key vulnerable sub-populations, but EPA does not adequately consider these impacts within the Proposal, or the final ISA and PA. For example, numerous commenters[66] noted at CASAC meetings in December 2019 and February 2020 that the committee and EPA should consider at-risk populations (including outdoor workers, communities of color, and communities of lower socioeconomic status), but the Agency failed to do so in its draft ISA and PA review documents. Commenters noted that an approach favored by one CASAC member failed to consider scientific evidence of impact on specific at-risk populations including the elderly, children, and those with diseases by discounting

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[66] Comments of California Air Resources Board and Office of Environmental Health Hazard Assessment. Regarding the U.S. EPA's External Review Draft of the ISA for Ozone and Related Photochemical Oxidants (2019). December 2, 2019. *Available at* https://yosemite.epa.gov/sab/sabproduct nsf/E5D4E292A9FC0D39852584C5006A8C01/$File/FINAL+Ozone+ISA+ARB+OEHHA+comment+letter+2dec19+signed+v2.pdf [hereinafter "CARB and OEHHA ISA Comments"]; Frey PA Comments pg. 5, 33; Comments of Gretchen T. Goldman. Regarding the U.S. EPA ISA for Ozone (2019). February 3, 2020. Pg. 3. *Available at* https://yosemite.epa.gov/sab/sabproduct nsf/6A65E491F6F2671E8525850300556483/$File/GTGoldman-O3-Feb11.pdf [hereinafter "Goldman ISA Comments"].

epidemiology evidence and favoring manipulative causation studies and thus would not allow CASAC to provide the advice the statute requires for EPA to fulfill its charge.[67]

In its failure to consider impacts on these populations of concern within the ISA, PA, and the Proposal itself, EPA has departed from past practice. For example, the 2013 ISA devoted an entire chapter to a discussion of increased-risk populations; to rationally protect such populations, EPA needs to complete a similar review for this ISA, or at least discuss at-risk populations for each health outcome. This concern[68] was presented to EPA and CASAC in December 2019, months before the recent ISA was finalized. This concern also relates to EPA and CASAC consideration of vulnerable groups within specific sections of the ISA. For example, as it relates to the relationship between short-term ozone and cardiovascular disease effects and total mortality, CASAC gave insufficient consideration of effects on the more vulnerable segments of the population.[69]

In addition to its failure to robustly consider the health harms inflicted by ozone air pollution on vulnerable groups broadly within the ISA and PA, EPA also failed to include at least one relevant study published within the initial ISA review period. A comprehensive systematic review and meta-analyses published by Bell et al. (2014)[70] synthesized evidence across 167 peer-reviewed studies meeting strict inclusion criteria (73 on mortality and 96 on hospitalizations and emergency department visits, including 2 examining both mortality and hospitalizations) in order to identify populations at heightened risk of health harms from ozone. That study found a significant positive relationship between short-term ozone exposure and mortality risks among older populations. In that study, per 10-ppb increase in daily 8-hour ozone concentration, mortality risk for younger persons, at 0.60% (95% CI): 0.40, 0.80), was statistically lower than that for older persons, at 1.27% (95% CI: 0.76, 1.78). Findings adjusted for publication bias were similar. Limited/suggestive evidence was found for higher associations among women; mortality risks were 0.39% (95% CI: −0.22, 1.00) higher than those for men. It also identified strong evidence for higher associations with unemployment or lower occupational status.

Recently, an epidemiological study examining the effects of air pollution and other meteorological factors on COVID-19 confirmed cases and deaths in Queens, New York found that increases in the daily maximum eight-hour ozone concentration was "…statistically and positively associated with new confirmed cases related to COVID-19…".[71] The study was

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[67] *See* Goldman ISA Comments, *supra* n. 66, pg. 3.
[68] *See* CARB and OEHHA ISA Comments, *supra* n. 66, pg. 9.
[69] *Id.,* pg. 5.
[70] Bell, Michelle L., Antonella Zanobetti, and Francesca Dominici. "Who Is More Affected by Ozone Pollution? A Systematic Review and Meta-Analysis." *American Journal of Epidemiology* 180, no. 1 (July 1, 2014): 15–28. https://doi.org/10.1093/aje/kwu115.
[71] Adhikari, Atin and Yin, Jingjing. "Short-Term Effects of Ambient Ozone, PM2.5, and Meteorological Factors on COVID-19 Confirmed Cases and Deaths in Queens, New York." *International Journal of Environmental Research and Public Health 17 (June 5, 2020).* https://doi.org/10.3390/ijerph17114047.

conducted in response to recently published studies from China that reported short-term exposures of pollutants like ozone and other meteorological factors were significantly associated with COVID-19 cases.[72] The Queens study found that a one-unit increase in the moving average of ozone was associated with a 10.51% in daily new COVID-19 cases.[73] Notably, authors state that "[a]lthough ozone levels were found to be increasing during the COVID-19 outbreak in Queens, none of the data points for the height-hour max ozone exceeded the EPA health-related regulatory standard of 0.07-0.085 ppm (unhealthy for sensitive groups)." The author's observation that the height-hour max ozone level was not exceeded suggests the current standard may not be protective when accounting for impacts to individuals exposed to the SARS-CoV-2 virus. Given the emerging evidence linking air pollution and COVID-19 infections, EPA should consider how air pollutants, like ozone, would impact public health in the near and long term.

Moreover, in its current review EPA has not considered particular risks of ozone exposures to outdoor workers, whose patterns in exposure, underlying health conditions, income distribution, and other underlying health determinants can at times differ from those of the general population.[74]

As explained above, the Clean Air Act requires EPA to protect these vulnerable subpopulations from ozone's adverse effects. EPA ignores its statutory obligation and acts arbitrarily in failing to do so.

### F. EPA's near-exclusive focus on lung function decrements demonstrated in controlled human experiments on healthy young adults arbitrarily overlooks important factors and sensitive populations for whom the standards must be protective with an adequate margin of safety

In proposing to retain the current primary standard, the Administrator proposes to "give[] particular attention to the longstanding evidence of respiratory effects causally related to short-term $O_3$ exposures." 85 Fed. Reg. at 49,869/1. EPA thus repeats its exceedingly well-founded, long-standing conclusion that short-term ozone exposure causes respiratory effects. *Id.* at 49,844/2-46/3, 49,869/2; *accord, e.g.*, PA at 3-23 to -28; ISA at ES-8, IS-24 to -31 & tbl.IS-4. Among those respiratory effects are lung function decrements (measured as decreases in $FEV_1$), respiratory symptoms, and airway inflammation. *E.g.*, 85 Fed. Reg. at 49,845/1-2. EPA notes repeatedly that highly probative, controlled human experiments on healthy young adults have

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[72] Yongjian, Z.; Jingu, X.; Fengming, H.; Liqing, C. "Association between short-term exposure to air pollution and COVID-19 infection: Evidence from China." *Science of the Total Environment,* (April 13, 2020). https://doi.org/10.1016/j.scitotenv.2020.138704

[73] *Id* at 71.

[74] Moda, Filho, and Minhas. "Impacts of Climate Change on Outdoor Workers and Their Safety: Some Research Priorities." *International Journal of Environmental Research and Public Health* 16, no. 18 (September 17, 2019): 3458. https://doi.org/10.3390/ijerph16183458.

shown statistically significant increases in lung function decrement and respiratory symptoms occur just above 70 ppb and statistically significant increases in inflammation occur at 60 ppb. *Id.* at 49,842/3, 49,851/2, 49,870/2. EPA also notes that more sensitive populations, such as people with asthma, are more vulnerable to experiencing harms from the same level of ozone than healthy young adults are. *Id.* at 49,846/1, 49,848/1, 49,857/3; *see also id.* at 49,869/2-3, 49,870/3. Yet, the Administrator's proposed conclusions hardly mention inflammation at all, and puts significantly less weight on harmful exposures to at least 60 ppb ozone levels, instead almost entirely addressing lung function decrement and respiratory symptoms at the 70 ppb benchmark exposure level. *See id.* at 49,868/3-74/1. Further, in proposing to retain the current standard's level, the Administrator fails to explain how his reliance on controlled human experiments on exclusively healthy young adults protects more sensitive populations. Understanding the level of ozone at which sensitive populations experience effects and which effects are adverse is fundamental to assessing whether this Proposal rationally satisfies the Clean Air Act's health-protective mandate. As explained below, the Administrator's Proposal is arbitrary.

**1. EPA failed to rationally consider new information regarding adversity of effects**

In numerous past NAAQS reviews, EPA has given significant weight to the American Thoracic Society's expertise regarding what constitutes an adverse effect of air pollution. *See, e.g.*, *Murray Energy*, 936 F.3d at 612 (EPA "chose to adopt the ATS definition of adversity"); *ATA III*, 283 F.3d at 375-76 ("in deciding when certain observed physiological effects of ozone 'become so significant that they should be regarded as adverse' to individuals' health, EPA looked to guidelines published by the American Thoracic Society."); 84 Fed. Reg. 9866, 9878/2, 9883/3, 9892/2, 9900/2-3 (Mar. 18, 2019); 73 Fed. Reg. 37,818, 37,849/2-50/3, 37,868/1, 37,871/2 (July 11, 2007); *see also* 85 Fed. Reg. at 49,840/2 (noting that in 2015 review, EPA considered, in determining adversity of effects, "commonly accepted guidelines or criteria within the public health community, including statements of the American Thoracic Society (ATS), an organization of respiratory disease specialists"). Indeed, in the 2015 review, EPA departed from its 2008 approach to determining how lung function decrement changes can amount to an adverse effect, and the D.C. Circuit relied on EPA's purported adherence to the then-current ATS guidelines about what constitutes an adverse effect of air pollution in upholding the change. *Murray Energy*, 936 F.3d at 612.

Since the 2015 NAAQS, ATS has updated its guidelines.[75] Importantly, in the newly updated guidelines, ATS expressly stated that "small lung function changes should be considered adverse in individuals with extant compromised function, such as that resulting from asthma, even without accompanying respiratory symptoms," a change from its prior guidelines, which

[75] Thurston et al., A Joint ERS/ATS Policy Statement: What Constitutes an Adverse Health Effect of Air Pollution? An Analytical Framework, 49 Eur. Respiratory J. 1600419 (2017) [hereinafter "ATS Guidelines"].

did not expressly address this circumstance.[76] The newly updated guidelines also emphasize the importance of considering impacts on especially susceptible subpopulations, and discuss how a focus on broad group-level average effects can mask more substantial (harmful) effects experienced by a subset of the group.[77]

In this Proposal, EPA has not rationally considered the new ATS guidelines. It notes the new ATS statement that "'small lung function changes' in individuals with preexisting compromised function, such as asthma, 'should be considered adverse…even without accompanying respiratory symptoms,'" and that the ATS guidelines emphasize the importance of examining effects in subsets of broader populations (including a population like "study subjects"). 85 Fed. Reg. at 49,848/3. But EPA fails to rationally discuss or otherwise implement these guidelines. Instead, EPA examines the number of study subjects in chamber studies who experience $FEV_1$ decrements of at least 15%. *Id.* at 49,851/2-3; *see also id.* at 49,863/1-2 (similarly highlighting the 15% $FEV_1$ decrement threshold). EPA nowhere offers any explanation as to why it is solely considering the number who experience 15% $FEV_1$ decrement. The PA acknowledges that, in prior reviews, "the CASAC concurred with the EPA's use in the 2014 HREA of estimated $FEV_1$ decrements of ≥15% as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, and an $FEV_1$ decrement of ≥10% as a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease," and that, in the risk assessment, "mid- to upper-end of the range of moderate levels of functional responses and higher (i.e., $FEV_1$ decrements ≥15% and ≥20%) are included to generally represent potentially adverse lung function decrements in active healthy adults, while for people with asthma or lung disease, a focus on moderate functional responses ($FEV_1$ decrements down to 10%) may be appropriate." PA app.3D at 3D-73, 3D-76. EPA's lack of any explanation for fixing exclusively on 15% decrement, rather than 10% decrement, in its analysis

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[76] *Id.,* ATS Guidelines, at 7; see also ATS, Samet et al., What Constitutes an Adverse Health Effect of Air Pollution?, 161 Am. J. Respir. Crit. Care Med. 665, 670-71 (2000). Notably, in its 2008 review of the ozone NAAQS, EPA took an approach that is consistent with the newly updated ATS guidelines. It found that lung function decrement of 10% or greater was "harmful (or 'adverse') to asthmatics." *Mississippi*, 744 F.3d at 1349 (citing 73 Fed. Reg. at 16,454-55). Indeed, EPA in the 2008 final rule "strongly" rejected comments suggesting that "transient decreases in $FEV_1$ of 10-20% are not by themselves significant or meaningful to asthmatics," explaining that for such people, this level of lung function decrease "would likely interfere with the normal activities for many individuals, and would likely result in more frequent medication use." 73 Fed. Reg. at 16,463/2-3.

[77] ATS Guidelines, at 3 tbl.1 ("[s]usceptibility" is one of the "[c]onsiderations for assessing adversity of clinical or pathological effects"), 5 (discussing study and noting that for "young healthy subjects, individual risk of a clinical event is minimal, but population risk, including that of susceptible subpopulations, such as the elderly, is probably substantial"), 5 ("considerations of health equity and environmental justice (e.g. socioeconomically disadvantaged populations being more exposed to air pollutants) are also similarly relevant to an assessment of adversity at the population level, with a similar shift in exposure and risk being of greater adversity to such vulnerable populations."), 7 (warning that "a small but statistically significant mean reduction in $FEV_1$ in a population means that some people had larger reductions, with the likelihood that reductions in a subset of susceptible subjects can have passed a threshold for clinical importance"), 8 (reaffirming discussion on preceding page regarding $FEV_1$ decrement).

in the Proposal of the chamber study results is arbitrary, particularly as the 15% decrement threshold has no apparent tie to the sensitive subjects who the standard must protect.

Beyond its arbitrary use solely of a 15% $FEV_1$ threshold, EPA also does not rationally consider effects on a subset of study subjects. It discusses just the raw number of subjects who experienced such a decrement. The raw number alone provides no information about how results might be generalized to a broader population—which is a key consideration in determining the public health importance of an effect caused by air pollution. Further, to the extent the Administrator examines effects on a subset of study subject in proposing conclusions, he merely uses the subset results to conclude that the higher the level of ozone, the more people who experience effects. *See* 85 Fed. Reg. at 49,863/1-2. Such an analysis just says that at a higher level, more effects occur, which leaves unexamined and unanswered the question of whether effects occur at a particular level (or whether those effects are adverse).

That the ATS guidelines do not generally expressly establish numerical thresholds and often avoid specificity does not free EPA from its heavy burden under the Clean Air Act and Administrative Procedure Act to explain its decision-making process, especially in the tremendously important context of protecting public health. Moreover, EPA's interpretation of the ATS guidelines regarding numerical criteria in this arena is overstated. First, in context, the guidelines' statement that "[t]here cannot be precise numerical criteria, as broad clinical knowledge and scientific judgments, which can change over time, must be factors in determining adversity," relates to authors' concerns that, as knowledge develops, we may find new effects and need to be able to apply new knowledge to say whether they're adverse. Thurston et al., *ATS Guidelines*, at 4. Second, in discussing precisely the issue of interpreting $FEV_1$ decrements observed in chamber studies of ozone exposure, the guidelines expressly mention the 10% $FEV_1$ decrement threshold, *id.* at 7-8, indicating that, like EPA historically has, the guidelines regard the 10% threshold as worthy of consideration. Thus, EPA's failure to discuss the clinical significance of such a level—particularly for people with existing lung disease—is arbitrary. *See also infra* § IV.F.3.

Further confirmation of EPA's arbitrary approach toward the newly updated ATS guidelines comes from CASAC. CASAC highlighted the newly updated guidelines in recommending to EPA that lung function decrement in the absence of respiratory symptoms should be considered adverse for children with asthma. CASAC Consensus Responses on PA 8-9; *see also id.* at A-15 (comments of Dr. Frampton[78] similarly raising point). Contrary to

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[78] Notably, current CASAC member Dr. Mark W. Frampton is also one of the co-authors of the updated ATS guidelines. CASAC Consensus Responses on PA at ii (listing as one CASAC member "Dr. Mark W. Frampton, Professor Emeritus of Medicine, Pulmonary and Critical Care, University of Rochester Medical Center, Rochester, NY"); Thurson et al., *ATS Guidelines*, at 1-2 & n.11 (listing as author "Mark W. Frampton," and giving his affiliation as "Pulmonary and Critical Care, Depts of Medicine and Environmental Medicine, University of Rochester Medical Center, Rochester, NY, USA").

CASAC's express recommendation, as explained above, EPA fails to rationally discuss this point.

### 2. EPA arbitrarily focuses on lung function decrements and respiratory symptoms ahead of lung inflammation

As corroborated by studies cited in the ISA, exposure to ozone causes lung inflammation, emphysema, and interstitial fibrosis with progressive loss of lung function. Chronic lung inflammation is a characteristic feature of lung diseases as chronic obstructive pulmonary disease and asthma.[79] Systemic inflammation has been linked to a number of cardiovascular disease-related outcomes and is an important indicator of disease development. For example, circulating cytokines such as IL-6 can stimulate the liver to release inflammatory proteins (e.g., CRP) and coagulation factors that can ultimately increase the risk of thrombosis and embolism (ISA at 4-27). Importantly, Tables 4-28 and 4-29 of the ISA (beginning at page 4-108) demonstrate that evidence of inflammation is apparent after short-term exposures ranging from 12-35 ppb.

The 2011 Kim study showed a statistically significant increase in inflammation for healthy young adults exposed to 60 ppb of ozone over 6.6 hours of moderate exercise. 85 Fed. Reg. at 49,851-52 tbl.1, 49,870/2. This is important because respiratory inflammation is a well-documented harm resulting from short-term ozone exposure. *E.g.*, ISA at IS-25 tbl.IS-4, IS-17, app.3 at 3-28 to -39. Over time, even with lower levels of exposure than the current standard targets, ozone can result in inflammation that can cause permanent lung damage and development of severe lung disease. ISA at IS-35, app.3 at 3-90 to -94, 3-102 to -104. It is particularly concerning for people with lung disease like asthma, which is an "inflammatory lung disease," *id.* app.3 at 3-39, as "airway inflammation…is a primary feature in the clinical definition and characterization of asthma severity," and people with asthma may be particularly prone to experiencing inflammation from ozone exposure. *Id.* app.3 at 3-49, 3-53 to -54. As well as being harmful in itself, it also provides coherence for epidemiologic studies tying ozone exposure to other serious health harms, like emergency room visits. ISA at IS-29 to -31, app.3 at 3-2, 3-4, 3-8 to -10, 3-81 to -83, 3-85 tbl.3-2.

Consistent with inflammation's serious consequences, CASAC highlighted how inflammation is "a key component in the pathophysiology of asthma," and that it and other ozone-induced effects "likely contribute to the risk of an asthma exacerbation." CASAC Consensus Responses on PA 8; *accord id.* at A-14 (comments of Dr. Frampton). And, as mentioned above, CASAC explained,

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[79] Groves, Angela M., Andrew J. Gow, Christopher B. Massa, Jeffrey D. Laskin, and Debra L. Laskin. "Prolonged Injury and Altered Lung Function after Ozone Inhalation in Mice with Chronic Lung Inflammation." *American Journal of Respiratory Cell and Molecular Biology* 47, no. 6 (December 2012): 776–83. https://doi.org/10.1165/rcmb.2011-0433OC.

> It is reasonable to expect that, in people with asthma, <u>any</u> increase in airway inflammation is an adverse effect, with the potential to increase the risk for an asthma exacerbation. Repeated episodes of airway inflammation may enhance airway remodeling, which occurs in asthma, and leads to irreversible reductions in lung function.

*Id.* at 8 (emphasis added); *accord id.* at A-14 (comments of Dr. Frampton).

But in proposing to retain the 2015 ozone standard, the Administrator focuses on study results regarding lung function decrement and respiratory symptoms, an EPA-acknowledged adverse combination of effects that occurred with statistical significance in a study of exposure to ozone levels just above 70 ppb. *See* 85 Fed. Reg. at 49,868/3-74/1; *see also, e.g.*, *id.* at 49,866/2-3 (acknowledging combination of lung function decrements and respiratory symptoms is adverse). Accordingly, the Administrator proposes to once again emphasize the 70 ppb level of ozone, giving lesser weight to exposures to 60 ppb, a level at which ozone causes inflammation, with even less weight going to single such exposures. *Id.* at 49,872/2-3. The Administrator fails to rationally explain how this approach protects against the harms inflammation causes. Indeed, CASAC found that EPA was putting too much weight on lung function decrement, and instead highlighted the importance of lung inflammation as an adverse effect for people with asthma. CASAC Consensus Responses on PA 8-9; *accord id.* at A-13 to -14 (comments of Dr. Frampton); *see also* 85 Fed. Reg. at 49,845/3 (describing concerns 2013 ISA described about inflammation and lung function decrement and symptoms).

The Administrator's failure to explain his deprecation of inflammation is particularly important. He proposes to ultimately rely largely on the results of the exposure assessment to purportedly justify retaining the existing standard.[80] 85 Fed. Reg. at 49,871/1 ("As at the time of the last review, the exposure and risk estimates developed from modeling exposures to $O_3$ in ambient air are critically important to consideration of the potential for exposures and risks of concern under air quality conditions of interest, and consequently are critically important to judgments on the adequacy of public health protection provided by the current standard."); *see also id.* at 49,871/1-73/1 (discussing exposure analysis). Specifically, he proposes to heavily rely on the exposure assessment's finding that there would be no more than 1% of children with asthma (and all children), experiencing at least one dangerous 7-hour exposure to 70 ppb of ozone in a year. *Id.* at 49,872/2, 49,873/1; *see also id.* at 49,860 tbl.2. By contrast, the Administrator proposes that such exposures to 60 ppb of ozone are "of lesser concern than occurrences for the next higher benchmark of 70 ppb," and to give even less weight to single such exposures to 60 ppb of ozone (as opposed to multiple such exposures). *Id.* at 49,872/2-3. His Proposal allows exposures to 60 ppb, measured as a percent of children with asthma (and all children), approximately an order of magnitude greater than exposures to 70 ppb. *See id.* at

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[80] For this paragraph's purposes, we assume for the sake of argument that the Administrator's reliance on the exposure assessment were rational and lawful.

49,860 tbl.2 (maximum percent of children with asthma and all children with at least one exposure to 70 ppb benchmark is 1.0% and 0.9%, respectively; to 60 ppb benchmark is 11.2% and 10.6%, respectively). Even if the Administrator's proposed greater weight on multiple exposures to the 60 ppb benchmark (as opposed to single such exposures) were rational, the percentage of children so exposed would still be meaningfully different from the percentage exposed to the 70 ppb benchmark at least once per year. *See id.* (up to 4.9% of children with asthma and 4.3% of all children would experience multiple exposures to 60 ppb benchmark). The Administrator must strengthen the standard to prevent such a large percentage of children—particularly especially vulnerable children—from experiencing such dangerous exposures. *See Coal. of Ass'n of Battery Recyclers*, 604 F.3d at 618 ("this court has held that NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children, and if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." (cleaned up)). At the very least, the Administrator must rationally explain (as he thus far has not) how the standard provides requisite protection for sensitive populations. *American Lung*, 134 F.3d at 392-93.

### 3. EPA fails to rationally explain how its approach protects more sensitive populations who are not subjects in controlled human experiments

Of the scientific evidence underlying the Administrator's Proposal to retain the current standard, the Administrator relies most heavily on chamber studies whose participants are solely healthy young adults. *See, e.g.*, 85 Fed. Reg. at 49,869/3-70/3. The Administrator notes EPA's prior identification of adverse effects demonstrated in chamber studies, which includes the adverse combination of lung function decrement and respiratory symptoms demonstrated to occur in healthy young adults at 72 ppb (or, EPA now contends, 73 ppb, *e.g.*, 85 Fed. Reg. at 49,856/2 n.80, 49,870/2, 49,872/1-2).[81] *See* 85 Fed. Reg. at 49,871/1-2; *e.g.*, 80 Fed. Reg. at 65,325/2, 65,330/2-31/2, 65,346/3, 65,363/1-2, 65,364/1. But, as explained above, the NAAQS must protect sensitive subpopulations, not merely healthy young adults. EPA acknowledges that people with asthma are more vulnerable to ozone. *E.g.*, 85 Fed. Reg. at 49,846/1, 49,848/1-49/1, 49,857/3-58/1, 49,863/3, 49,869/2-3. Yet the Administrator does not explain how he accounts for this greater vulnerability.

The consideration the Administrator gives to children with asthma focuses on curbing (but not eliminating) exposures to at least 70 ppb of ozone and, to a lesser degree, exposures to at least 60 ppb of ozone. *E.g.*, *id.* at 49,871/1-73/1. Nowhere does EPA explain what the results of chamber studies on healthy young adults mean for more sensitive populations exposed at similar levels: what do these studies mean for lung function decrement in such populations exposed at that level? What is the clinical significance of such lung function decrement? What about other

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[81] This study accounts for the Administrator's focus on exposures to 70 ppb. *See, e.g.*, 85 Fed. Reg. at 49,856/2 & n.80, 49,870/2, 49,872/1-2.

effects that healthy young adults may not experience, but more sensitive populations would as a result of exposure at that level? It is possible to answer these questions. For example, in the prior review, CASAC expressly found that the chamber studies (which EPA agrees have not changed) showed that "in healthy subjects, decreases in lung function and respiratory symptoms occur at concentrations as low as 72 ppb and that these effects almost certainly occur in some people, including asthmatics and others with low lung function who are less tolerant of such effects, at levels of 70 ppb and below." EPA-HQ-OAR-2008-0699-0190 at 6 (discussing effects of 8-hour exposures to ozone). But without addressing such questions, EPA cannot rationally explain how it meets the statutory test of assuring the absence of adverse effect in sensitive populations. *See American Lung*, 134 F.3d at 392-93.

To be sure, EPA points to a few additional studies of people with asthma that EPA thinks means lung function response between people with asthma and people without asthma is similar, *id.* at 49,849/1, but, as CASAC notes, those studies do not look at people with more severe asthma or children. CASAC Consensus Responses on PA 8; *accord id.* at A-13, A-15 (comments of Dr. Frampton). Nor does EPA address what the significance of such lung function decrement is for sensitive populations, like children with asthma. *See id.* at 8 (warning that "suggest[ion] that lung function decrements in the absence of symptoms do not represent an adverse health effect…should not apply to children with asthma"); *id.* at A-15 (comments of Dr. Frampton).

EPA thus assumes that the level of lung function impairment—and the significance of such impairment—is similar for people who can bear it the least. There is no basis for that assumption. Moreover, as explained above, NAAQS are supposed to be protective and precautionary, including for sensitive populations. EPA's assumption is thus not just unexplained but also inconsistent with the Act and the controlling judicial interpretations of it.

#### 4. Not strengthening the standard in view of this evidence would be arbitrary and unlawful

For the reasons given above, EPA's proposed decision not to strengthen the standards is arbitrary. Further, given the evidence available to it, its proposed decision is unlawful under the Clean Air Act.

As discussed above, the D.C. Circuit has made clear that NAAQS must protect against adverse effects in sensitive population—"[i]f a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *American Lung*, 134 F.3d at 389; *accord Coal. of Ass'n of Battery Recyclers*, 604 F.3d at 618; *see Lead Indus.*, 647 F.2d at 1153 ("the Administrator is to set standards which ensure that there is 'an absence of adverse effects.'"). In these binding decisions, the D.C. Circuit relied on, among other things, the Senate Report on the Clean Air Act Amendments of 1970. *See Coal. of Ass'n of Battery Recyclers*, 604 F.3d at 618 (quoting *American Lung* and noting that *American Lung* quotes S. Rep. No. 91-1196, at 10 (1970)); *American Lung*, 134 F.3d at 389 (quoting S. Rep. No. 91-1196,

at 10, and citing *Lead Industries* and noting that *Lead Industries* quotes S. Rep. No. 91-1196, at 10); *Lead Indus.*, 647 F.2d at 1152-53 (quoting S. Rep. No. 91-1196, at 10). That same Senate Report provides important additional detail about when "air quality is sufficient to protect the health of [sensitive individuals]":

> [W]henever there is an absence of adverse effect on the health of a statistically related sample of persons in sensitive groups from exposure to the ambient air. An ambient air quality standard, therefore, should be the maximum permissible ambient air level of an air pollution agent or class of such agents (related to a period of time) which will protect the health of any group of the population.
>
> For purposes of this description, a statistically related sample is the number of persons necessary to test in order to detect a deviation in the health of any person within such sensitive group which is attributable to the condition of the ambient air.

S. Rep. No. 91-1196, at 10. This test is fully consistent with the same portion of the same Senate Report that EPA cites, which explains that "[i]n establishing an ambient standard necessary to protect the health of these persons, reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group." *Id.*; *see also, e.g.*, 85 Fed. Reg. at 49,833/2 n.1 (citing and quoting same).

As mentioned above, the prior CASAC found that an 8-hour exposure to 70 ppb of ozone "almost certainly" causes the adverse combination of lung function decrements and respiratory symptoms in people with asthma. EPA-HQ-OAR-2008-0699-0190 at 6. This conclusion was based on the statistically significant results of the Schlegle study. Accordingly, under the Act, the NAAQS cannot lawfully be at the 70 ppb level, for such a level allows 70 ppb of ozone to occur every day, and EPA accepts the scientific evidence that shows adverse effects will occur for people with asthma when they are exposed to ozone at that level. And, to the extent EPA finds adverse effects occur at or below that level—as it must, per the preceding sections—the standard must be lower still.

## G. Scientific studies compel strengthening the standard

### 1. Evidence of harms at levels that occur under the standard

EPA's own review of epidemiological studies mandates strengthening the standard. The epidemiology literature synthesis presented in the ISA indicates that a stronger standard (below 70 ppb) is merited, given robust evidence of health harms at lower exposure levels. An 8-hour maximum limit of 60 ppb aligns with the draft ISA finding evidence of lung function impairments, pulmonary inflammation, injury, oxidative stress and other respiratory symptoms

in children and adults exposed to ozone concentrations at that level or lower.[82] Many studies, including Kim et al. (2011), Schelegle et al. (2009), Adams (2006), and Brown et al. (2008), and Korrick et al. (1998)[83] provided the basis for EPA's conclusion that 60 ppb ozone concentrations can cause lung function decrements.[84] Studies published since March 2019 further confirm this link. For example, Dominici et al. (2019) analyzed data from 61 million Medicare enrollees, between the years 2000 and 2012, using exposure estimates based on sophisticated hybrid models with a resolution of 1 $km^2$ which included populations living in less well monitored areas. That study identified an association between all-cause mortality in a two pollutant analysis – including at levels below the current ozone NAAQS. Another study by Rhee et al. (2019), detailed earlier, also found that an increase 1 ppb in annual average ozone levels was associated with statistically significant increases in annual hospital admission rates for ARDS of 0.72% (95% CI, 0.62-0.82) and 0.15% (95% CI, 0.08-0.22), respectively. Importantly, this effect remained in in low-pollution regions meeting the current NAAQS (annual average PM2.5 level < 12 $\mu g/m^3$ and annual average ozone level < 45 ppb). In those areas, the 1 ppb annual increase in ozone was associated with an increase in annual hospital admission rates for ARDS of 0.27% (95% CI, 0.16-0.38).

### 2. EPA arbitrarily discounts scientific studies

In its Proposal, EPA distorts the available epidemiology studies by discounting those that analyzed health impacts in areas that met the current standard for some (but not all) of the study duration or those with mixed findings across several cities, some of which in exceedance of the standard. It notes that "[t]he extent to which reported associations with health outcomes in the resident populations in these studies are influenced by the periods of higher concentrations during times that did not meet the current standard is unknown", and asserted that multicity study findings "complicat[e] interpretations regarding the contribution of concentrations in the small subset of locations that would have met the current standard compared to that from the larger number of locations that would have violated the standard." However, elsewhere in the Proposal EPA taken steps to further analyze reported findings from Schelegle et al. (2009) that showed reduced lung function and increased pulmonary inflammation at levels below the current NAAQS to argue that no further strengthening of the standard is needed because, in its interpretation, average during the entire study period did not meet the current NAAQS. Elsewhere, EPA has used the fact that short- and long-term exposures occur concurrently to

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[82] Draft ISA at IS-24 to IS-25.

[83] Korrick S A, Neas L M, Dockery D W, Gold D R, Allen G A, Hill L B, Kimball K D, Rosner B A, and Speizer F E. "Effects of Ozone and Other Pollutants on the Pulmonary Function of Adult Hikers." Environmental Health Perspectives 106, no. 2 (February 1, 1998): 93–99. https://doi.org/10.1289/ehp.9810693

[84] Comments of Peter Valberg and Julie Goodman. Regarding the U.S. EPA's ISA for Ozone (External Review Draft) (2019). November 25, 2019. Pg. 6. *Available at* https://yosemite.epa.gov/sab/sabproduct nsf//23AC2DE8637E771F852584BE006CD0D7/$File/Gradient_Ozone_ISA_Testimony.pdf

avoid adequate consideration of both single and multicity studies. EPA asserts in the Proposal that "[t]he quantitative exposure and risk analyses completed in this review update and in many ways improve upon analyses completed in the last review" when it has not conducted appropriate analyses of the scientific studies that inform these analyses. EPA has therefore inconsistently weighed the evidence, conducted biased analyses, and arbitrarily dismissed the findings of specific studies without justification.

Importantly, §109(b)(1) of the Clean Air Act calls for creation of NAAQS that are 'requisite to protect the public health' with 'an adequate margin of safety'. This suggests that we are not limited by evidence where a model unequivocally shows an effect with no ambiguity whatsoever, nor is EPA limited to consideration of studies in areas meeting the current NAAQS when considering whether to revise the standard.

EPA and some CASAC members insists on prioritizing evidence from "manipulative or interventional causation" studies and discounts other forms of causation (e.g., epidemiological causation, but-for causation, mechanistic causation, etc.). Epidemiological studies are not the sole determinant of causality; rather, they provide supplemental support to evidence obtained from other disciplines and demonstrate a coherence of information across studies.[85]

Lastly, the Administrator makes note of "uncertainty" that remains because there are few observations available at concentrations levels substantially below the current standard.[86] This lack of information, rather than a reason to maintain the weak 2015 standard, should motivate a strengthened ozone standard, because of the likelihood of adverse health effects at levels substantially lower than current federal limits. The very multicity domestic epidemiologic studies that would provide the studies the Administrator claims would help resolve uncertainty for him will continue to be difficult to execute without further declines in ambient ozone concentrations mandated by the Agency.

### H. EPA's treatment of the exposure and risk analysis is arbitrary

EPA relies on its updated exposure assessment to support its proposed retention of the primary standard. Specifically, EPA points to the exposure assessment to claim that small percentages of key populations (including children and asthmatic children) would experience multiple exposures of concern in areas just meeting the current 70 ppb standard.[87] EPA's approach is inconsistent with the Clean Air Act, which promises air in which people can engage in their normal range of activity free from adverse effects. Moreover, due to critical limitations

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[85] Comment of Jennifer Richmond-Bryant. Regarding the U.S. EPA's Draft Ozone ISA (2019). December 3, 2019. Pg. 2. *Available at* https://yosemite.epa.gov/sab/sabproduct.nsf/81594E33A5C673CE852584BD0078F919/$File/O3+ISA+Public+Comments+WRITTEN.pdf

[86] *See, e.g.,* 85 Fed. Reg. at 49,871-2.

[87] 85 Fed. Reg. at 49860, Tbl. 2.

of the APEX model discussed below, EPA's exposure assessment provides no support for EPA's population-level claims. First, APEX uses high-level demographic variables like age and gender to establish activity profiles. But EPA has failed to establish that these high-level demographic variables are predictive of time spent outdoors with elevated ventilation rates, the critical metric for predicting exposures of concern. Second, APEX's modeling of individuals is flawed and systematically underestimates the likelihood of multiple exposures of concern for simulated individuals, thereby overstating the protectiveness of the modeled air quality standards. Critically, EPA's assessment provides no relevant information for key groups, including outdoor workers and summer camp attendees, who are most likely to experience harmful effects due to prolonged and repeated harmful ozone exposure. For all the reasons that follow, EPA's approach is unlawful and arbitrary.

### 1. The Clean Air Act requires NAAQS to be set without consideration of how often people will intersect with unsafe air

EPA's reliance on its exposure assessment is unlawful and inconsistent with the Act. Section 109 of the Act mandates that EPA set the NAAQS at a level that allows the public to spend time outdoors engaged in their normal activities and that the air will be clean enough to "protect the public's health with an adequate margin of safety." This mandate "carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health." 116 Cong. Rec. 81 (Dec. 18, 1970) (remarks of Senator Muskie, floor manager of the conference agreement). Indeed, EPA has previously recognized this to be the case:

> Standards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect given concentration levels. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment.

44 Fed. Reg. at 8,210.

Here, EPA is unlawfully using its exposure assessment to subvert this mandate. EPA relies on the exposure assessment to support a standard that results in levels of air quality that are unsafe for people engaging in normal outdoor activity based on EPA's projection that only a small percentage of people will experience multiple exposures of concern. As set forth below, EPA's methodology for projecting exposures of concern is flawed and systematically understates the fraction of people who will experience harmful exposures. Especially in light of these deficits in EPA's model, a precautionary and protective approach must be applied. When such uncertainties suggest that it might be unsafe to be active outside, or that some at-risk groups could experience more frequent exposures of concern than indicated by the modeling, EPA must act in favor of protecting sensitive groups.

### 2. EPA's has failed to rationally explain the basis for limiting its exposure assessment to eight cities or for the eight cities chosen

EPA's exposure assessment accompanying the current Proposal is far more limited than for the 2015 standard. Whereas in 2015 EPA evaluated 15 urban areas, accounting for 19 million school age children and 85 million people aged 5 to 95,[88] the "streamlined"[89] list of eight study areas in the present exposure assessment represent less than half (42 million people) of the prior analysis.[90] While EPA acknowledges that "the exposure and risk analyses are not intended to provide a comprehensive national assessment,"[91] it fails to provide a rational basis for limiting the assessment to the degree and in the manner it did. This restricted assessment is arbitrary, capricious, and an abuse of the Agency's discretion.

EPA's criteria for selection of urban study areas are inadequately explained. In the Policy Assessment, EPA states that it "developed criteria" for selection of urban areas for the exposure and risk analysis.[92] Yet the Agency provides no information on how those criteria were developed or why they are appropriate. EPA simply asserts—without explanation—that the set of areas "was chosen to ensure it reflects the full range of air quality and exposure variation expected in major urban areas in the U.S. with air quality that just meets the current standard."[93] It is not clear how (or whether) most of the identified criteria bear on whether the set of chosen areas reflects the full range of air quality and exposure variation expected in major U.S. urban areas. Among other things:

- EPA fails to explain why the urban study areas used in this analysis should be a subset of those from the 2014 Health Risk and Exposure Assessment.[94]
- EPA fails to provide any basis for either its lower bound Combined Statistical Area/Metropolitan Statistical Area population of 2 million or its upper bound of 10 million.[95] Instead, EPA irrationally claims that those arbitrarily-selected bounds demonstrate that "[t]he eight study areas represent a variety of circumstances with regard to population exposure to short-term concentrations of $O_3$ in ambient air."[96] To the contrary, they merely demonstrate that EPA selected urban areas within apparently arbitrary population bounds.

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[88] 2014 Final HREA at 5-10, Tbl. 5-1 (Aug. 29, 2014).
[89] 85 Fed. Reg. at 49854/2.
[90] *See* 2020 Policy Assessment, *supra*, n. 64, at 3C-14, Tbl. 3C-1.
[91] *Id.*, at 3-61.
[92] *Id.*, at 3D-16.
[93] 85 Fed. Reg. at 49854/2.
[94] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-16.
[95] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-17.
[96] 85 Fed. Reg. at 49854/2.

- EPA fails to explain why the urban study areas must have at least 10 ambient air monitors.[97] Beyond the fact that the number 10 itself is arbitrary, eliminating urban areas with fewer than 10 monitors makes little sense because EPA's modeling does not have an accurate way of modeling people's movement around the study area. Other than having the ability to model commuting behavior, the model presumes that activity occurs within a given air district. EPA provides no indication of why APEX modeling of an urban area with fewer than 10 ambient air monitors would be less accurate than one with 10 or more.

Ultimately, EPA's selection of study cities is arbitrary because EPA did not even adhere strictly to its own criteria. For example, EPA included Sacramento even though its 2015-2017 DV was 86 ppb, a concern that CASAC flagged in its consensus letter.[98] And EPA excluded cities from the prior review that meet its criteria, including Cleveland, OH, Washington, DC, and Houston, TX,[99] without adequate explanation.

### 3. EPA fails to show that the APEX model provides meaningful estimates of population-level exposures for the urban areas analyzed

Even if EPA's selected urban areas were representative in all the ways that EPA claims[100]—which it has not established—EPA fails to demonstrate that APEX provides data that meaningfully reflect population-level exposures. This is because the demographic data that APEX uses to establish user profiles have not been shown to reflect the variables that correlate with whether people are likely to spend extended periods of time outdoors at moderate levels of physical activity—the preconditions for exposures of concern. While acknowledging that "a single profile does not, in isolation, provide information about the study population," EPA claims that "a distribution of profiles represents a random sample drawn from the study area population" and, "[a]s such, the statistical properties of the distribution of simulated profiles are meant to reflect statistical properties of the population in the study area."[101] But EPA fails to establish that this is so.

APEX functions by "[c]onstruct[ing] an activity event sequence (a minute-by-minute time-series) by selecting a sequence of appropriate daily activity diaries for the simulated individual (using demographic and other influential variables)."[102] "**[A]ctivity patterns of the sampled individuals** (e.g., the specification of indoor and other microenvironments, the duration of time spent in each) **are assumed by the model to be similar to individuals with similar demographic characteristics**, according to activity data such as diaries compiled in EPA's

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[97] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-17.
[98] *See* CASAC Review of PA, *supra* n. 33 at 10.
[99] The 2015-2017 design value for Houston is 81 ppb, which is just outside EPA's range of 60 to 80 ppb, but notably much closer to that range than Sacramento (DV of 86 ppb).
[100] 85 Fed. Reg. at 49854/2.
[101] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-20.
[102] *Id.,* at 3D-16.

Consolidated Human Activities Database (CHAD)."[103] According to the model's documentation, these demographic characteristics are: age, gender, race, and work status.[104] But EPA provides no regression analysis ($R^2$ value) or other quantitative or qualitative analysis to establish that these variables alone or in combination reasonably and accurately explain the amount of time an individual spends outdoors engaging in moderate (or higher) levels of exertion. If these variables do not capture the relevant variability in this metric, then an extrapolation of behavior from thousands of simulated individuals based exclusively on their demographic characteristics provides no meaningful information about how many people would experience exposures of concern.[105]

### 4. EPA fails to show that the APEX model provides meaningful estimates of individual exposures

The population-level problems with APEX are compounded by equally profound individual-level issues with the model. EPA acknowledges that "exposures could be underestimated for some population groups that are frequently and routinely outdoors during the summer (e.g., outdoor workers, children)."[106] In particular, "longitudinal activity patterns do not exist for these and other important population groups (e.g., those having respiratory conditions other than asthma), thus limiting the extent to which the exposure model outputs reflect these groups that might routinely experience high exposure concentrations."[107] Given EPA's focus on assessing multiple exposures of concern, this reliance on modeling that fails to accurately represent the groups most likely to experience such multiple exposures is fatal to EPA's reliance on its exposure modeling, and is arbitrary, capricious, and an abuse of discretion.

APEX models exposures in a way that homogenizes individuals based on demographic characteristics and mutes important variability. As the model's documentation explains, "APEX creates seasonal or year-long sequences of activities for a simulated individual by sampling human activity data from more than one subject in CHAD," resulting in "uncertainty . . . about season-long exposure event sequences."[108] EPA acknowledges that "[t]his approach **can tend to underestimate the variability from person to person because each simulated person**

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[103] APEX, Version 5.2: Volume I: User's Guide (Oct. 2019), at 3, *available at* https://www.epa.gov/sites/production/files/2019-12/documents/apex52_usersguide_vol1_october2019.pdf (hereinafter APEX Documentation, Vol. I).
[104] APEX Documentation Vol. I at 21.
[105] There are other limitations with APEX as well, including the fact that "The population activity pattern data supplied with APEX (CHAD activity data) are compiled from a number of studies in different areas and for different seasons and years. Therefore, the combined data set may not constitute a representative sample." APEX Documentation, Vol. I at 5.
[106] *See* 2020 Policy Assessment, *supra*, n. 64, at 3-72.
[107] *Id.,* at 3-72.
[108] APEX Documentation Vol. I, at 5.

**essentially becomes a composite or an "average" of several actual people in the underlying activity data (which tends to dampen the variability)**."[109]

For example, "[s]imulated individuals are assigned activity diaries longitudinally without regard to occupation or school schedule . . . ."[110] Rather, "[o]nce APEX identifies the basic personal attributes of a simulated individual . . . and daily air temperatures . . ., activity pattern data obtained from CHAD . . . are then selected based on age, sex, temperature category, and day of the week."[111] The model does recognize the need for autocorrelation in developing longitudinal activity pattern sequences,[112] but EPA selected a method for autocorrelating (the diversity & autocorrelation method) that produces lower estimates of multiple exposures of concern than, for example, the Markov-chain clustering method it considered.[113] And EPA has not shown that any of the autocorrelation methods it evaluated provides a reasonable simulation of groups such as outdoor workers or children attending summer camp that consistently spent long periods of time outdoors with elevated levels of respiration.

### 5. Key groups are not appropriately modeled or considered in the exposure assessment

Due at least in part to the limitations discussed above, key groups that are most likely to experience multiple exposures of concern or are particularly vulnerable are not appropriately modeled or considered in EPA's exposure assessment. This is arbitrary.

#### i. Children attending outdoor summer camps

Every year more than 14 million children, and adults, attend camps in the United States, in addition to over 1.5 million camp workers.[114] Most camps last for at least a week,[115] and many

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[109] APEX Documentation Vol. I at 5.
[110] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-92.
[111] *Id.,* at 3D-54.
[112] With regard to the three alternate methods for longitudinal activity pattern sequences that EPA considered, EPA explains that Che et al. (2014) found: "little difference was observed across the methods with regard to estimates of the mean exposures of simulated individuals. Differences were observed, however, in the number of multiday exposures exceeding a selected benchmark concentration." 2020 Policy Assessment at 3D-60. Those differences were substantial, about 12-14%. *Id.*
[113] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-60.
[114] American Camp Association, ACA Facts and Trends, *available at* http://www.acacamps.org/media/aca-facts-trends (accessed Sept. 9, 2020).
[115] American Camp Ass'n, Camper Enrollment Report 2017, at 4, available at https://www.acacamps.org/sites/default/files/resource_library/2017_CamperEnrollmentReport.pdf.

for a month or two,[116] frequently offering overnight camps. The most popular camper age is 9-12 years old,[117] and most camp activities take place outdoors. According to one survey, over 75 percent of both overnight and day camps said campers spent more than seven hours a day outside in the open air and only one camp reported less than two hours a day spent in the open air.[118] Studies of children at summer camps, where they experience sustained outdoor activity, show that short-term ozone exposure is associated with decreased respiratory function,[119] even when restricted for levels above 60 ppb.[120] Studies of children at summer camp with asthma have also shown increased risk of respiratory symptoms on high pollution days as well as decreases in lung function.[121]

EPA's exposure assessment does not meaningfully address summer camp attendees. As noted above, in APEX "[s]imulated individuals are assigned activity diaries longitudinally without regard to occupation or school schedule . . . ."[122] The model does not attempt to simulate children whose summer days are primarily spent engaging in outdoor activity. Epidemiological studies looking at active children who spend significant time outdoors call into question the representativeness of EPA's modeling. For example, McConnell et al. showed that active children who played three or more sports growing up in communities with eight-hour ozone levels ranging from 55.8 ppb to a maximum of 69 ppb were three times more likely to develop asthma than their peers in communities with lower ozone levels, ranging from 30.6 to 50.9 ppb.[123] EPA's exposure assessment provides no meaningful information about these regularly active children.

### ii. Outdoor workers

There are millions of outdoor workers in the United States. According to the Bureau of Labor Statistics, in 2014 there were approximately 29 million workers in industries with outdoor work including agriculture, forestry, fishing, and hunting (2.1 million), construction (7.0 million), leisure and hospitality (12.5 million), mining, quarrying, and oil and gas extraction (0.5

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[116] *Id.*
[117] *Id.* at 16.
[118] P.A. James & K.A. Henderson, Camps and Nature Report (2007), *available at* http://www.acacamps.org/sites/default/files/images/research/understand/camps_nature_report.pdf.
[119] *See e.g.*, P.L. Kinney, G.D. Thurston, M. & Raizenne (1996). The effects of ambient ozone on lung function in children: A reanalysis of six summer camp studies, *Env. Health Perspect.*, 104(2): 170-174; .D. Thurston, M. Lippmann, M.B. Scott, & J.M. Fine (1997). Summertime haze air pollution and children with asthma, *Am. J. of Resp. and Crit. Care Med.*, 155(2): 654-660.
[120] Spektor, D.M., et al. (1988). Effects of ambient ozone on respiratory function in active, normal children, *Am. Rev. of Resp. Disease*, 137(2): 313-320.
[121] D. Thurston, M. Lippmann, M.B. Scott, & J.M. Fine (1997). Summertime haze air pollution and children with asthma, *Am. J. of Resp. and Crit. Care Med.*, 155(2): 654-660.
[122] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-92.
[123] R. McConnell et al. (2002). Asthma in exercising children exposed to ozone: A cohort study, Lancet, 359(9304): 386-391.

million), transportation and warehousing (4.2 million), and utilities (0.6 million).[124] By EPA's own admission, "[a]bout one third of workers were required to perform outdoor work in 2018." 85. Fed. Reg. 49,850.

EPA acknowledges that it did not attempt to simulate outdoor workers in its present review of the primary standard.[125] Instead it points back to the "targeted analysis" (single study area, single year) that was conducted in the 2014 Health Risk and Exposure Assessment (HREA)[126] and asserts that if a similar approach were used for this assessment, the results would be "expected" to be "similar" to 2014.[127] Assuming this is correct, the results of the 2014 analysis confirm that outdoor workers face outsize risks of adverse effects in areas just meeting a range of standards, including the current 70 ppb standard. As EPA explained in the 2014 HREA:

> The percentages of people experiencing one or more FEV1 decrements ≥ 15% during the 2006 $O_3$ season in Atlanta are 3.6 times higher for outdoor workers than for the general population (ages 19-35) under the existing [75 ppb] standard, and range up to 5.3 times higher for the alternative standards [down to 60 ppb]. The percents of people experiencing six or more FEV1 decrements ≥ 15% during the 2006 O3 season in Atlanta are 24 times higher for outdoor workers than for the general population under the existing [75 ppb] standard, and range up to 150 times higher for the alternative standards [down to 60 ppb].[128]

For the now-current 70 ppb standard, EPA's modeling found that 3.2 percent of outdoor workers would experience at least one FEV1 decrement of 15 percent or greater and nearly 1 percent (0.93%) would experience <u>six or more</u> such FEV1 decrements. The present 70 ppb standard is plainly inadequate to protect this vulnerable group.

EPA's basis for its "expect[ation]" is also unexplained and thus arbitrary. To the extent it relies on the overall output of the 2014 HREA being "similar" to the overall output of the new exposure estimate, EPA fails to explain how an overall similarity implies that all the subgroups that go into making up that overall result are also similar, rather than where the results for one subgroup have shown higher impacts, but are canceled out by lower impacts on another group. Further, EPA goes into great detail describing the underlying dissimilarities between the 2014 HREA and the current exposure assessment. These include significant changes in the areas studied. The overall output of the two studies may be similar, but, given the difference in input, EPA fails to provide any rational basis for concluding that this targeted analysis is also similar.

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[124] Bureau of Labor Statistics, Jobs for People Who Love Being Outdoors (July 2017), at Chart 1, available at https://www.bls.gov/careeroutlook/2017/article/outdoor-careers htm.
[125] *See* 2020 Policy Assessment, *supra*, n. 64, at 3-62.
[126] *Id.,* at 3-62, n.78.
[127] 85 Fed. Reg. at 49859 n.89.
[128] 2014 Health Risk and Exposure Assessment at 6-28.

#### iii. People with asthma

Despite its recognition that, under similar exposure circumstances, the health risk to people with asthma is "greater . . . relative to other population groups,"[129] EPA's exposure assessment irrationally and arbitrarily presumes people with asthma will experience identical lung function decrements to healthy individuals when confronted with the same exposures of concern.

EPA acknowledges that controlled human exposure studies are conducted using healthy young adults[130] and "recognize[s] the lack of evidence from controlled human exposure studies at the lower concentrations of greatest interest (e.g., 60, 70 and 80 ppb) for children and for people of any age with asthma."[131] Thus, EPA concludes, "the health effects documented in controlled human exposure studies of healthy adults may [] contribute to more severe outcomes when occurring in people with asthma."[132]

Irrationally, in its exposure assessment, EPA nevertheless presumes people with asthma will experience the same lung function decrements as healthy people for a given exposure, extrapolating FEV decrements for people with asthma based on the same susceptibility as healthy individuals.[133] EPA even caveats that: "there is uncertainty regarding the interpretation of the exposure and risk estimates and the extent to which they represent the populations at greatest risk of O3-related respiratory effects."[134] But EPA still plows forward undaunted with its reliance on the exposure assessment to purportedly show exposure risks to people with asthma are acceptable. This is arbitrary.

### 6. EPA arbitrarily fails to acknowledge or account for averting behavior

The exposure assessment irrationally ignores the possibility that the results are influenced by averting behavior, a possibility EPA analyzed and discussed in 2015, but entirely failed to address in this review. In 2015, EPA recognized that many people, including children, avert outdoor activity and that its exposure estimates may be inaccurate due to their failure to capture averting behavior. In discussing activity diaries in that review, EPA noted that "we do not know if any diary day represents the activities of an individual who averted,"[135] and EPA conducted a "no averting" simulation to address this possibility.

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[129] *See* 2020 Policy Assessment, *supra*, n. 64, at 3-71.
[130] *Id.,* at 3-71.
[131] 85 Fed. Reg. at 49857.
[132] 85 Fed. Reg. at 49857; 2020 Policy Assessment at 3-71.
[133] 2020 Policy Assessment at 3-66.
[134] *Id.*, at 3-72; *see also* 85 Fed. Reg. at 49857-58.
[135] 2014 Health Risk and Exposure Assessment at 5-53, n. 27.

In the present review, averting is nowhere discussed.[136] Yet, EPA fails to offer any explanation why the possibility that averting behavior influenced the activity diaries relied on in the APEX modeling is no longer an issue in this review. If the activities documented in the activity diaries were influenced by averting and reflect the actions of people who chose to stay inside due to poor air quality, this further undercuts the representativeness of EPA's exposure modeling by understating the amount of time people would spend outdoors with healthier air. This is arbitrary.

### 7. Other issues with the exposure assessment

There are several additional problems with EPA's exposure assessment that further render the Agency's reliance on it arbitrary and unlawful. These include:

- Inadequate consideration of environmental justice: While EPA acknowledges in numerous places that there are strong correlations between asthma prevalence and race, EPA did not address correlations between asthma and race in attributing asthma prevalence to simulated study populations.[137]
- Failure to follow CASAC advice regarding quantitative uncertainty analysis: CASAC commented in its consensus letter that EPA failed to provide uncertainty bounds on its exposure and risk estimates, explaining that the ranges presented "represent variability between cities, not uncertainty."[138] CASAC noted that "this type of uncertainty is a prime candidate for a quantitative uncertainty analysis because there are estimates on the uncertainties associated with the air quality estimates."[139] Yet EPA has not addressed this in its final Policy Assessment nor proposed rule.
- Failure to adequately address CASAC advice regarding model performance evaluation: In its consensus letter on the policy assessment, CASAC urged that, "[i]n addition to the ozone [model performance evaluation] MPE, it would be useful to perform an MPE for the ozone precursors (NOx and VOCs)."[140] CASAC explained that, "[i]f the precursor concentrations don't match the observations, the HDDM sensitivity results may not be accurate even if the ozone concentrations match observations."[141] Nevertheless, EPA did not provide a model performance evaluation for ozone precursors in its final Policy Assessment or proposed rule.
- Failure to address EPA's own analysis showing a lower standard would significantly reduce exposures of concern for sensitive groups: Even if EPA's reliance on its exposure assessment were not arbitrary, EPA fails to articulate a rational basis for rejecting lower standards, which (per EPA's modeling) substantially reduce and nearly eliminate

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[136] There is no discussion of averting behavior and the possibility that activity diaries were influenced by averting behavior in the proposed rule or the final Policy Assessment.
[137] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-25.
[138] *See,* CASAC Review of PA, *supra* n. 33, at 10.
[139] *Id.*
[140] *Id.*, at 11.
[141] *Id.*

exposures of concern for children and children with asthma—two important sensitive groups.[142]

### 8. EPA arbitrarily limited and dismisses the risk assessment

EPA unlawfully and arbitrarily proposes to dismiss the risk assessment. At base, EPA rejects it because the risk assessment extrapolates in an effort to address sensitive populations. *See* 85 Fed. Reg. at 49,858-59 & n.87; *see also id.* at 49,857. But EPA's statutory responsibility is to protect sensitive populations based on the information available to EPA. As explained above, EPA has limited the information it chiefly relies on to studies solely of healthy young adults. Those studies cannot ethically test the most sensitive populations. EPA has thus positioned itself to never be able to comply with the statute: the studies it relies on cannot test the populations it must protect, and EPA rejects extrapolation to address those populations. EPA's position is unlawful under the Act and arbitrary.

The draft ISA incorporates content that would normally be published separately as the draft HREA and WREA. "Combining assessment steps in this manner such that they are reviewed concurrently and without sequencing or iteration undermines the integrity of the review process."[143]This is especially concerning as the HREA is important to setting the primary ozone standard.

## I. To the extent the CASAC's recommendations have any validity, EPA has unlawfully and arbitrarily departed from some of them

As explained above, EPA's CASAC was illegally constituted and failed to meet its obligations during the ozone review. Despite these enumerated failings, the Agency itself must fulfil certain obligations in responding to and incorporating the advice of the CASAC. However, just like CASAC failed to fulfill its obligations to the Agency, so too did the Agency fail to meet its statutory obligations with respect to the committee. These obligations are separate and distinct from those of the committee itself, and EPA must fulfil its statutory obligations to consider the advice of CASAC.

The Act expressly requires EPA, in developing standards, to consider the advice of the statutorily created CASAC and rationally explain any important departure from CASAC's recommendations. 42 U.S.C. §§ 7409(d)(2)(B), 7607(d)(3). When CASAC makes a scientific finding, it is not enough for EPA merely to "disagree" with CASAC's findings on policy grounds: "to the extent that CASAC has exercised scientific judgment, EPA must respond in kind." *Mississippi*, 744 F.3d at 1358. Nor can EPA rotely invoke "uncertainty" to justify

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[142] *Cf.* 2020 Policy Assessment, *supra* n. 33, at 3-66, Tbl. 3-4 *with id.* at 3-69, Tbl. 3-5.
[143] *See* Former CASAC Advice Letter, *supra,* n.7, pg. 7).

disagreeing with CASAC's scientific judgment. *Id.* at 1357. Instead, "EPA must explain why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it. This is especially true given the added layer of stringency imposed by EPA's obligations under section 307(d)(6)." *Id.* Even if CASAC makes a policy, rather than scientific, recommendation that EPA departs from, EPA must explain its reasoning for not accepting the recommendations of CASAC. *Am. Farm Bureau Fed'n*, 559 F.3d at 521. Even if the Act did not so require, settled principles of administrative law would require EPA to reconcile any disparity between its standards and those recommended by CASAC. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Under the Act, EPA's Proposal must "set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by [CASAC]," and "if the Proposal differs in any important respect from any of these recommendations," must set forth "an explanation of the reasons for such differences." 42 U.S.C. § 7607(d)(3). Thus, EPA "must fully explain" its reasons for any departure from CASAC's recommendation. *Mississippi v. EPA*. 744 F.3d 1334, 1354 (D.C. Cir. 2013). EPA must also provide such an explanation in the final rule. Id. 1355. Further, "EPA must be precise in describing the basis for its disagreement with CASAC. If EPA's quarrel is with CASAC's scientific analysis, then in order to preserve the integrity of CASAC's scientific role, EPA must give a sound scientific reason for its disagreement." *Id.* As an example—and others are given throughout these comments—though the Proposal reaffirms many times that EPA agrees with CASAC that the current review does not "substantially differ"[144] from the 2015 review, unlike the 2015 review, the Administrator only proposes a standard set at 70, as opposed to, at minimum, exploring a full range of standards between 60 and 70 ppb, and specifically, a standard below 70, to account for CASAC's previous finding, reiterated by a part of the committee during this review, that a standard set at 70 would not include an adequate margin of safety.[145]

The Proposal does not directly discuss proposing a range of standards to below 70 to consider, like the 2015 standard. Instead, the Administrator points to the "slight differences of the current exposure and risk estimates from the 2014 HREA estimates for the lowest benchmark" that he notes are in part due to "the use of air quality data reflecting concentrations much closer to the now-current standard than was the case in the 2015 review" as a reason to maintain the standard at 70 ppb and "a more stringent standard is not needed." 85 Fed. Reg. 49,873. Much like background ozone levels and their purported impact on the standards' attainability in setting the standard cannot inform the NAAQS-setting process, so too does the

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[144] *See, e.g,* "the Administrator considers the advice and conclusions of the CASAC, including particularly its overall agreement that the currently available evidence does not substantially differ from that which was available in the 2015 review when the current standard was established. 85 Fed. Reg. 49,869,

[145] *See, e.g.,* "[The Administrator] also notes that another part of the CASAC indicated its agreement with the prior CASAC comments on the 2014 draft PA, in which the prior CASAC opined that a standard set at 70 ppb may not provide an adequate margin of safety (Cox, 2020, p. 1)"

fact that air quality is improving due to progress meeting legally required standards seem irrelevant to the inquiry of whether or not a lower standard is appropriate. EPA has failed to fulfil its statutory obligations to fully explain its departures from CASAC's advice, an obligation that it must meet regardless of any procedural or substantive flaws with CASAC's review.

## V. THE ADMINISTRATOR'S PROPOSED DECISION TO RETAIN THE SECONDARY STANDARD FOR OZONE IS UNLAWFUL AND ARBITRARY ON ITS MERITS.

It is well-established that ozone harms growing plants, and that it harms them in a different way from how it harms humans. For humans, EPA has long focused on short-term peak ozone levels, whether over a 1- or 8-hour period, for such exposures cause a welter of well-documented adverse effects on human health, especially when people breathe at elevated rates. By contrast, ozone harms plants over the course of a growing season as the amount of ozone they are exposed to accumulates. Thus, scientists have developed the W126 metric, which looks at weighted, cumulative ozone levels, over an extended time period. EPA has recognized this W126 metric over the last 15 years as the most biologically relevant form for protecting vegetation. These two ways of looking at ozone levels do not overlap perfectly: a community without harmful short-term peaks may have persistent ozone levels that can cumulatively harm plants, and vice versa.

Yet EPA has repeatedly declined to set the standard in this biologically relevant form, instead reverse engineering its reasoning on the secondary standard to justify adopting the primary standard as the secondary standard. Unsurprisingly, EPA's decisions regarding the secondary standard have been repeatedly rejected by the D.C. Circuit because EPA ignored the Act's requirements and made irrational decisions. *See Murray Energy*, 936 F.3d at 617-20 (EPA arbitrarily departed from the science and failed to specify a level of air quality requisite to protect public welfare); *Mississippi*, 744 F.3d at 1358-62 (EPA illegally and arbitrarily failed to specify a level of air quality requisite to protect public welfare). EPA proposes to once again override the science and keep the secondary standard as the biologically ill-fit primary standard. Just like its two prior final actions, this Proposal is arbitrary and unlawful for the reasons given below.

### A. EPA's legal obligations in setting and reviewing the secondary standard

The Act requires EPA to set and periodically revise secondary ambient air quality standards that protect public welfare, 42 U.S.C. §§ 7408(a), 7409(a)-(b), and

> [S]pecify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the

> public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.

*Id.* § 7409(b)(2).

Under the Act, "[t]o ensure that the NAAQS take account of the current science," EPA must complete a thorough review of the standards "at least once every five years." *Id.* § 7409(d)(1); *Nat'l Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 923 (D.C. Cir. 2014) ("To ensure that the NAAQS take account of current science, the Clean Air Act directs EPA to review the standards at least once every five years.") (citation omitted). During this review, EPA must revise the criteria and standards or promulgate new standards as appropriate. 42 U.S.C. § 7409(d)(1). The secondary ("welfare") standards "shall specify a level of air quality the attainment and maintenance of which…is requisite to protect the public welfare from any known or anticipated adverse effects." 42 U.S.C. § 7409(b)(2); *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 530 (D.C. Cir. 2009). Effects on welfare include impacts on "soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants." 42 U.S.C. § 7602(h). Senator Muskie, one of the prime architects of the Act, in speaking about the amendments for public welfare during the Senate debates, noted that the protections for public welfare "are especially important because some pollutants may have serious effects on the environment at levels below those where health effects may occur" and will be set to be "protective against any know[n] or adverse environmental effects."[146] The congressionally mandated "ongoing, periodic review and revision process set up by Congress…ensure[s] that regulatory guidelines and standards which protect human safety and welfare are kept abreast of rapid scientific and technological developments," *American Lung Ass'n v. Browner*, 884 F. Supp. 345, 347 (D. Ariz. 1994), and that "as the contours and texture of scientific knowledge change…EPA's NAAQS review necessarily changes as well." *Mississippi*, 744 F.3d at 1344; *see also* discussion and caselaw cited above. The CASAC is chartered to offer recommendations on the secondary as well as the primary NAAQS.

### B. EPA's repeated failures to obey the Act's requirements when it establishes secondary standards means it is acting here on remand of two NAAQS, as well as a fresh review.

In 2008, EPA revised the ozone NAAQS, setting the secondary ozone standard once more equal to the primary standard. 73 Fed. Reg. 16,436. EPA had proposed to set a standard with W126 form, but, after the Office of Management and Budget and then-President Bush noted their extra-statutory preference for a secondary standard equal to the primary, EPA ultimately

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[146] Legislative History of Clean Air Act Amendments of 1970 at 227 (Senate Debate on S. 4358, Sept. 21, 1970).

decided not to. *Id.* at 16,497/2-3; *see also* Final Opening Br. of State Pet'rs 32-36, *Mississippi v. EPA*, No. 08-1200 (DC. Cir. Aug. 27, 2012) (#1391391) (detailing history). EPA's 2008 decision was unlawful because EPA failed to specify the requisite level of air quality to protect against adverse effects. *Mississippi*, 744 F.3d at 1361-62 ("Because EPA failed to determine what level of protection was 'requisite to protect the public welfare,' EPA's explanation for the secondary standard violates the Act.").

EPA incorporated its response to the *Mississippi* remand into the 2015 ozone NAAQS. 80 Fed. Reg. at 65,369/2. But the 2015 secondary ozone NAAQS was itself arbitrary. CASAC provided clear scientific advice that EPA's proposed three-year averaging approach lacked scientific grounding, and that, if EPA insisted on pursuing it anyhow, EPA should set the three-year average to prevent damaging single-year exposures that a three-year average "obscure[s]." *Murray Energy*, 936 F.3d at 617. But real-world data showed that the 3-year W126 benchmark EPA relied on did not prevent those harmful levels, and EPA had no rational response. *Id.* Nor had EPA rationally shown that "single-year effects matter less than a three-year average." *Id.* Because of its holding about the irrationality of EPA's three-year averaging, the Court expressly declined to reach the question of whether EPA had rationally refused to use the W126 index because, purportedly, the existing form of the standard was "'highly correlated' to a three-year average of the W126 index." *Id.* at 618. Further, EPA had received expert scientific advice regarding levels of air quality requisite to protect against visible leaf damage but refused to specify such a level by relying on purported "uncertainties." *Id.* at 619. The *Murray Energy* Court held that EPA's refusal was arbitrary. *Id.* at 618-20. Accordingly, the Court remanded the secondary standard to EPA. *Id.* at 627-28.

EPA has now proposed to respond to the *Murray Energy* remand. 85 Fed. Reg. 49,830, 49,879/3 (Aug. 14, 2020) ("This review of the secondary $O_3$ standard also considers the August 2019 decision by the D.C. Circuit on the secondary standard established in 2015 and issues raised by the court in its remand of that standard to the EPA such that the decision in this review will incorporate the EPA's response to this remand."). Thus, this Proposal represents EPA's response not just to the *Murray Energy* remand, which addressed EPA's response to the *Mississippi* remand, but also the *Mississippi* remand. Accordingly, the records of the 2008 and 2015 secondary standards are relevant here, and EPA must rationally address CASAC's advice given in those records. *See BNSF Ry. v. Surface Transp. Bd.*, 741 F.3d 163, 166-67 (D.C. Cir. 2014) (reviewing agency action on remand and looking to pre-remand record); *West Virginia v. EPA*, 362 F.3d 861, 872 (D.C. Cir. 2004) (reviewing EPA action on remand and looking to pre-remand record).

## C. The welfare harms caused by ozone are extensive and well-established.

### 1. Adverse effects to vegetation and ecosystems

Ozone adversely affects public welfare by harming vegetation and ecosystems. Ozone has long been known to be highly phytotoxic. It disrupts the normal storage of nutrients and carbon and visibly damages foliage. Ozone exposure has adverse effects on public welfare in the form of harm to crop and forest productivity, resilience, scenic beauty, and ecosystem functioning. Ecosystem-service impacts include, but are not limited to, cultural (e.g. recreation) and product (e.g. agriculture) related services.

In this review EPA is clear that harm to vegetation and ecosystems from ozone exposure is pervasive and serious. EPA identifies four new specific ecological effects in addition to the eight identified in the last review and changes its determination regarding ozone's effects on "Alteration of terrestrial community composition" from "Likely to be causal" to "causal." The final 2020 ozone ISA documents the ecosystem effects that the Agency considers causal and likely casual,[147] including:

- Visible injury to plants and tree foliage effects- Causal
- Reduced vegetation growth- Causal
- Reduced plant reproduction- Causal/New
- Increased tree mortality- Likely to be causal/New
- Reduced yield and quality of agricultural crops - Causal
- Alteration of herbivore growth and reproduction - Likely to be causal/New
- Alteration of plant-insect signaling - Likely to be causal/New
- Reduced productivity in terrestrial ecosystems - Causal
- Reduced carbon sequestration in terrestrial ecosystems - Likely to be causal
- Alteration of belowground biogeochemical cycles - Causal
- Alteration of terrestrial community composition-Causal/New
- Alteration of terrestrial ecosystem water cycling - Likely to be causal

The current review incorporates the latest science, which has advanced our understanding around ozone's specific role in adversely impacting plant reproduction and contributing to plant mortality, and also adversely impacting the insects and other animals that rely on plants. Previously EPA had treated decreased plant reproduction and increased mortality as an aspect of reduction in vegetative growth; but new studies included in this review more clearly characterize these impacts and demonstrate that they are adverse ecological effects in their own right. Fruit number and fruit weight reductions were fairly consistent in a synthesis of 123 studies and

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[147] U.S. EPA. Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-20/012, 2020 at ES-13, Table ES-2.[hereinafter "2020 ISA"]

occurred at ozone levels from 40 ppb to >100 ppb. Plant-insect signaling can be disrupted at ozone levels >=50 ppb, changing and reducing the volatile compounds that enable plant signaling.[148]

Additionally, this review includes science that strengthens the conclusion that ozone has a causal impact of altering terrestrial community composition by harming a large number of species. The breadth of impact of ozone is demonstrated by Agathokleous et al. (2015)[149], a meta-analysis of 195 published papers which EPA cites as evidence, with 80% of the wild plant species experiencing negative effects of ozone exposure, representing 210 genera and 85 families.[150] Ozone can also harm other terrestrial organisms such as fungi, bacteria, and soil invertebrates.

Evidence for the causal relationship between ozone exposure and foliar injury has become even stronger with the addition of field studies in National Parks and Forests.[151] A new study by Neufeld et al. looked at foliar damage and other adverse impacts from ozone on two Coneflower species from Great Smoky Mountain and Rocky Mountain (ROMO) National Parks.[152] While one species was well known to be sensitive to ozone, this work, and that of Kohut et al. (2012), confirmed that the ROMO species can also be injured, and both species had reductions in photosynthetic rate and stomatal conductance with elevated ozone. Neufeld et al. (2018) detected statistically significant ozone injury on both plants, in pots at a North Carolina facility, at an ambient 12-hr W126 level of 9.3 ppm-hr, accumulated from April 1 - Aug 4, 2011, and a corresponding maximum 3-month 12-hr W126 value of 6.4 ppm-hr over this timeframe (calculated from data provide by H. Neufeld).

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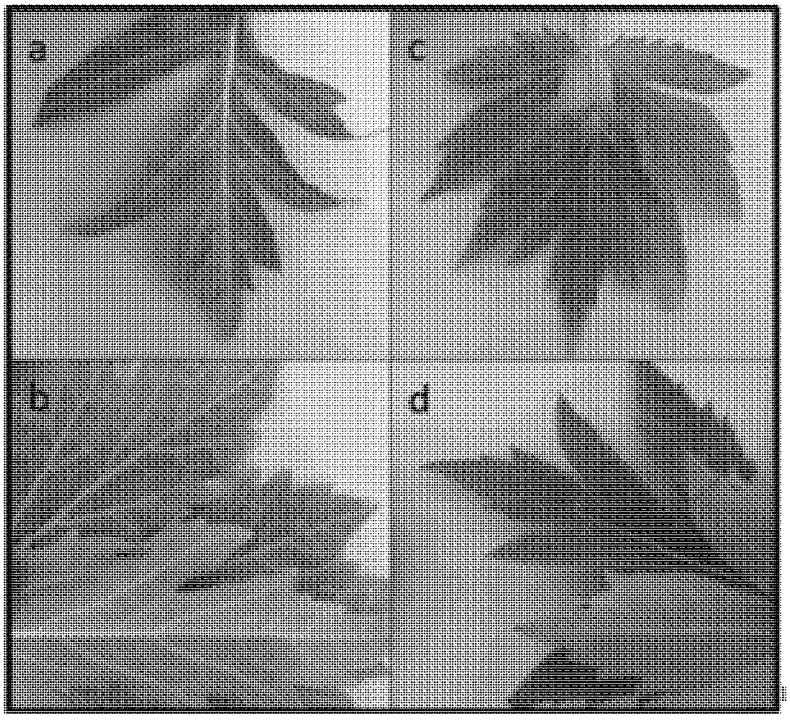
[148] *Id.,* at 8-89

[149] Agathokleous, E; Saitanis, CJ; Koike, T. (2015). Tropospheric O-3, the nightmare of wild plants: a review study. Journal of Agricultural Meteorology 71: 142-152, *available at* http://dx.doi.org/10.2480/agrmet.D-14-00008.

[150] *See* 2020 ISA, *supra,* n. 147, at 8-143-160, Table 8-20; Agathokleous, et al. (2015).

[151] Smith, G. (2012). Ambient ozone injury to forest plants in Northeast and North Central USA: 16 years of biomonitoring. Environ Monit Assess 184: 4049-4065, *available at* http://dx.doi.org/10.1007/s10661-011-2243-z, Kohut, R; Flanagan, C; Cheatham, J; Porter, E. (2012). Foliar ozone injury on cutleaf coneflower at Rocky Mountain National Park, Colorado. West N Am Nat 72: 32-42, *available at* http://dx.doi.org/10.3398/064.072.0104.

[152] Neufeld, H. S., Sullins, A., Sive, B. C., & Lefohn, A. S. (2019). Spatial and temporal patterns of ozone at Great Smoky Mountains National Park and implications for plant responses. *Atmospheric Environment: X, 2*, 100023, *available at* https://doi.org/10.1016/j.aeaoa.2019.100023



[153]

Foliar stipple on cutleaf coneflower (*Rudbeckia laciniata L.)* var. *ampla* (a, b) and var. *digitata* (c, d) on August 10, 2011 after growing outdoors at Appalachian State University, Boone, NC USA. Both varieties have an absence of injury on abaxial surfaces, which is consistent with ozone exposure symptoms. Note blue/black stipple on var. *ampla*, characteristic of that seen on leaves of this variety in Rocky Mountain National Park, whereas stippling is initially purple/brown on var. *digitata* and then quickly coalesces into brown necrotic areas.

Ozone-sensitive species with documented ozone injury remain important bioindicators. Just as important is that foliar injury from ozone is recognized as a deleterious ecological effect by EPA and one that can impact plant health, timing of leaf senescence, and scenic beauty.

Biomass loss is a known causal impact of ozone exposure that is damaging to forest health and plant survival. A recent synthesis of global studies documents hundreds of species that are known to experience growth loss with ozone exposure, of which 57 are native to the U.S..[154] EPA presented a number of new studies in the 2020 ISA that continue to support that ozone causes biomass loss at the individual tree level as well as across landscapes. Gustafson et al. (2013) used a model to scale results from the Aspen FACE study to the landscape level and found ozone significantly reduced landscape biomass and reduced net carbon storage so much that it essentially eliminated the increased carbon storage observed in the study in the presence of

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[153] Neufeld, et al.

[154] *See* 2020 ISA, *supra,* n. 147, at 8-31; Bergmann, E., Bender, J., & Weigel, H.-J, Impact of tropospheric ozone on terrestrial biodiversity: A literature analysis to identify ozone sensitive taxa. Journal of Applied Botany and Food Quality, Vol 90 (2017): Journal of Applied Botany and Food Quality, *available at* https://doi.org/10.5073/JABFQ.2017.090.012.

elevated CO2 for this species.[155] Biomass loss from ozone exposure has also been shown in other scaling up studies for silver birch, quaking aspen,[156] Ponderosa pine and aspen,[157]and eastern cottonwood, black cherry, aspen, and tulip poplar.[158]The impact of decreased biomass storage across forests is highly significant in scientific and policy terms because carbon sequestration by trees is an important removal mechanism of atmospheric carbon dioxide.

Ecosystem services should be considered as a key construct to assess the relationships between ozone impacts to vegetation and other harms to public welfare. Ozone pollution has both direct ecological impacts, such as the damage that happens to plant and tree foliage when exposed to ozone, as well as the resulting impacts to cultural (e.g., recreation) and product (e.g., agriculture) related services. EPA retains the 2013 Ozone ISA affected ecosystem services of:

Decreased productivity

Decreased carbon sequestration

Decreased crop yield

Altered water cycling

Altered community composition

Altered pollination

Altered forest products

While this list clearly overlaps with the ecological effects determination identified, ecosystem services provide another, independently viable method of consideration of these impacts. By using ecosystem services to characterize the impact to public welfare, EPA can develop methods to assess what might be expected to change under air quality scenarios representing varying alternatives for a secondary standard. As EPA recognizes, in addition to the many benefits of reduced ozone pollution that EPA can readily evaluate, there are additional benefits that are difficult to quantify but are extremely important to the public welfare

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[155] Gustafson, EJ; Kubiske, ME; Sturtevant, BR; Miranda, BR. (2013), Scaling Aspen-FACE experimental results to century and landscape scales. Landsc Ecol 28: 1785-1800, *available at* http://dx.doi.org/10.1007/s10980-013-9921-x.

[156] Resco de Dios, V; Mereed, TE; Ferrio, JP; Tissue, DT; Voltas, J., Intraspecific variation in juvenile tree growth under elevated CO2 alone and with O3: A meta-analysis, *Tree Physiology*, *36*:6 (2016), 682–693, *available at* http://dx.doi.org/10.1093/treephys/tpw026.

[157] Lapina, K; Henze, DK; Milford, JB; Travis, K., Impacts of Foreign, Domestic, and State-Level Emissions on Ozone-Induced Vegetation Loss in the United States. Environ Sci Technol 50, 2 (2016), 806-813, *available at* https://pubs.acs.org/doi/10.1021/acs.est.5b04887.

[158] Capps, S. L., Driscoll, C. T., Fakhraei, H., Templer, P. H., Craig, K. J., Milford, J. B., & Lambert, K. F. (2016). Estimating potential productivity cobenefits for crops and trees from reduced ozone with U.S. coal power plant carbon standards. Journal of Geophysical Research: Atmospheres, 121(24), 14,679-14,690, *available at* https://doi.org/10.1002/2016JD025141.

nonetheless. EPA appears to provide little to no update on the latest ecosystem services literature and it is unclear if it is because this work is lacking or EPA was deficient.

The causal effects defined above clearly show that when ozone is present in the ambient air there are significant and multiple costs to vegetation, and while some species are more sensitive than others, ozone impacts happen across numerous *Plantea* taxa, and that there are consequential and cumulative impacts for the ecosystems and landscapes, including damage to wildlife habitat. EPA is legally obligated to set the ozone standard at a level that prevents these adverse effects on public welfare.

### 2. Adverse effects to climate

Our groups are concerned that the proposed rule does not properly characterize the welfare impacts of radiative forcing from ozone. Ozone not only harms vegetation, but also is a potent greenhouse gas. Multiple ISAs state that there is a "relationship between the changes in tropospheric $O_3$ concentrations and effects on climate."[159] The proposed rule also states that "as in the last review, the current evidence, augmented since the 2013 ISA, continues to support a causal relationship between the global abundance of $O_3$ in the troposphere and radiative forcing, and a likely causal relationship between the global abundance of $O_3$ in the troposphere and effects on temperature, precipitation, and related climate variables." 85 Fed. Reg. at 49,882/3-83/1. The important facts about ozone's climate impacts are known. First, it is clear that ozone has a strong warming impact, especially in Northern mid-latitudes (where the United States is) and in the Arctic. Second, whatever its exact radiative forcing, ozone is the third strongest greenhouse gas. Third, it is well-established that ozone formation can be reduced through decreases in methane, nitrogen oxides, carbon monoxide and VOCs. As EPA acknowledges, reducing these precursors would significantly benefit public health as well as climate. Consequently, Administrator Wheeler must consider the direct as well as indirect climate impacts of ozone as he makes his judgment about setting the level of the secondary standard.

The Arctic region deserves special consideration both due to the Class I areas located within Alaska[160] near the Arctic Circle and because ozone-mediated climate impacts in the Arctic have implications for the contiguous United States.

Ozone has a larger impact in the Arctic than in other regions.[161] This is so both because ozone remains in the atmosphere longer than average in the Arctic winter and spring[162], and

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[159] U.S. EPA. Integrated Science Assessment (ISA) of Ozone and Related Photochemical Oxidants (Final Report, Feb 2013). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-10/076F, 2013, at 2-47 [hereinafter "2013 ISA"]; 2020 ISA, *supra,* n. 147 at IS-82.

[160] The Class I areas within Alaska are: Denali National Park, Bering Sea Wilderness Area, Simeonof Wilderness Area, and Tuxedni Wilderness Area. 40 CFR Part 81, Subpart D.

[161] 2013 ISA, *supra* n. 159, at 10-13,14,18.

[162] *Id.* at 10-18.

because ozone is most effective at absorbing shortwave radiation, such as that reflected from snow and ice, in the Arctic.[163] In fact, ozone is estimated to exert a radiative forcing of approximately 1 $W/m^2$ during the Arctic summer[164] and to have increased temperatures as much as 0.5 °C in the winter and spring in the Arctic in the last century.[165]

The Arctic is a unique region that hosts an intricate and highly specialized ecosystem. Many of the species in the region are the last survivors from the last ice age. Because the environment is harsh, species in the Arctic are highly adapted to survive in a narrow range of conditions. Furthermore, the inhabitants of the Arctic have no options for migration in the face of a warming environment; they are already as far north as possible and there is no higher elevation to which these species can climb. Arctic species rely upon fundamental features of the Arctic landscape, such as sea ice, permafrost, and seasonal snowpack. Yet, these features are already declining or disappearing, and the region is teetering on the brink of various climatic "tipping points."

The Arctic is currently experiencing climate changes of a magnitude not experienced anywhere else on Earth. For instance, the Arctic is warming at twice the rate of the rest of the world.[166] Furthermore, sea ice is melting at precipitous and unprecedented rates.[167] Greenland ice sheets are contracting at accelerating rates and permafrost is experiencing deeper and more frequent freeze/thaw cycles.

Adverse impacts resulting from the accelerated loss of Arctic sea ice extend well beyond the Arctic Ocean and its coast. By reflecting the sun's energy back into space, sea ice is an effective insulator, preventing heat in the Arctic Ocean from escaping upward and warming the lower atmosphere.[168] The decline of sea ice amplifies warming in the Arctic, which in turn has major implications for temperature patterns over adjacent, permafrost-dominated land areas and for weather patterns across the Northern Hemisphere.[169] Higher temperatures will thaw out extensive expanses of permafrost, resulting in the potential release of methane and carbon dioxide currently frozen in Arctic soils, thereby accelerating further warming.[170] Additional warming in the Arctic resulting from the loss of sea ice will also affect weather patterns by altering atmospheric circulation patterns, leading to more extreme weather events and affecting

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[163] *Id.* at 10-13.
[164] *Id.*
[165] *Id.* at 10-18.
[166] IPCC, CLIMATE CHANGE 2007: SYNTHESIS REPORT at 30 (2007).
[167] *See, e.g.*, Stroeve, J. et al., *Arctic Sea Ice Extent Plummets in 2007*, 89 EOS 2 (January 8, 2008); R. Kwok and D.A. Rothrock, *Decline in Arctic sea ice thickness from submarine and ICESat records: 1958-2008*, 36 GEOPHYS. RESEARCH LETT L15501 (2009).
[168] World Wildlife Fund, Martin Sommerkorn & Susan Joy Hassol, eds., Int'l, ARCTIC CLIMATE FEEDBACKS: GLOBAL IMPLICATIONS (2009), 19-20, *available at* https://www.worldwildlife.org/publications/arctic-climate-feedbacks-global-implications-report.
[169] *Id.* at 18.
[170] *Id.*

transportation, agriculture, forestry and water supplies.[171] Loss of sea ice in the Arctic Ocean will therefore have serious repercussions as climactic feedbacks resulting from higher temperature increases accelerate, the timing of the seasons is altered, and shifting circulation patterns cascade through the Arctic and beyond.

These climate impacts will directly affect proximate Class I areas within Alaska. In addition, a strong secondary standard for ozone is a critical part of the overall effort to avoid cascading catastrophic consequences for the lower 48 states.

### 3. Adverse effects to public lands

Class I areas under the Act (National Parks, Wildernesses, Forests, and Refuges) hold special value and context to the public and therefore warrant strong protection. Air pollution that harms ecosystems and scenic beauty in these national public lands adversely affects public welfare because, among other things, these special places were set aside for conservation of their natural values, for use and enjoyment by the public, and under the Clean Air Act, as places to have the most pristine air quality. 42 U.S.C. § 7472. EPA must limit the impacts from ozone pollution to Class I areas to fulfill, and act consistently with, the Congressional mandates to protect and preserve these places for the foregoing purposes. Advancing protections to safeguard the air and resources in these areas is critical to meeting the Clean Air Act objective.

In giving priority to these areas, the Administrator must consider that Class I areas include many mountain systems that can have high background ozone with little change in diurnal concentrations, even during the daylight hours. Consequently, when ozone pollution events occur, they build upon these high background levels and therefore exacerbate overall cumulative impacts. Class I areas also include many wetland ecosystems, which support significant diverse wildlife, and where foliar injury from ozone can be more severe.

In addition to the ozone impacts to vegetation, EPA must consider the climate change impacts of ozone in Class I areas. Ozone increases radiative forcing, which in turn exacerbates climate harms in national parks and other Class I areas. National parks are significantly threatened by a rapidly warming planet. Impacts range in degree and breadth and include coastal areas affected by rising oceans, deserts experiencing extreme heat events, and alpine regions beleaguered by extended drought.

For example, rising sea levels in Florida's Everglades National Park threaten the mangrove ecosystem that filters saltwater and thereby preserves freshwater wetlands. Rising temperatures and drought in New Mexico's Bandelier National Monument have driven bark beetles to higher elevations, causing high mortality rates to the piñon pines. Rising temperatures

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[171] Francis, J. and Stephen Vavrus, *Evidence Linking Arctic Amplification to Extreme Weather in Mid Latitudes*, 39 GEOPHYS. RES. LETT. L06801 (2012), *available at* https://agupubs.onlinelibrary.wiley.com/doi/full/10.1029/2012GL051000.

in Yellowstone National Park are also killing whitebark pine trees, which translates to reduced chances of grizzly bear survival in Yellowstone because grizzlies rely heavily on whitebark pine seeds as a critical source of nutrition. Warmer temperatures in Great Smoky Mountains National Park could increase ozone levels, further damaging critical tree and plant species. Scientists have linked these and other changes occurring in our national parks directly to climate change.

In 2014, NPS published a study that examined the extent to which 289 parks are experiencing extreme climate changes when compared to the historical records from 1901–2012.[172] Results show that parks are overwhelmingly at the extreme warm end of historical temperatures. The 2014 Parks Study also points to changes in precipitation patterns since 1901. These findings are supported by previous scientific research. Parks that have been experiencing extremely warm and dry climates include Kalaupapa National Historical Park in Hawaii, Mojave National Preserve in southern California, and Lake Mead National Recreation Area in Nevada and Arizona. Parks that have become extremely warm and wet include Cape Lookout National Seashore in North Carolina, Florissant Fossil Beds National Monument in Colorado, and Delaware Water Gap National Recreation Area in New Jersey and Pennsylvania.

The Appalachian National Scenic Trail (ANST) was designated as a unit of the National Park System and the first National Scenic Trail in 1968. The Appalachian Trail follows the hills and valleys of the Appalachian mountain range in the eastern United States. The 2014 Parks Study found the recent mean temperatures on the ANST were ranked as "extreme warm" compared to the historical data set. Further, climate data collected at a northern ANST mid-elevation site in the White Mountain National Forest, where winter recreation is very important to local economies, show that snowpack is disappearing 15 days earlier in the spring and annual snowfall has declined by 69 inches over the time period of 1935–2012.[173]

According to the 2014 Parks Study, species within national parks are experiencing extreme climates, causing changes to plant and animal behavior. For example, temperate tree species in the Great Lakes region appear most sensitive to higher summer temperatures, while white-tailed deer are more sensitive to winter conditions.

There is a growing body of evidence that links recent increases in drought and wildfire frequency and intensity to climate change.[174] Climate change has resulted in increasing temperatures, decreases in total precipitation and snow accumulation, increases in insect and

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[172] Monahan & Fisichelli, Climate Exposure of U.S. National Parks in a New Era of Change (2014), *available at* https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0101302.
[173] Appalachian Mountain Club unpublished data.
[174] *See* Sommers et al., Wildland Fire Emissions, Carbon, and Climate: Science Overview and Knowledge Needs, 317 Forest Ecology and Mgmt. 1, 1–8 (2014); Climate Science Special Report (CSSR), Fourth National Climate Assessment, Chapter 8: Droughts, Floods and Wildfire at 8.1-8.1.2, *available at* https://science2017.globalchange.gov/chapter/8/; David L. Peterson, Climate Change Intensifying Wildfire on National Forests, U.S. Forest Service Blog, (June 2, 2016), https://www.fs.fed.us/blogs/climate-change-intensifying-wildfire-national-forests.

disease outbreaks, and an extended growing season; all factors that increase the risks of drought and wildfire.

A 2018 NPJ Climate and Atmospheric Science study found that "the declines in western snowpack represent a substantial loss of snow storage… [and] that since 1915 western U.S. snowpack has declined by 21% or 36 km, greater than the volume of water stored in the West's largest reservoir, Lake Mead."[175]

Likewise, according to a 2015 U.S. Forest Service report: "Climate change has led to fire seasons that are now on average 78 days longer than in 1970. The U.S. burns twice as many acres as compared to three decades ago and Forest Service scientists believe the acreage burned may double again by mid-century."[176]

Finally, the National Climate Assessment from 2017 concludes: "Given the larger projected increases in temperature at high altitudes compared to adjacent lower altitudes and the resulting changes in both snowpack depth and melt timing in very warm future scenarios…, and assuming no change to water resource management practices, several important western U.S. snowpack reservoirs effectively disappear by 2100 in this dynamical projection, resulting in chronic, long-lasting hydrological drought."[177]

The increased risk of wildfire and more frequent, sustained droughts from a changing climate is overlaid on other human-related stressors and activities including land development, disturbance, and use; and fuel build up from past fire suppression. While some ecosystems, particularly in the western U.S., are naturally fire prone and have evolved around periodic fire, many of these areas are already seeing even more extreme drought and the typical fire regime and revegetation cycle may not be sustainable as the fires become too frequent and severe. For example, climate change could exacerbate the amount of land burned by wildfires at Yellowstone National Park three to ten times from 1990–2100.[178] Future fire regimes will also be impacted by changes in revegetation patterns and fuel loads, which interact with climate conditions.

We note that, though Class I areas merit particular protection, other public lands, including those owned by states, are similarly treasured, important, and vulnerable to ozone-caused harms. All these lands are especially important in the time of COVID-19, when we are encouraging people to spend time outdoors, and in view of the Great American Outdoors Act's

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[175] Mote et al., Dramatic Dec lines in Snowpack in the Western US, Climate and Atmospheric Science, 1(2) NPJ Climate and Atmospheric Sci. 1, 2 (2018), 4, *available at* http://www nature.com/articles/s41612-018-0012-1.pdf.
[176] United States Dept. of Agriculture (USDA), *The Rising Costs of Wildfire Operations: Effects of the Forest Service's Non-Fire Work*, 2–3, *available* at https://www.fs.fed.us/sites/default/files/2015-Fire-Budget-Report.pdf.
[177] CSSR, Fourth National Climate Assessment, Chapter 8: Droughts, Floods, and Wildfire, *available at* https://science2017.globalchange.gov/chapter/8/.
[178] Gonzalez et al., Disproportionate magnitude of climate change in United States national parks, Environ. Res. Lett. 13 (2018) 104001, 9. (citing Westerling et al. 2011), *available at* https://iopscience.iop.org/article/10.1088/1748-9326/aade09/pdf.

commitment to investing in maintaining public lands and permanent funding of the Land and Water Conservation Fund. EPA must also protect those lands.

### i. Intense wildfires are not all natural

Wildfires in heavily forested areas are of particular concern in the context of climate change because of their role in annual sequestration of carbon dioxide and as long-term sinks for storing terrestrial carbon. Lightning strikes, which are expected to increase with warmer weather, are the more common ignition source in remote wildlands, while human-caused ignition of wildfires is more common in more populated areas. In mountain systems, the early arrival of spring means temperatures rise sooner and snow melts occur earlier, significantly increasing the risk for wildfires at mid-elevations in Colorado.[179] According to the National Climate Assessment, "by the latter half of the century, as temperature continues to increase, it will be too warm to snow in many current snow-producing situations and precipitation will mostly be rainfall."[180] The loss of snow packs will dramatically change how quickly and routinely certain areas run out of sustained melting that historically have prevented drought and are essential to keep areas moist throughout the summer. Drier and warmer conditions also limit forest recovery from fire. A recent study in the U.S. Rocky Mountains found post-fire tree regeneration was significantly lower in 2000–2011 compared to 1988–1999, attributing it to climate-induced changes.[181]

The toll on human health and outdoor recreation from massive wildland fires was demonstrated in the summer of 2017 in the western U.S., where numerous air quality action days were called due to fire. This is only expected to worsen in our future climate as one study predicts: "Under future climate change, we estimate that more than 82 million individuals will experience a 57% and 31% increase in the frequency and intensity, respectively, of Smoke Waves."[182] They define Smoke Waves as two or more days with elevated fine particulate levels. This summer and fall's wave of fires across the West Coast further shows the harmful impacts of

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[179] Westerling, et al., Warming and Earlier Spring Increase Western U.S. Forest Wildfire Activity, 313 Sci. 940, 940–43 (2006).

[180] CSSR, Fourth National Climate Assessment, Volume 1 Chapter 7: Precipitation Change in the United States, at 7.1.1 (2017), *available at* https://science2017.globalchange.gov/chapter/7/.

[181] Stevens-Rumann et al., Evidence for declining forest resilience to wildfire under climate change. Ecology Letters (2017). doi: 10.1111/ele.12889, *available at* http://files.cfc.umt.edu/phiguera/publications/Stevens-Rumann_et_al_2018_Ecology_Letters.pdf.

[182] Liu et al., Particulate Air Pollution from Wildfires in the Western U.S. Under Climate Change, 138 Climatic Change 655, 655–66 (2016); *see also* Adam J.P. Smith et al., *Climate Change Increases the Risk of Wildfires*, ScienceBrief (Sept. 2020 update), *available at* https://sciencebrief.org/uploads/reviews/ScienceBrief_Review_WILDFIRES_Sep2020.pdf.

wildland fires.[183] Distressingly, there is evidence that the number of fires in 2020 is not at all exceptional, notwithstanding their striking and severe impacts.[184]

At specific parks, climate change is a driving force behind wildfire related concerns across the nation. For instance, drought and hotter temperatures have led an increase in buffelgrass, an invasive species, in Saguaro National Park.[185] Buffelgrass is changing the desert ecosystem by making it susceptible to wildfire for the first time.[186] Furthermore, "[w]hen ignited, buffelgrass burns at very high temperatures and promotes rapidly spreading fires; it also re-grows quickly after fires." The introduction of buffelgrass, along with hotter and drier temperatures will increase occurrences of wildfire in desert ecosystems, such as Saguaro National Park.[187] Fires can cause other impacts to the ecosystems of National Parks, such as the changing of the dominant tree species at Isle Royale National Park.[188] In the last 50 years, temperatures at Mesa Verde have risen "at a much faster rate than they did over the preceding century."[189] These higher temperatures may cause much larger fires across the Southwest as "forests across the western mountains are drier more often and for longer periods, more wildfires are ignited and they spread more easily."[190] Furthermore, "the average number of large wildfires of more than 1,000 acres across the western United States has increased from 140 per year in the 1980s to 250 per year between 2000 and 2012."[191] These fires have devastating impacts at Mesa Verde, beyond burning forests and vegetation, including "spalling, the peeling away of the rock face as the water in the sandstone evaporates, which can destroy ancient rock carvings."[192] Intense fires can also dry out the soil making the area susceptible to flooding.[193]

### ii. The impacts of wildfires

As the intensity and frequency of wildfires continue to grow, in part because of anthropogenic climate change, so will the burden these fires place on the federal government and

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[183] *E.g.*, *Ore. grieves for natural places wiped out by blazes*, Greenwire (Sept. 23, 2020), https://www.eenews.net/greenwire/stories/1063714479/; *Seeping under doors, bad air won't ease up in the West*, Greenwire (Sept. 16, 2020), https://www.eenews net/greenwire/stories/1063713847/.
[184] Thomas Frank, *U.S. watches wildfires in horror. But it's an average year*, Climatewire (Sept. 17, 2020), https://www.eenews.net/climatewire/stories/1063713927/.
[185] Saunders et al., National Parks in Peril: The Threats Of Climate Disruption (Oct. 2009), 22, *available at* http://www rockymountainclimate.org/website%20pictures/National-Parks-In-Peril-final.pdf.
[186] *Id.*
[187] *Id.*
[188] Fisichelli et al., *Climate, Trees, Pests, and Weeds: Change, Uncertainty, and Biotic Stressors in Eastern U.S. National Park Forests*, Forest Ecology and Management 327 (2014), 32.
[189] Holtz et al., Union of Concerned Scientists, National Landmarks at Risk: How Rising Seas, Floods, and Wildfires are Threatening the United States' Most Cherished Historic Sites (May 2014), 36, *available at* https://www.ucsusa.org/sites/default/files/2019-09/National-Landmarks-at-Risk-Full-Report.pdf.
[190] *Id.*
[191] *Id.*
[192] *Id.* at 37.
[193] *Id.*

local communities. *See* 42 U.S.C. §7602(h) (welfare effects include "effects on…damage to and deterioration of property … as well as effects on economic values"). For instance, in the latter part of the 20th century, from 1986–1999, federal firefighting suppression costs split between the Department of Interior and U.S. Forest Service ranged from a low of around $203 million in 1986 to a high of $918 million in 1994–95.[194] From 2000–2016, there were only four years in which federal firefighting cost fell below $1 billion, and in 2015 those costs exceeded $2.13 billion.[195] For the U.S. Forest Service, fire operations made up only 16 percent of its annual appropriated budget in 1995. By 2015, fire operations exceeded over 50 percent of their annual budget.[196] Without a clear path forward to address climate change, the costs of fighting fires on federal lands will likely continue to rise, resulting in more federal money being spent on fire suppression as opposed to other essential national park budgetary needs.

Taken together, these data show that welfare effects from climate change—including contributing effect from tropospheric ozone—not only can be "anticipated," but in fact are already occurring in the nation's National Parks and other Class I areas. EPA must address the dire need to reduce direct and indirect climate impacts from ozone, in addition to addressing vegetation effects, when setting the standard.

All publicly protected lands are visited for recreation and rejuvenation and are often important wildlife habitat areas. This nexus of sensitive ecological systems with the significant ecosystem services must be weighted in the context of the public welfare.

### D. EPA's proposed re-adoption of the arbitrary 2015 secondary ozone standard is arbitrary and unlawful.

#### 1. EPA's reliance on the advice of this CASAC, which was improperly convened, and which lacks the expertise necessary to review the standard, is arbitrary.

As discussed in section III, the Administrator's reliance on recommendations from the current CASAC during this NAAQS review is unlawful and arbitrary because the Agency illegally and arbitrarily limited the pool of potential appointees when selecting most of the members based on the Pruitt directive.

Particularly relevant here, as EPA has heard already in this review, this CASAC lacks expertise on ozone's effects on vegetation, whereas the prior CASAC had it. EPA-HQ-OAR-2018-0279-0329 (Oral Comment of H. Christopher Frey, Ph.D.) 5 ("In the last review, there were multiple experts for effects on plants, but there were none in this review."). Indeed, none of

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[194] *See* National Interagency Fire Center, Federal Firefighting Costs (Suppression Only), https://www nifc.gov/fireInfo/fireInfo_documents/SuppCosts.pdf.
[195] *Id.*
[196] USDA, *The Rising Cost of Fire Operations: Effects on the Forest Service's Non-Fire Work* (2015), 2, *available at* https://www fs.fed.us/sites/default/files/2015-Fire-Budget-Report.pdf.

the members of the current CASAC have the expertise necessary to evaluate the public welfare impacts of ozone. Per their own self-reported biographies, none of the CASAC members has any specific expertise on the types of welfare harms ozone causes.[197] The closest a member comes appears to be Dr. Ronald J. Kendall, who is a wildlife toxicologist.[198] But ozone's welfare effects land most directly on plants or climate, not on wildlife.

By contrast, the previous CASAC had a 20-member ozone review panel that included scientists with directly relevant expertise, such as Dr. Kathleen Weathers (also a member of the chartered CASAC), who "studies ecosystem processes within and among aquatic, airborne, and terrestrial systems;"[199] Dr. David A. Grantz, whose academic research and work focuses directly on the impacts of ozone on growing plants;[200] Dr. Howard S. Neufeld, whose academic research and work focuses directly on the impacts of "ozone on plants native to Great Smoky Mountains National Park;"[201] and Dr. Peter Woodbury, whose academic work focuses on "agricultural and forest ecosystems," including how ozone affects them.[202]

Despite this CASAC's lack of relevant, meaningful expertise, the Administrator proposes to rely on its ill-informed advice as a basis for retaining the current secondary standard. The Administrator expressly says that "[i]n reaching [his proposed conclusions 'that the current secondary $O_3$ standard provides the requisite protection against known or anticipated adverse effects to the public welfare, and should therefore be retained, without revision'], the Administrator has carefully considered…the advice and recommendations from the CASAC." 85 Fed. Reg. at 49,907/1; *see id.* at 49,907/2, 49,913/2 (noting that CASAC recommended retaining current secondary standard); *see also id.* at 49,906/2-07/1 (providing a summary of CASAC's advice). Further, in "draw[ing] on the considerations and conclusions in the PA," including the "rationale presented for those conclusions," the Administrator "notes the CASAC" positively assessed the PA's discussion of the secondary standard. *Id.* at 49,907/2. Even more granularly, the Administrator cites this CASAC as support for his proposed conclusions regarding visible leaf damage, *id.* at 49,908/2, for his focus on relative biomass loss, *id.* at 49,910/1; for his "focus on a 3-year average W126," *id.* at 49,910/3; for his reaffirming the same conclusion EPA

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[197] *See* EPA, *Members of the Clean Air Scientific Advisory Committee*, https://yosemite.epa.gov/sab/sabpeople nsf/WebExternalCommitteeRosters?OpenView&committee=CASAC&secondname=Clean Air Scientific Advisory Committee .

[198] EPA, *Ronald J. Kendall*, https://yosemite.epa.gov/sab/sabpeople nsf/WebPeople/KendallRonald%20J.?OpenDocument; *see also* CASAC 2020 Policy Assessment Letter at A-18 ("Ronald J. Kendall was assigned" to review draft policy assessment's chapter on secondary standard).

[199] *See* Cary Institute of Ecosystem Studies, *Dr. Kathleen C. Weathers*, https://www.caryinstitute.org/science/our-scientists/dr-kathleen-c-weathers.

[200] *See* Kearney Agricultural Research and Extension Center, *Dr. David A. Grantz*, http://kare.ucanr.edu/About_us/Staff_Directory/?facultyid=850.

[201] *See* Appalachian State University, *Dr. Howard S. Neufeld*, https://biology.appstate.edu/directory/dr-howard-s-neufeld.

[202] *See* Cornell School of Integrative Plant Science, *Peter Woodbury*, https://scs.cals.cornell.edu/people/peter-woodbury/

reached in 2015 that a 17 ppm-hrs benchmark, measured as a 3-year W126 average, would be "'effective in particularly protecting the public welfare in light of vegetation impacts form [*sic*] ozone,'" *id.* at 49,911/2 (quoting this CASAC's written advice); and for his overall judgments regarding welfare effects and how to assess ozone's impacts on them (which includes the decisions summarized in this sentence), *id.* at 49,911/1. All of these determinations are arbitrary because CASAC lacked the expertise required to provide meaningful, independent, scientific review of the secondary standard and thus its advice and recommendations on the secondary standard cannot bear any weight.

Instead, the only legally operative CASAC advice at issue here is the advice given by the actually expert panels in the past. Those panels have repeatedly made clear that the secondary standard must be (1) biologically relevant to the harms ozone causes (i.e., in a cumulative form, rather than the 8-hour form EPA prefers); (2) a single-year average to protect against the harms ozone causes even in just a single growing seasons (i.e., not the 3-year average that allows single-year levels that exceed the scientifically based threshold for unacceptable relative biomass loss, even though EPA prefers such a 3-year average); and (3) one that protects against adverse effects from visible leaf damage (i.e., is set lower than the 17 ppm-hrs level EPA prefers).[203] The Administrator must rationally explain his departures from those recommendations and that advice. As the D.C. Circuit has held, EPA has not done so in the past, and, as explained below, the Administrator has once again failed.

### 2. EPA arbitrarily and unlawfully relies on purported uncertainty to justify an under-protective approach.

In proposing to reject alternatives (like establishing a single-year W126 benchmark or setting a lower threshold for protecting against visible leaf damage) or decline to analyze important impacts of ozone (like on climate change) that could or would support a more protective standard, EPA repeatedly emphasizes purported uncertainty, *e.g.*, 85 Fed. Reg. at 49,910/3, variability, *e.g.*, *id.*, and lack of precision, *e.g.*, *id.* at 49,900/3, 49,901/2-02/2, 49,910/1-3, or known quantitative relationships, *e.g.*, *id.* at 49,908/1-2, 49,909/2-3. As to many of the harmful effects of ozone, which EPA agrees are causal or likely to be causal, EPA fails

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[203] *E.g.*, CASAC Letter 2014a at iii-iv, 11-16; EPA-HQ-OAR-2018-0279-0315 at 2, 17 (2012 CASAC letter on first draft policy assessment for 2015 ozone NAAQS); EPA-HQ-OAR-2018-0279-0071 at 1-2 (2010 CASAC letter on proposed reconsideration of 2008 ozone NAAQS); https://yosemite.epa.gov/sab/sabproduct nsf/4AF876432433128885257425006 9E494/$File/EPA-CASAC-08-009-unsigned.pdf at 2-3 (2008 CASAC letter on final 2008 ozone NAAQS); https://yosemite.epa.gov/sab/sabproduct nsf/FE915E916333D776852572AC007397B5/$File/casac-07-002.pdf at 3 (2007 CASAC letter on final policy assessment (then called staff paper) for 2008 ozone NAAQS); EPA-HQ-OAR-2018-0279-0256 at 2, 5-7 (2006 CASAC letter on second draft policy assessment (then called staff paper) for 2008 ozone NAAQS); *see also* EPA-HQ-OAR-2018-0279-0070 (2014 CASAC letter on second draft welfare risk and exposure assessment for 2015 ozone NAAQS).

even to reach a conclusion as to whether the effects are adverse or at what level of ozone the effects become adverse. This is inconsistent with the statutory requirement to "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air," 42 U.S.C. § 7409(b)(2), and arbitrary. EPA's reliance on uncertainty is likewise unlawful and arbitrary. The D.C. Circuit has rejected the notion that EPA must "wait until it has perfect information before adopting a protective secondary NAAQS. Rather, the Act mandates promulgation of secondary standards requisite to protect public welfare from any 'anticipated adverse effects associated with' regulated pollutants, suggesting that EPA must act as soon as it has enough information (even if crude) to 'anticipate[]' such effects." *ATA III*, 283 F.3d at 380 (quoting 42 U.S.C. § 7409(b)(2); emphasis and alteration in original). By requiring refined information, EPA thus violates the Act.

Further, it is well-established that EPA cannot rotely point to "uncertainty" to justify its actions. *See, e.g.*, *State Farm*, 463 U.S. at 52. Nor can EPA justify a refusal to rely on certain data by saying that those data are less certain than other data. *See, e.g.*, *Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 81-83 (D.C. Cir. 2006). Rather, what actually matters is whether EPA can rationally say that it is rejecting data or alternatives as too uncertain. EPA fails to do so here, instead irrationally rejecting options based solely on their being less certain than other options.

### 3. EPA arbitrarily and unlawfully fails to specify a level of air quality that is requisite to protect against several known and anticipated adverse welfare effects caused by ozone.

#### i. EPA unlawfully and arbitrarily treats tree growth loss as a surrogate for all vegetation-related adverse welfare impacts.

EPA proposes to use the relative biomass loss (RBL) functions for trees as a proxy for "the broad array of O3 vegetation-related effects." 85 Fed. Reg. at 49,899. EPA's approach is unjustified, irrational, and arbitrary. Further, by relying on an unjustified surrogate, EPA fails to comply with its statutory obligation to specify a standard that protects the public welfare from "any known or anticipated adverse effects." 42 U.S.C. § 7409(b)(2).

EPA has a statutory obligation to "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator . . . is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. *Id.* (emphasis added). EPA may not use surrogates in a manner inconsistent with this statutory obligation. *See Sierra Club v. EPA*, 353 F.3d 976, 985 (D.C. Cir. 2004) (recognizing limits on EPA's discretion to use surrogates to ensure that EPA still complies with its statutory obligation to set standards that reflect the performance of the best performing

sources and what they can achieve with regard to hazardous air pollutants when setting technology-based standards for hazardous pollution under Clean Air Act section 112). Here, EPA contravenes its statutory obligation by using one adverse effect as a surrogate for another without showing that prevention of the former will prevent the latter. EPA does not even claim, let alone establish with evidence, that the prevention of adverse relative biomass loss will protect the public welfare against other vegetation-related adverse effects. EPA does not even claim that tree growth loss is reliably correlated with other vegetation-related effects, like crop loss, visible leaf damage, and alteration of plant-insect signaling.

EPA also does not claim that W126 levels that will prevent adverse welfare effects from tree growth loss will also prevent these other adverse effects. Crop loss, for example, is observed mainly in annual plants, not trees, and EPA has developed different E-R functions to characterize the response of crops to ozone, confirming that tree growth loss does not predict crop loss. Likewise, visible leaf damage does not necessarily correspond to tree growth loss. It is measured differently, and EPA claims (see below) that it lacks sufficiently reliable data to predict visible leaf injury. *E.g.*, 85 Fed. Reg. at 49,899 ("With regard to foliar injury, the lack of clear quantitative relationships that would support predictive E–R functions was recognized."). A fortiori, EPA cannot claim that prevention of tree growth loss will prevent adverse levels of visible leaf injury. Nor can EPA rationally claim that tree growth loss is a valid surrogate for other vegetation-related adverse effects that it claims to lack sufficient data to quantify and predict, such as disruption of plant-insect communication. Moreover, the expert CASAC has instructed EPA that visible leaf damage is a more sensitive adverse welfare effect than tree growth loss.[204] In fact, CASAC has instructed EPA that W126 values would have to be reduced below levels that limit tree growth loss to 2% to protect adequately against visible leaf damage.[205] EPA proposes to adopt a secondary standard that allows tree growth loss far above 2%, and therefore cannot possibly claim that such a standard will protect against visible leaf injury.

Another fatal flaw in EPA's reliance on tree growth loss as a surrogate for all other vegetation-related effects is that EPA proposes to retain a three-year average as the form and averaging period of the standard, on the ground that, in light of year-to-year variations "that influence the occurrence and magnitude of $O_3$-related effects in any year," EPA allegedly "has greater confidence" in a three-year average. 85 Fed. Reg. at 49,900. Even if this approach were justified as to tree growth effects, the effect of which builds up from year to year (which it is not, as explained below), it would not be justified as to effects like visible leaf injury and annual crop loss, the welfare effects of which are felt in a single growing season, and for which the public welfare therefore requires protection from high levels that may occur in a single year.

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[204] CASAC Letter 2014a at 14 (emphasis added).
[205] *Id.* ("Visible foliar injury is even more sensitive than RBL of 2%.").

EPA claims that this surrogacy approach was approved by the expert CASAC, citing the 2014 CASAC letter on the second draft PA for the last review. 85 Fed. Reg. at 49,899 n. 176. The CASAC's conclusions do not support EPA's approach, and in fact are inconsistent with it. As the CASAC letter makes clear, the CASAC endorsed RBL as a surrogate for other welfare effects that result from tree growth loss. *Id.* (quoting CASAC letter) ("The CASAC concurs that biomass loss in trees is a relevant surrogate for damage to tree growth that affects ecosystem services such as habitat provision for wildlife, carbon storage, provision of food and fiber, and pollution removal."). CASAC does not suggest, as EPA now claims, that tree growth loss is a surrogate for all vegetation-related effects, such as crop loss, visible leaf damage, or disruption of plant-insect communication. Indeed, if CASAC had agreed that tree growth loss is a surrogate for all vegetation-related adverse effects, it would not have identified benchmarks for other adverse effects that differ from the tree-growth loss benchmarks and advised EPA to set a standard protective of those other benchmarks. Yet that is what CASAC did. *See Murray Energy*, 936 F.3d at 618 (quoting CASAC letter advising that a level of 10 ppm-hrs is required to protect against visible leaf damage); CASAC Letter 2014a at 14 (advising that a level of 7 to 15 ppm-hours is required to protect against unacceptable crop loss).

**ii. EPA's analysis of visible leaf damage—a distinct and well-established adverse welfare impact—is arbitrary and unlawful.**

EPA proposes to conclude that the current secondary standard "provides sufficient protection" against visible foliar injury. 85 Fed. Reg. at 49,909. But the agency does not specify the target level necessary to protect against foliar injury. Instead, it points to putative "important uncertainties" in the "understanding of the $O_3$ exposure conditions that will elicit visible foliar injury." 85 Fed. Reg. at 49,908. EPA's action is arbitrary and unlawful. First, EPA offers no rational explanation as to why it disregarded the 10 ppm-hrs target recommended by the 2015 CASAC and thus fails to respond to the *Murray Energy* remand. Second, the Agency's conclusion about the sufficiency of the current standard is based on flawed analyses.

In *Murray Energy v. EPA*, the D.C. Circuit held that EPA's decision not to set a target level to protect against visible leaf damage during the 2015 review was arbitrary and capricious. 936 F.3d at 620. CASAC had advised EPA of its "scientific judgment" that "a level of 10 ppm-hrs is required to reduce foliar injury." *Id.* at 618 (quoting CASAC). But EPA rejected this advice in the final rule and concluded instead that there were too many "uncertainties and complexities" in the evidence to specify a level of air quality to protect against foliar injury. 80 Fed. Reg. at 65,407-08. The court rejected EPA's reasoning, holding: (1) that EPA must explain what evidence is available and rationally explain how it reached the conclusion that this evidence leaves EPA "unable to choose a level at all"; and (2) that "[w]here CASAC has 'reached a scientific conclusion that adverse [welfare] effects [are] likely to occur,' EPA must, 'explain why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it.'" 936 F.3d at 619 (*quoting Mississippi*, 744 F.3d at 1357).

To begin with CASAC's recommendation, as discussed above, this rulemaking is, in part, EPA's response to the *Murray Energy* remand. EPA must thus explain why it could not rely on the CASAC analysis. EPA does not engage with this question in the proposed rule. The Agency refers to the current CASAC's recent vague assertion that "uncertainties continue to hamper efforts to quantitatively characterize the relationship of [visible foliar injury] occurrence and relative severity with ozone exposures," 85 Fed. Reg. at 49,907, but nowhere addresses the actually expert CASAC's clear scientific judgment that a level of 10 ppm-hrs is required. Indeed, in the same breath that it points to "uncertainties," the current CASAC recognizes, as it must, that "[v]isible foliar injury from ozone exposure has been well characterized for decades," and that the documentation of these effects extends to a large cross-section of "many tree, shrub, herbaceous, and crop species."[206] Once again, EPA does not rationally explain why the available evidence prevents EPA from specifying a level of protection. Nor does EPA rationally explain "why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it." 936 F.3d at 619.

EPA arbitrarily proposes to conclude that the current secondary ozone standard "provides sufficient protection of natural areas, including particularly protected areas such as Class I areas, from $O_3$ concentrations in the ambient air that might be expected to elicit visible foliar injury of such an incidence and severity as would reasonably be judged adverse to the public welfare." 85 Fed. Reg. at 49909. As an initial matter, EPA's proposed conclusion arbitrarily and unlawfully fails to comply with the requirement the Act gives it. Moreover, the evidence that EPA offers to support this conclusion is flawed and unconvincing for the reasons discussed below.

First, EPA's Proposal arbitrarily and unlawfully avoids identifying a level at which it finds ozone's effects on visible leaf damage to be adverse. (As explained below, such a level is well below 17 ppm-hrs.) Instead, EPA alludes generally to some level of ozone "that might be expected to elicit visible foliar injury of such an incidence and severity as would reasonably be judged adverse to the public welfare." 85 Fed. Reg. at 49909. As that phrasing makes apparent, EPA is disclaiming making any such judgment, instead using a doubly passive and conditional phrasing—"might be expected" and "would reasonably be judged." But the Act commands "the Administrator" to exercise "judgment" in setting a secondary NAAQS that "shall specify a level of air quality requisite…to protect the public welfare from any known or anticipated adverse effects." 42 U.S.C. § 7409(b)(2). The Proposal thus makes clear that the Administrator is not exercising any judgment of his own on this issue, which is unlawful and irrational. *See Johnson v. Copyright Royalty Bd.*, 969 F.3d 363, 391 (D.C. Cir. 2020) ("One thing is clear from that passive-voice phrasing: Whoever it is that might be 'consider[ing]' the decision a 'rehearing,' it is not the Board." (alteration in original)).

Second, as for the evidence EPA offers in support of its statement, the EPA provides an analysis of the USFS FHM/FIA ozone biomonitoring data set (see EPA 2020 Appendix 4C

[206] 2020 CASAC Letter on the Integrated Science Assessment at 22.

Policy Assessment). The data are a useful piece of evidence that documents ozone injury across multiple bioindicator plants, years, and sites. But this bioindex metric is averaged twice, across each species and then across all species, which can mute representation of highly injured individuals. Accordingly, to ensure EPA is providing protection for vulnerable species, this data must be considered in its entirety along with additional information in setting a level protective of foliar injury. EPA has neither looked fully at this data nor looked at additional information. In fact, EPA does not provide the foundational pieces of this same dataset in the 2020 PA that was presented in the EPA 2014 PA and WREA (*see* WREA Section 7.2, and Figure 7-9 below) identifying 10.46 ppm-hrs as a benchmark level for foliar injury and a level that 58% of National Parks were exceeding this level at least 3 years over the study period. This previous analysis was part of key evidence that led the expert CASAC to recommend a level below 10 ppm-hrs.

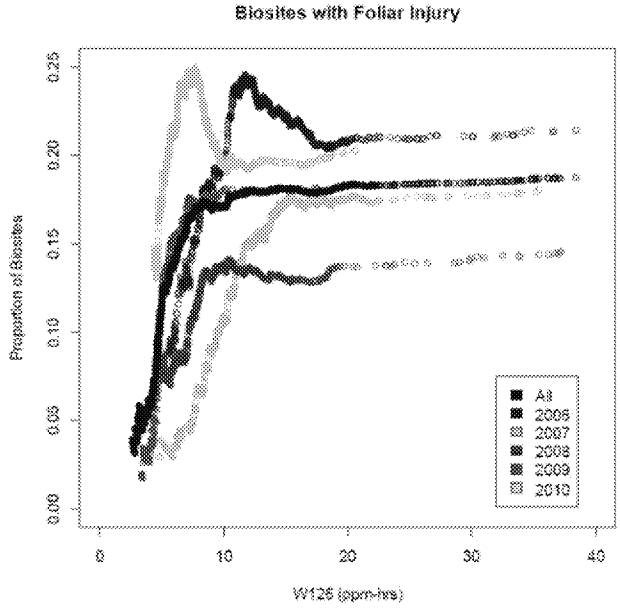


**Figure 7-9 Cumulative Proportion of Sites with Foliar Injury Present, by Year**

Instead of building on the previous evidence, EPA focuses on 25 ppm-hrs as an important point in its 2020 analysis of the biomonitoring data, based on the magnitude of increase in the rate of increase of biosite index scores of moderate to severe (Moderate BI = 15-25, heavy BI >25). There are at least three arbitrary aspects to this. First, EPA's focus on moderate to severe biosite index scores is arbitrary. The >0-4.9 and 5-15 biosite index score must be considered because, though the USFS method considers this as very light to light foliar injury, it also lists possible risk as "Visible injury to highly sensitive species, e.g., black cherry" and "Visible injury to moderately sensitive species, e.g., tulip poplar." Even if BI >15 is the focus, a third of biosites had an index greater than 15 with less than 7 ppm-hrs cumulative ozone exposure, which is significant. If all BI scores above zero are included, this lower threshold saw over 500 biosites with foliar injury. Second, in leaping on 25 ppm-hrs, EPA relies on the magnitude of increase in a rate of increase. It is hardly obvious why that particular derivative of a derivative is a

meaningful metric for determining the level at which ozone exposure has an adverse effect on visible leaf damage, and EPA nowhere explains why it is.

Third, more injury with higher ozone levels is expected, but it is arbitrary to use the higher percent of high BI scores in the > 25 ppm-hrs group for a threshold. That is because the mere fact that there's more injury at higher levels (measured as a percent of sites with high BI scores) doesn't say anything about whether there are adverse effects at lower levels, and the higher percentage at higher levels isn't necessarily meaningful, because there are fewer sites with any data at those levels. EPA must instead consider the overall number of sites that had injury, including those that had very light to moderate, as the purpose of the FIA data set is as indicators of damage, including very sensitive to less sensitive species. EPA must consider the expert CASAC's consideration of the FHM/FIA data, and that clearly shows injury is occurring at levels as low as 3 ppm-hrs and in the range of 5-10 ppm-hrs (Figure 7-9 above).

Additional data also point to a much lower threshold for foliar injury than 25 or 17 ppm-hrs. Foliar injury has been found at levels as low as a 12-hr W126 maximum 3-month value of 6.4 ppm-hrs in potted coneflower.[207] Lefohn and Musselman 2012 recommended a 24-hr W126 threshold of 6.37 ppm-hrs, with N100=4, for the Forest County Potawatomi Community. The authors based their recommendation on multiple sources including Davis 2007 who documented ozone injury on 4 indicator species. EPA references Davis 2007 and 3 other similar studies in the 2014 Policy Assessment in Table 5-7 (*see* page 5-57 of the EPA 2014 PA) re-created in Table 1 below. These studies used sum60 as an ozone metric, and EPA provided 12-hr W126 values; however, the number of months included in these values are not clear. We supplement EPA's table with the maximum 3-month 12-hr W126 sum calculated from the monthly 12-hr W126 sums provided in the Tropospheric Ozone Assessment Report (TOAR) database. In 2003 of the Davis 2007 survey, when all 4 indicators had ozone injury, the maximum 3-month 12-hour W126 was 7.7 ppm-hrs. Even if the W126 metric were not the relevant one and the 8-hour primary standard were, Myers et al. 2018, in chambers experiments, found injury in different species of milkweed that increased with the season, and occurred below 70 ppb.

Table 1. Visible foliar injury incidence in four National Wildlife Refuges, similar to EPA 2014 Policy Assessment Table 5-7 with updated maximum 3-month 12-hr W126 values [208]

| Study | Site Name/EPA monitor ID # | Year | 4th highest daily maximum | 12 hr. W126 | % Plants with visible injury | TOAR max. 3 month 12 hr W126 | TOAR Months of max. |
|---|---|---|---|---|---|---|---|

[207] Neufeld et al. 2018, calculated from 2011 data provided by H. Neufeld.

[208] *See* 2014 PA at 5-517, tbl. 5-7. Supplemented with maximum 3-month 12-hr W126 sums calculated from the monthly 12-hr W126 sums provided in the Troposhperic Ozone Assessment Report (TOAR) database.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | 8-hr average | (number of months unknown) | | | |
| Davis, 2009 | Cape Romain NWR, SC/ 450190046 | 2002 | 0.075 | 20 | 5-32 | 10.6 | April-June |
| | | 2003 | 0.074 | 11 | 3-13 | 9.8 | June-Aug. |
| Davis 2007a | Moosehorn NWR, ME/ 230090102 [209] | 2002 | 0.1 | 24 | 0-17 | 11.9 | June-Aug. |
| | | 2003 | 0.083 | 22 | 0-13 | 10.8 | June-Aug. |
| | | 2004 | 0.082 | 14 | 3-10 | 7.0 | June-Aug. |
| Davis 2007b | Seney NWR, MI/ 261530001 | 2002 | 0.083 | 11 | 0-13 | 6.1 | April-June |
| | | 2003 | 0.076 | 15 | 1-6 | 7.7 | May-July |
| | | 2004 | 0.074 | 10 | 2-6 | 3.8 | May-July |
| Davis & Orendovici 2006 | NWR, NJ/ 340010005 [210] | 2001 | 0.095 | 39 | 0-45 | No data | No data |
| | | 2002 | 0.092 | 53 | 0-4 | No data | No data |
| | | 2003 | 0.085 | 36 | 0-4 | No data | No data |

The National Park Service also calculates exposures to evaluate ozone injury and damage as the running maximum 3-month, cumulative 12 one-hour (0800–1959) W126 and provides threshold values, see Table 2. In NPS field surveys to assess foliar injury caused by ozone, such as Kohut (2020),[211] they recognize EPA's 2010 draft review that identified a range for foliar injury, stating: "While EPA proposed a W126 3-mo standard in the range of 7–15 ppm-hr to protect vegetation, the threshold it identified for foliar injury is 5–9 ppm-hr."[212]

[209] Values are from Cadillac Mountain in Acadia National Park (the closest available data) and likely an overestimate of the values at Moosehorn NWR, which is north and inland.
[210] No data for this site are in the TOAR database.
[211] Kohut 2020. Field Surveys to Assess Foliar Ozone Injury on Plants in National Parks and Monuments on the Colorado Plateau, Natural Resource Report NPS/NRSS/ARD/NRR—2020/2112.
[212] *Id.*

Table 2. NPS Injury thresholds for the W126 3-mo index in cumulative ppm-hr [213]

| Ecosystem component | W126 3-mo threshold | Response |
|---|---|---|
| Foliar injury in natural ecosystems | 5–9 ppm-hr | Foliar injury |
| Tree Seedlings in natural ecosystems | 7–13 ppm-hr | Growth reduction |
| Tree seedlings/saplings in plantations | 9–14 ppm-hr | Growth reduction |

The expert CASAC frames its overall recommendation of 7–15 ppm-hrs on the basis of all the evidence of casual effects to vegetation, including the foliar injury information. In CASAC's comments on the second draft Policy Assessment in 2014, they explicitly state: "A level below 10 ppm-hrs is required to reduce foliar injury."[214]

Notably, CASAC recognized the significance of the USFS FHM/FIA ozone biomonitor data, but did not limit its consideration of that data in the way that EPA now proposes to do. Further, CASAC's focus on the 10 ppm-hrs level is consistent with the CASAC committee's consensus comments on the draft WREA, where they clearly point to the level of 10 ppm-hrs as a point near which there is "a change in the E-R slope."[215] Noting "this slope change is not a threshold for no injury," CASAC explained that it was significant enough to make "10 ppm-hrs [be] a reasonable candidate level for consideration in the WREA, along with other levels."[216] EPA failed to examine that level before, and it continues to depart without rational explanation from CASAC's plain, science-based recommendation.

EPA's review of the FIA/FHM dataset provides a clear relationship between the W126 metric and foliar injury when sites that showed positive injury are sorted by soil moisture. This relationship is significant in that it allows land managers to recognize the W126 levels that can cause foliar damage that is not only unsightly to the public but also indicates plant stress. The high variability in foliar injury occurrence does not negate the positive findings because a robust relationship with W126 is still present, regardless of the presence of some variability. These positive findings necessitate action by EPA to protect the public welfare from the impacts that they represent.

While soil moisture at sites may be a factor in the level of injury observed, this environmental condition is just a risk factor that may or may not make a site and its plants at risk

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[213] *See* Kohut, Field Surveys to Assess Foliar Ozone Injury on Plants in National Parks and Monuments on the Colorado Plateau, Natural Resource Report NPS/NRSS/ARD/NRR--2020/2112 (2020), 5.

[214] CASAC Letter 2014a at iii.

[215] Letter from CASAC Chair Dr. H. Christopher Frey to U.S. EPA Administrator Gina McCarthy, re: CASAC Review of the EPA's Welfare Risk and Exposure Assessment for Ozone (Second External Review Draft) (EPACASAC-14-003), 15, June 18, 2014.

[216] *Id.*

but is not a determinant in the threshold. Soil moisture status does not cause the injury: ozone does. Even if soil moisture could be considered causal also, the mere fact that air pollution is one of many causes of an adverse impact does not relieve EPA of its obligation to protect the public welfare against adverse effects from air pollution. *See, e.g.*, 42 U.S.C. § 7408(a)(2)(A). EPA provides no valid reason for discarding or downplaying data showing particularly elevated levels of foliar injury at sites with moist soil conditions and higher W126 values. These results are completely consistent with other scientific evidence, and confirm that foliar injury occurs at ozone levels well below those EPA predicts occur under the current standard. Nor, given the robust data EPA has on foliar injury, does the contribution of soil moisture prevent EPA from specifying a level of protection. Thus, declining to specify a secondary standard protective against foliar injury based on soil moisture would be unlawful and arbitrary.

To the extent EPA is suggesting that it can deem visible foliar injury as not being an adverse effect on welfare, such a suggestion is unlawful and arbitrary. EPA itself has repeatedly identified foliar injury as adverse effects in prior reviews. In its 2010 reconsideration Proposal, EPA stated: "In an area such as a national park, where visitors come in part for the aesthetic quality of the landscape, the Administrator recognizes that visible foliar injury incidence is an important welfare effect which should be considered in determining an appropriately protective standard level. 75 Fed. Reg. 2938, 3025 (Jan. 19, 2010). On the same page, EPA also said the 1996 consensus workshop findings (which, among other things, recommended levels of protection against foliar injury) should be given substantial weight. *Id.* And the 2010 Proposal went on to say:

> The Administrator also believes that in order to preserve wilderness areas in an unimpaired state for future generations, she must consider a level that affords substantial protection from known adverse $O_3$-related effects of biomass loss and foliar injury on sensitive tree species, as well as a level that takes into account potential "anticipated" adverse $O_3$-related effects, including effects that result in continued impairment in the year following $O_3$ exposure (i.e., carryover effects).

*Id.* at 3025-26.

Further, the 2014 CASAC specifically identified visible foliar injury as an adverse welfare effect, a conclusion that CASAC has never altered or rescinded.[217] Indeed, CASAC confirmed that it has not departed from its advice on foliar injury by noting in its most recent review that EPA does not appear to have fully responded to the issues identified by the D.C. Circuit in *Murray Energy*,[218] which included EPA's failure to specify a level that would protect against adverse welfare effects associated with foliar injury. EPA offers no reasoned basis for rejecting these conclusions, or the Park Service analyses discussed above.

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[217] CASAC Letter 2014a at 10.
[218] 2020 CASAC Letter on Policy Assessment at 21.

### iii. EPA unlawfully and arbitrarily fails to address ozone's adverse effects on climate.

As explained, EPA bears a heavy burden if it wants to be excused from carrying out its statutory obligations. It cannot merely assert uncertainty but rationally explain how the evidence supports the Agency's finding of such significant uncertainty that the agency cannot fully implement the statute. *See Murray Energy*, 936 F.3d at 618-20. Nor can EPA escape by making unsupported comparisons between the level of the primary standard and various levels of the secondary standard threshold. *See Am. Farm Bureau*, 559 F.3d at 530.

In this review, EPA finds once again that ozone plays a causal role in warming the atmosphere. *See* 85 Fed. Reg. at 49,882-83. Ozone's role in the greenhouse effect, climate forcing, and consequently climate change has been reinforced. However, EPA cites uncertainty around the amount of radiative forcing caused by tropospheric ozone and the extent to which changes in weather can be attributed to ozone as justification to not specify a level of air quality to protect against its adverse impacts. *See id.* at 49,883. EPA also presents uncertainties in its determination that ozone is likely causal in reducing carbon sequestration, a key mechanism to counter climate change. *See id.* at 49,900. Yet EPA does not claim that these uncertainties and evidence limitations are so profound that they render the agency unable to specify a protective standard, let alone explain such a conclusion. It is unlawful and arbitrary for EPA to decline to protect the public welfare from the climate impacts of ozone based on the mere existence of uncertainties and data limitations.

Further, EPA links biomass loss, which it also found to be causally related to ozone, to carbon sequestration. 85 Fed. Reg. at 49899. Although EPA points to uncertainty in quantifying the amount of carbon uptake due to avoided ozone damage, EPA compiles evidence of significant annual biomass loss in long lived perennial trees in the 2020 ISA, an impact that scales up to the landscape level.[219] EPA also recognizes that hundreds of species are documented to suffer biomass loss due to ozone exposure.[220]

In 2015, EPA specifically pointed to the fact that reduction of carbon storage is an important public welfare harm from ozone and considered it an important rationale for the need to revise the previous standard. *See* 80 Fed. Reg. at 65,370. This is further supported by the 2020 ISA that cites consistent findings of carbon storage loss with ozone damage.[221] In the 2014 WREA, EPA estimates that transitioning to a W126 of 7 ppm-hrs would increase carbon sequestration and produce carbon dioxide reductions equal to taking 11 million cars off the road.[222] Indeed, EPA qualifies this estimate as likely low, as EPA's analysis did not include the

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[219] Gustafson et al. 2013; Lapina et al., 2016; and Capps et al. 2016.
[220] Bergmann et al., 2017.
[221] 2020 ISA at 8-103.
[222] 2014 WREA at 6-49.

forests on public lands, and therefore the climate benefits of reducing ozone exposure to 7 ppm-hrs would likely be much greater. EPA's do-nothing Proposal would forego this carbon sink. Increased atmospheric carbon on this scale qualifies as an adverse welfare effect. Yet EPA does not even attempt to protect against the degree of such effects predicted to occur at levels below 17 ppm-hrs.

EPA fails to rationally explain its failure to identify or provide requisite protection levels against this important welfare impact. It does not even try in this action. Further, in its last effort, where it actually attempted to confront the evidence, EPA's analysis was arbitrary. Specifically, at one point in its 2014 proposed rule, the agency sought to minimize the significance of additional carbon storage that would be provided with more protective W126 levels. EPA asserted that as a percent of the estimated carbon storage under the current standard, estimates of storage over 30 years under the 15, 11 and 7 ppm-hrs scenarios are less than 0.1% (13 MMtCO2e), just under 1% (593 MMtCO2e) and under 2% (1,600 MMtCO2e). 79 Fed. Reg. 75,234, 75,325 (Dec. 17, 2014). But by EPA's own measures, 1,600 MMt over 30 years (estimated at the 7 ppm-hrs level) is actually very significant. By comparison, EPA's past projections for its Clean Power Plan (i.e., setting standards of performance for carbon emissions from existing power plants under Clean Air Act §111(d) are that it will reduce CO2 emissions by roughly 300-500 MMt per year. *See* 79 Fed. Reg. 34,830, 34,931-33 (June 18, 2014). So, the carbon reduction benefits of a 7 ppm-hrs ozone standard over 30 years would be very roughly equal to about 4 years of the benefits from EPA's Clean Power Plan. EPA can hardly claim that such benefits are insignificant from a public welfare perspective.

In addition, EPA's failure to actually estimate, discuss, and assess the climate impacts of ozone pollution and its welfare implications is arbitrary and departs from the advice of CASAC without rational explanation. CASAC advises that EPA "should more thoroughly address the effects of ozone on climate change."[223] "At a minimum," CASAC instructs, "estimates of the change in warming caused by a change in ozone should be discussed and implications for human welfare in the United States should be evaluated."[224] EPA's departure from CASAC's advice is unlawful and arbitrary.

#### iv. EPA unlawfully and arbitrarily fails to protect the public welfare with regard to adverse effects on crop yields.

Though the quantitative relationship between ozone exposure and relative yield loss (RYL) in crops is well-established, EPA arbitrarily claims that it need not "separate[ly] consider[]" or "provide a more appropriate focus" on crop yield effects because of "complexities" in evaluating their public welfare impact. 85 Fed. Reg. at 49,912.

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[223] 2020 CASAC Letter on PA, *supra* n. 33, at 22.
[224] *Id.*

The ozone-related growth effects on agricultural and commodity crops have been "extensively studied," and "robust E-R functions" have been developed. 85 Fed. Reg. at 49,878. CASAC has, in fact, advised EPA of its judgment that 5% yield loss constitutes an adverse welfare impact and that a range of 7 ppm-hrs to 15 ppm-hrs is protective of median crop loss of 5% or less.[225] CASAC noted that, at a level of 7 ppm-hrs, all analyzed crop species would have a yield loss of less than 5%.[226]

EPA does not give effect to CASAC's recommendation, nor does it provide a reasonable explanation for failing to do so. EPA admits that its analysis of air quality at sites meeting the current standard shows that they are experiencing RYL of 5.1%, a level that CASAC has instructed constitutes an adverse welfare effect. This is arbitrary and unlawful. The Agency points to "complexities involved in interpreting the significance of such small RYL estimates" to support its decision not to set a standard that protects against crop loss, but offers no explanation for why RYL of 5.1% is "small." 85 Fed. Reg. at 49,906. According to EPA, these complexities stem from: the "extensive management of crops" that "may to some degree mitigate potential $O_3$-related effects," the use of "variable management practices" to achieve "optimal yields," and various other environmental conditions that may impact crop yield. *Id.* But EPA does not claim that these complexities prevent it from specifying ozone levels requisite to protect the public welfare from crop loss, let alone rationally explain such a claim, especially given that CASAC has proposed a benchmark. And the mere fact that factors other than ozone also affect crop health and productivity does not excuse EPA's failure to address the impact of ozone.

EPA also points to alleged uncertainty in the applicability of established E-R functions in current agricultural areas, 85 Fed. Reg. at 49,898, but gives no reason for that alleged uncertainty other than to repeat that agricultural management practices may influence the harm from ozone. The impact of ozone on crops is well-established by a large body of evidence across a wide range of crops, and EPA provides no rational reason why this data would not be applicable to current agricultural areas, regardless of the obvious fact that agricultural management will also affect the productivity of crops. Again, merely pointing to a potential complicating factor is insufficient to excuse EPA's failure to specify a level to protect against this well-established and well-characterized adverse effect.

EPA also claims that the "question of assessing overall public welfare impacts for such RYL estimates" is complicated by the fact that changes in yield of commercial crops and commodities "may affect producers and consumers differently." 85 Fed. Reg. at 49,906. EPA here seems to claim that reducing crop loss may actually be detrimental to the public welfare. But EPA fails to explain why this would be so and provides no record support for such a claim. The argument also doesn't square with EPA's acknowledgment that producers use variable

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[225] CASAC Letter 2014a at 14.
[226] *Id.*

management practices to produce "optimal yields." For each of these reasons, EPA's refusal to specify a level to protect the public welfare against crop losses is unlawful and arbitrary.

### 4. EPA arbitrarily and unlawfully proposes a 3-year average, 17 ppm-hours general target level of protection.

EPA arbitrarily and unlawfully proposes to retain a three-year average, 17 ppm-hrs target level of protection, which is ill-suited to protect against adverse impacts to the public welfare caused by ozone. In reaffirming this target level, EPA fails to respond to the *Murray Energy* remand. Indeed, in its letter review of EPA's policy assessment, CASAC states that it is "not clear" that EPA has fully addressed the *Murray Energy* decision.[227] *Murray Energy* requires EPA to "either lower the standard to protect against unusually damaging cumulative seasonal exposures that will be obscured in its three-year average, or explain its conclusion that the unadjusted average is an appropriate benchmark notwithstanding CASAC's contrary advice." 936 F.3d at 618. EPA accomplishes neither in the proposed rule.

Instead, EPA retains the three-year average, 17 ppm-hrs benchmark, which based on the RBL data presented in Table 4A-3 allows for 5.3% biomass loss in the median of 11 species in a single year, with at least 6% biomass loss for 5 species, including as much as 35.6% in one tree species. A biomass loss of 6% has been found by the expert CASAC to be "unacceptably high." *Murray Energy*, 936 F.3d at 613 (quoting CASAC).

During the 2015 review, CASAC advised that, if EPA were to use a three-year average benchmark, "the level of the standard should be revised downward such that the level for the highest three-month summation in any given year of the three-year period would not exceed [its] scientifically recommended" range of single-year benchmarks. 936 F.3d at 617 (quoting CASAC). This would be necessary to "protect against single unusually damaging years that will be obscured in the average." *Id.* In the final rule, EPA proposed a three-year average, 17 ppm-hrs benchmark and argued that it was appropriate because it was below the 19 ppm-hrs that was associated with a median across 11 species of 6% annual growth loss. 80 Fed. Reg. at 65,406-07.

But, in *Murray Energy*, the D.C. Circuit concluded that EPA had not demonstrated "how its chosen benchmark protects against 'unusually damaging years.'" 936 F.3d at 617. The court also noted that "EPA's use of a benchmark that *averages out* to less than 6% biomass loss over three years does not accord with CASAC's advice." *Id.* Here, EPA once again arbitrarily proposes not to "revise downward" and instead to retain the same three-year average target.

#### i. EPA's analysis of relative biomass loss is arbitrary.

Even assuming relative biomass loss were the controlling effect for purposes of the secondary standard's stringency, the 6% annual relative biomass loss target EPA proposes to

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[227] 2020 CASAC Letter on Policy Assessment, *supra* n. 33, at 21.

retain and therefore use is far too high to protect the public welfare.[228] Previous CASACs clearly established an ecological end point of 1-2% annual RBL as negatively impacting forest trees which are long lived perennials therefore experiencing cumulative loss year after year. A biomass loss of 2% per year compounds, adding up year after year in forests that should be thriving over 30-100 years. In this review EPA does not offer a scientifically based or otherwise rational basis for concluding otherwise. Further, CASAC found the level of 7 ppm-hrs is the only level analyzed for which the relative biomass loss for the median tree species is less than or equal to 2%. Accordingly, EPA must protect against tree biomass loss greater than 2% annually by adopting a W126 level of 7 ppm-hrs to protect forests and ecosystems, especially in Class I areas. The 2020 PA and other material in the record provides clear evidence that tree biomass loss increases with increasing W126 levels above 7 ppm-hrs based on concentrations exposure response curves. Further, sensitive tree species that experience significant biomass loss when exposed to ozone are integral to our nation's forest and even urban/suburban landscaping and greenways.

EPA has incorrectly reasoned that an upper level of the W126 for protecting tree biomass loss, as relative biomass loss, should be 17 ppm-hrs because this aligns with previous CASAC comment that >6% biomass is unacceptably high and because 17 and 15 (CASAC recommended upper limit) have the same median percent loss (5.3%).[229] Further, EPA claims that there is little difference from 17 down to 9 ppm-hrs because there is no change in the number of tree species at or below 2% biomass loss, e.g. 5 out of 11. EPA's rationale is arbitrary because it departs from the evidence and the expert CASAC's recommendation without rational explanation. Three facts make this clear:

1. expert CASAC percent loss judgments are based on an annual form of the W126 standard, yet EPA is proposing a 3-year averaging for the standard.

2. percent biomass loss values that DO CHANGE dramatically from the low end of expert CASAC's recommendation to the current standard as seen in PA Appendix 4A, Table 4A-3, which show the ranges here:

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[228] Although *Murray Energy* rejected an argument that EPA's prior reliance on a 6% target was arbitrary based on the record in that case, 936 F.3d at 615-16, nothing in *Murray Energy* prevents EPA from revising its prior determination to better accord with the scientific evidence and the advice of the expert CASAC.

[229] The 2020 Policy Assessment reports a median value of 4.5% RBL at a level of 15 ppm-hrs, see Table 4A-3.

| Species | W126 = 7 | W126 = 10 | W126 = 17 |
|---|---|---|---|
| Red Alder | 1.8% | 2.8% | 5.3% |
| Ponderosa Pine | 2.4% | 3.6% | 6.7% |
| Aspen | 3.4% | 5.2% | 9.8% |
| Tulip poplar | 1.5% | 3.2% | 9.4% |
| Eastern White Pine | 2.6% | 4.6% | 10.7% |
| Black Cherry | 16.7% | 22.9% | 35.6% |

3. The expert CASAC clearly supports 7 ppm-hrs as appropriate to protect trees from significant biomass loss, at no greater than 2%, while EPA wrongly construed CASAC comment to indicate that 2% biomass loss is acceptable. Moreover, the CASAC's rejection of 17 ppm-hrs as the top of the range was not based solely on the assumption of a 6% biomass loss at that level. CASAC also relied on evidence of adverse effects at 10 and 7 ppm-hrs.[230]

One 2014 CASAC member provides more context in his individual comments where he states:

> We favor using a measure of central tendency of the data, specifically the median across species (the green line in Fig. 5-2). This analysis provides the median of best available estimates within each species, and the median across species with all species treated equally. Table 6-1 presents the RBL results for individual species for different levels of W126. This table demonstrates that a range of 7 ppm-hrs to 15 ppm-hrs will protect against RBL of 2% for at least 5 of the 12 species. We do not consider a value of 17 ppm-hrs from Table 6-1 because even though only 5 of 12 tree species are estimated to have relative biomass loss of 2 percent or less at this level, the median species has relative biomass loss of 6.0 percent, which is unacceptably high. With compounding over the harvest cycle or life span of these species, this will result in considerably greater cumulative RBL as discussed above. For the more sensitive tree seedlings, a value closer to the lower end of the range (7 ppm-hrs) would be more appropriate. The level of 7 ppm-hrs is the only level analyzed for which the relative biomass loss for the median tree species is less than or equal to 2 percent.[231]

The issue of percent RBL compounding is not only related to how loss would occur year after year, it also pushes the total standing biomass backward in terms of a tree's capacity to sequester carbon. The first point is simply that a loss of 2% per year becomes 6% after 3 years with all other things held equal. Over the lifetime of trees that live 50-100 years, the loss would be very detrimental. Even if a tree's growth or biomass accumulation is faster than 2% a year in

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[230] Even if EPA rationally excludes the cottonwood data and could rationally move the top of CASAC's range from 15 ppm-hrs to 17 ppm-hrs, our point in this sentence still stands.
[231] CASAC Letter 2014a at 14.

the presence of ozone, the impact of the loss would still factor in annually, as it would not grow as much as it would in the absence of ozone. The second point is that just like a loss in invested savings, a loss of biomass in one year makes it difficult to catch up in future years. This is particularly germane to the ability of an individual tree and a forest as a whole to sequester carbon moving forward.

Further, these RBL data, based on the E-R dataset, do not stand on their own and have been supported by other studies, as EPA recognizes in the 2020 ISA: "A meta-analysis by Wittig et al. (2009) found that average ozone exposure of 40 ppb significantly decreased annual total biomass by 7% across 263 studies."[232]

Of note, CASAC advised that levels above 15 ppm-hrs should not be options for the secondary standard. By way of example, CASAC noted that at 17 ppm-hrs, the median tree species has an "unacceptably high" loss of tree biomass (6%).[233] Further, they state that a level of "7 ppm-hrs is protective of ecosystem services" as it is the only level in which the median loss for the tree species examined is less than or equal to 2%.[234]

EPA must not misconstrue the reasoning and position of CASAC when making a final decision on the secondary standard. Instead the Agency must consider the science squarely and set a W126 secondary standard to 7 ppm-hrs to protect tree growth and health and thereby public welfare.

**ii. EPA fails to offer a reasonable explanation for why the three-year average, 17 ppm-hrs benchmark is appropriate, notwithstanding CASAC's advice to the contrary.**

During the 2015 review, CASAC advised EPA that it did not recommend the use of the three-year averaging period, finding that use of such an averaging period "is not supported by the available data."[235] CASAC instead advised using a single year benchmark, on the grounds that it is more biologically relevant, provides more protection to annual crops, protects perennials from the cumulative effects of ozone exposure, and protects against single unusually damaging years.[236]

EPA nonetheless finalized reliance on a three-year average benchmark and attempted to justify its decision by arguing that the benchmark provided a focus on welfare effects of "potentially greater" significance than effects "associated with a single year" of exposure. 80 Fed. Reg. at 65,404. In *Murray Energy*, the D.C. Circuit rejected this position as "inconsistent" with EPA's recognition that ozone effects in plants are cumulative and that a single season of

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[232] 2020 ISA, *supra* at 8-30.
[233] CASAC Letter 2014a at iii.
[234] *Id.*
[235] *Id.* at 13.
[236] *Id.*

high ozone exposure can have a "negative impact on species regeneration in subsequent years." 936 F.3d at 617. The court concluded that EPA had identified "no contrary evidence" to demonstrate why "single-year effects matter less than a three-year average" and remanded the issue to EPA to "explain its conclusion that the unadjusted average is an appropriate benchmark." *Id.* at 617-18.

Here, EPA yet again proposes reliance on a three-year average benchmark and fails to offer a reasonable explanation for why it is an appropriate benchmark to protect against harms to the public welfare.

EPA cites variability in ambient ozone concentrations from year to year, but fails to explain why that justifies a 3-year average over a single year standard. First, as the previous CASAC noted, the variability in a single-year W126 standard is reduced by the fact that it is the sum of 3 months of data, so it is not nearly as sensitive to extreme events as an hourly or 8-hour averaging period. EPA has asserted in the past review that the PA found greater significance for effects associated with multiple-year exposures, but that PA observation was referring to potential carryover effects from one year to the next. It does not show that a single year metric would provide inadequate protection, or that a 3-year average would provide better protection. In fact, the PA finds that use of 3-year averages may lead to underestimation of RBL. EPA further asserted in the past review that CASAC's concern about protecting against adverse effects associated with a single year's exposure "can be addressed through use of a three-year average metric, chosen with consideration of the relevant factors." 75 Fed. Reg. at 75,347. But EPA still does not explain how such an approach can address CASAC's concern, nor does EPA commit to adopting such an approach. EPA also asserts that the Administrator recognizes greater confidence in judgments related to public welfare impacts based on a three-year average metric, but fails to explain why this is so, and fails to cite scientific evidence in support. Finally, EPA disregards CASAC's advice that if a 3-year average is used, it should be set at a lower level than a single-year standard to protect against single unusually damaging years that will be obscured in the average. EPA does not and cannot claim that its selected 17 ppm-hrs, 3-year average, protects against single-year W126 values at or above the 19 ppm-hrs single-year level that EPA again says corresponds with the 6% RBL that must be prevented. EPA further offers no explanation for failing to follow CASAC's advice on this score.

EPA arbitrarily undermines the E-R functions it also touts, claiming there are few directly observing the relevant levels of ozone, raising questions about how the underlying experiments were translated to functions, noting that some of the functions rely on few experiments, and noting general variability and the existence of other factors besides cumulative ozone exposure that affect RBL. *See* 85 Fed. Reg. at 49,901, 49,910. Yet the E-R functions remain a solid foundation of quantitative data that EPA used to justify its last revision of the secondary standard. They are based on chamber experiments that controlled for other variables, which then identifies ozone's direct effects. EPA's treatment of the E-R functions also accounts for the variation by using multiple E-R functions for species when available and looking at median RBL

based on the E-R functions for 11 different species. But there are also larger-scale exposure studies including FACE that reinforce their findings in ozone biomass impact assessment. Expert CASAC made clear that E-R functions can be used with certainty, stating:

> Care should be taken not to overstate uncertainties. For example, there is quite a lot of certainty in estimates of biomass loss for forest tree seedling species and crop species for which E-R functions have been developed. Because several dominant crop species have E-R functions, there is a quite a lot of certainty about impacts of ozone on crop yield across most annual cropland in the U.S.[237]

Without rational explanation, EPA claims 3-year averaging meshes better with the E-R functions than does relying on annual W126 levels. 85 Fed. Reg. at 49,910. This is especially confounding as the E-R functions are based on shorter timeframes and prorated to 92 days when used to calculate the RBL. The argument that W126 annual values would be highly variable is also inconsistent with the fact that W126 is a 3-month cumulative metric, which would be much less variable than an 8-hour average.

EPA arbitrarily says it can't really predict the difference between biomass loss over 3-year periods with the same 3-year average W126 index but different patterns of annual levels (e.g., 17-17-17 vs. 10-17-24) by (1) pointing to an example it supplies in Appendix 4A of the PA for aspen, and (2) writing off differences between different exposure results as the residue of imprecision or inexactitude. 85 Fed. Reg. at 49,901. While using it to try to explain-away this important decision, EPA describes this analysis as "not intensive or elaborate and intended for illustration of a concept."[238] EPA presents its limitations as well, including that it does not account for carryover, which may be significant after a high exposure year, and that this example is only for aspen, but other species may not respond similarly. More concerning is that the analysis focused on how the biomass loss at variable annual levels compare to biomass estimated at the 17 ppm-hr level rather than to biomass levels under ambient, unpolluted conditions (based on the King et al. 2005 dataset ambient ozone averaged 37 ppb). Aspen will see biomass loss even at 10 ppm-hr; however, when EPA compares loss under a 10 vs 17 ppm-hrs year in its example it looks like at 4.9% gain. Clearly EPA's presentation of the data doesn't capture the full impact. If the estimated biomass loss were compared to ambient biomass data the biomass loss ranged between 5.3-16.3% in a single year and averages across the six years range from 9.9-11.7% for all the scenario patterns.

EPA points out that after year 1 the differences between total aboveground biomass was always less than 2% in their example. This is flawed reasoning for supporting EPA position that it can't predict biomass loss differences between a 1 year interval vs a 3 year interval because, as shown in Table 3, the impact on tree biomass is always greater than 5.3% with most years greater than 9% compared to ambient, which is more representative of the true impact; year one

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[237] CASAC Letter 2014a at 15.

[238] *See* 2020 Policy Assessment, *supra* n. 64, at 4A-21.

should not be excluded and in two of EPA's scenarios show 5% biomass loss in year 1; the percent difference in total tree biomass for the two scenarios shown below (10-24-17 vs 24-17-10) range from +4.9 to –5.0 in year 1 a differential of 9.9% and reach a differential of 2% in year 3 and year 6; expert CASAC used 2% RBL *in one year* as the most protective level and if EPA is not providing an analysis of the differences in annual growth impacts to which RBL is applied EPA is not addressing the issue directly; and finally, EPA must account for the cumulative impact over three years relative to 1, which it failed to do here.

Table 3. EPA Table 4A-7 (columns 1-6 and 9-10) and the percentages of the scenarios 17-17-17, 10-24-17, and 24-17-10 compare to ambient

| From EPA Table 4A-7 | | | | | | | | | Added | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Biomass (g/m2) under different W126 levels | | | % difference in total tree biomass compare to 17 | | | % difference in total tree biomass compare to ambient | | |
| Year | Ambient Biomass* | %growth | W126 17 | 10,24,17 | 24,17,10 | 10,24,17 | 24,17,10 | | W126 17 | W126 10,24,17 | W126 24,17,10 |
| Y0-1997 | 9.1 | | 9.1 | 9.1 | 9.1 | | | | | | |
| 1998 | 280.2 | 2979.1 | 254 | 266.1 | 240.9 | 4.9% | -5.0% | | -10.5% | -5.3% | -16.3% |
| 1999 | 849.5 | 203.2 | 767 | 752.9 | 754.4 | -1.9% | -1.7% | | -10.7% | -12.8% | -12.6% |
| 2000 | 1335.5 | 57.2 | 1206 | 1191.2 | 1215.1 | -1.2% | 0.8% | | -10.8% | -12.1% | -9.9% |
| 2001 | 1581.1 | 18.4 | 1427 | 1424.1 | 1425.1 | -0.2% | -0.1% | | -10.8% | -11.0% | -10.9% |
| 2002 | 2099.4 | 32.8 | 1895 | 1867.2 | 1892.6 | -1.4% | -0.1% | | -10.8% | -12.4% | -10.9% |
| Y6-2003 | 2695.2 | 28.4 | 2432 | 2404.6 | 2457.4 | -1.1% | 1.0% | | -10.8% | -12.1% | -9.7% |
| * this removes the foliage from previous year | | | | | | | | | | | |

Further, EPA's reliance on purported inexactitude, imprecision, or uncertainty as a rationale for privileging 3-year averaging is arbitrary for the reasons given above. Thus, for all the foregoing reasons, EPA's rejection of the expert CASAC's advice for adoption of a single-year W126 metric is arbitrary and violates EPA's duty to adequately justify a departure from CASAC's recommendation.

### 5. EPA Arbitrarily and Unlawfully Proposes to Use the Primary Standard's Form for the Secondary Standard.

EPA proposes to retain the primary standard's form for the secondary standard despite CASAC's conclusion that the single-year W126 index is the appropriate scientifically relevant

form and averaging time to ensure protection of the public welfare.[239] EPA fails to provide rational explanation as to why it is departing from CASAC's expert determination.

During the 2015 review of the secondary ozone standard, CASAC recommended that EPA use the single-year W126 index as the form and averaging time for the standard.[240] CASAC explicitly stated that the "form of the current standards is inadequate" to protect vegetation and ecosystem services from adverse effects.[241]

EPA rejected this advice and instead retained the existing form and averaging time: the three-year average of the fourth-highest daily maximum eight-hour ozone concentration. EPA argued that it was not necessary to adopt the W126 index because the ozone exposure levels associated with the existing form and averaging time and a three-year average of the W126 index were "highly correlated."[242] In *Murray Energy*, the D.C. Circuit explained that it could not assess the relevance of this claim, and thus the reasonableness of EPA's decision not to adopt the W126 index as the form and averaging time, because "EPA never explained why it was reasonable to focus on a three-year average of the W126 in the first place." 936 F.3d at 618.

Here, EPA again arbitrarily disregards the science and proposes to use the primary standard's form and averaging time for the secondary standard. Further, with its flawed discussion of the correlation between the DV and W126 metrics, EPA fails to offer a reasonable explanation for its decision not to adopt a single-year W126 standard.

#### i. EPA disregards the merits of W126.

The scientific foundation supporting the use of a cumulative standard to protect vegetation began in the 1997 review. At that time, EPA had a significant amount of science recognizing that the form of the standard used to protect human health was not appropriate for protecting vegetation. In the 2008 review, again in the reconsideration in 2010, in the 2015 review, and in the current review, EPA clearly supports the main assertions that ozone's impact on vegetation is cumulative and that higher ozone concentrations are more important in causing measurable impacts to plants than lower concentrations.[243] This is the foundation for the W126 metric, which uses a sigmoidal weighting function to weight higher concentrations more than lower levels and sums the seasonal ozone exposure. EPA has continued to focus on this type of metric as the "most biologically relevant metrics for consideration of $O_3$ exposures eliciting vegetation-related effects. Such a metric has an 'explanatory power' that is improved 'over using indices based on mean and peak exposure values.'"[244] As shown in the record for the current

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[239] *See* CASAC Letter 2014a at 12.
[240] *See id.* at iii.
[241] *Id.* at 11.
[242] EPA quoted in *Murray Energy*, 936 F.3d at 618.
[243] *See* 2020 ISA, *supra* n. 147, at IS.3.2.
[244] 79 Fed. Reg. at 75,316 (citing U.S. EPA, 2013a, ISA for Ozone, section 2.6.6.1, p. 2-44).

rulemaking, CASAC and EPA's staff have repeatedly and unequivocally recommended adoption of this metric for the secondary ozone standard.

Considering this long-standing support of the W126 metric, vetted in two reviews (and one re-consideration) over a nearly 25-year period, it is clear that the implementation of this metric is too long delayed. EPA must adopt this metric as the standard instead of the health-based metric that is used for the primary health standard.

#### ii. The DV 8-hour standard is not appropriate to address vegetation harms.

EPA cannot lawfully or rationally set a national welfare standard based on a metric designed to protect public health. It is arbitrary and unlawful for EPA to propose a welfare standard in the 8-hour form in direct contradiction with its own conclusion that public welfare protection is – as a matter of science – appropriately judged through the use of the cumulative seasonal W126-based metric. EPA's decision also disregards CASAC's advice that is founded on a plethora of scientific information and context built in this review and past reviews. This is the very definition of an arbitrary and capricious decision.

Moreover, EPA fails to offer a full scientific basis for rejecting CASAC's advice on this issue, as the law requires.[245] The agency makes no claim that reliance on the 8-hour form will do a better job of protecting welfare than the W126 form, and indeed the record provides no support for such a claim. Nor is there any claim by the agency that some statutorily relevant purpose is served by foregoing the W126 metric – which the agency agrees is more biologically relevant and appropriate. Implementation concerns are not legally or rationally relevant at the standard-setting stage.

EPA arbitrarily argues that the W126 form is inferior to the current form because W126 "would not explicitly limit the occurrence of hourly concentrations at or above specific magnitudes" (relevant, EPA says, to visible leaf damage, 85 Fed. Reg. at 49,913, an effect EPA arbitrarily and unlawfully does not specify an air quality threshold for), whereas the 8-hour standard "can provide control of both peak concentrations and concentration-weighted cumulative exposures," as EPA says the evidence shows. 85 Fed. Reg. at 49,913. EPA's argument is irrational. It is internally inconsistent: it criticizes W126 because it "would not <u>explicitly</u> limit" hourly levels but praises the current form that also doesn't <u>explicitly</u> limit cumulative exposures. *Id.* EPA also ignores that a cumulative standard would be implemented alongside the primary standard, which focuses on 8-hour exposures, and fails to consider the possibility of having both a cumulative standard and a standard that focuses on shorter exposures, like the primary PM NAAQS.

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[245] *Murray Energy*, 936 F.3d at 614; *Mississippi*, 744 F.3d at 1358 ("to the extent that CASAC has exercised scientific judgment, EPA must respond in kind.").

EPA's attempt to justify use of the primary standard form and averaging period by claiming that compliance with the primary standard will provide incidental protection against excessive cumulative exposure is also arbitrary because it relies on happenstance. The expert CASAC made clear that:

> The form of the current standard is inadequate to provide [the requisite welfare] protection. From correlation analysis based on the Higher Order Direct Decoupled Method (HDDM), the EPA suggests that a W126 level of 15 ppm-hrs may in many cases be similar to the current standard. However, as noted in the CASAC's review of the Second Draft WREA (EPA-CASAC-14-003), the CASAC finds that a W126 level of 15 ppm-hrs may not be similar to the current standard, since the actual approaches that would be used to achieve such a level are likely to be different than those assumed in the HREA air quality scenarios for just meeting the current standard. Specifically, and quoting from our review of the Second Draft WREA:
>
>> "The currently reported finding of only small differences in risk between just meeting the current standard and a W126-based level of 15 ppm-hrs must not be interpreted to mean that just meeting the current standard will be as protective as meeting a W126-based standard at 15 ppm-hrs. There are two key factors that must be considered when making this comparison. First, air quality was simulated in the Second Draft WREA based on the magnitude of across-the-board reductions in NOx emissions required to bring the highest monitor down to the target level. Meeting a target level at the highest monitor requires substantial reductions below the targeted level through the rest of the region. This artificial simulation does not represent an actual control strategy and may conflate differences in control strategies required to meet different standards and different targets. As a result, there may be a number of monitors that meet the current standard but would not meet an alternative W126 standard. Second, and equally important, the current form of the standard is much less biologically relevant for protecting vegetation than is a seasonal, peak weighted index such as the W126, which was designed to measure the cumulative effects of ozone exposure."[246]

The expert CASAC reiterated that the unsuitability of the primary standard form and suitability of the W126 form is a scientific judgment.[247]

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[246] CASAC Letter 2014a at 11-12.
[247] *Id.* at 12-15.

EPA itself has previously agreed that the lack of a relationship between 8-hour and cumulative levels "indicates that in some locations, [ozone] air quality patterns can lead to elevated cumulative, seasonal [ozone] exposures without the occurrence of elevated daily maximum 8-hour average [ozone] concentrations." 79 Fed. Reg. at 75,344/2. And even this CASAC notes that the primary standard does not protect against ozone exposures measured in ways that differ from the current form, explaining that "decreasing peak ozone concentrations will not consistently decrease the mean ozone concentrations."[248] Though the specifics of the scenario the current CASAC discusses differ from the distinction between the primary standard form and the W126 metric, the basic point stands: the primary standard focuses on controlling one type of ozone exposure, and cannot be rationally relied on to control other types.

Moreover, even on its own terms, EPA's comparison between the level of protection fails. EPA's own data over 19 years show numerous areas that met the 0.070 ppm 8-hour health standard but violated thresholds measured under the W126 metric that correspond with adverse welfare effects. As explained above, the proper, scientifically based threshold is 7 ppm-hrs, measured over a single year. There are over 3,000 instances where a monitor met the primary standard but exceeded the 7 ppm-hrs single-year threshold. That same result holds even under EPA's unsupported preferred 3-year average. Further, as the table below shows,[249] there are numerous instances of monitors meeting the existing primary standard but violating even the under-protective thresholds EPA prefers, whether expressed as single-year or 3-year averages.

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[248] 2020 CASAC Review of Policy Assessment, *supra* n. 33, at 4.

[249] The following four tables are derived from air quality data EPA provided on W126 values and 8-hour design values at https://www.epa.gov/air-quality-analysis/ozone-naaqs-review-analyses-and-data-sets, which EPA incorporated into the docket at EPA-HQ-OAR-2018-0279-0073 and EPA-HQ-OAR-2018-0279-0310. For the all-sites data, we followed EPA's data-completeness approach given at PA app.4D, at 4D-3 to -4. (The Class I-proximate area data appears already to have been cleared of insufficiently complete data.) Nevertheless, there appear to be discrepancies between the results EPA describes at PA 4-66 tbl.4-1 and the results we derived for all sites: we found more instances of sites with 8-hour design values complying with the 70 ppb primary standard, but exceeding the 17 ppm-hrs (3-year average) benchmark EPA arbitrarily set.

| | # Observations | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **3-yr W126 average | | | | ***1-yr W126 average | | | |
| *Design Value (ppb) | ≥ 19 (ppm-hrs) | > 17 (ppm-hrs) | > 7 (ppm-hrs) | Total | ≥ 19 (ppm-hrs) | > 17 (ppm-hrs) | > 7 (ppm-hrs) | Total |
| ≤ 70 | 2 | 21 | 3020 | 8197 | 50 | 117 | 3009 | 8970 |
| 65-70 | 2 | 21 | 2744 | 4529 | 48 | 113 | 2546 | 4864 |
| 68-70 | 2 | 21 | 1809 | 2358 | 41 | 93 | 1571 | 2523 |

*ranges inclusive of boundaries

** Annual 4th Max Percent Complete ≥ 75; Annual W126 Percent Complete ≥ 75; 3-Year Average 4th Max Percent Complete ≥ 90; 3-Year Average W126 Percent Complete ≥ 90. Rows where 3-year average W126 values were not given were excluded from totals.

*** Annual 4th Max Percent Complete ≥ 75; Annual W126 Percent Complete ≥ 75. Rows where annual W126 index value was not given were excluded from totals.

As the table below indicates, similar results hold even for just the monitors in or near Class I areas.

| | # Observations | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 3-yr W126 average | | | | 1-yr W126 average | | | |
| *Design Value (ppb) | ≥ 19 (ppm-hrs) | > 17 (ppm-hrs) | > 7 (ppm-hrs) | Total | ≥ 19 (ppm-hrs) | > 17 (ppm-hrs) | > 7 (ppm-hrs) | Total |
| ≤ 70 | 2 | 7 | 193 | 498 | 41 | 62 | 586 | 1494 |
| 65-70 | 2 | 7 | 160 | 219 | 41 | 62 | 477 | 657 |
| 68-70 | 2 | 7 | 102 | 115 | 36 | 54 | 295 | 345 |

*ranges inclusive of boundaries

EPA is well aware of this mismatch. Even in the prior review, in the 13-year period studied by EPA, there were more than 1,300 occurrences where monitors reached or exceeded CASAC's 7 ppm-hours benchmark for protecting tree growth (even after averaging over three years), while meeting the health standard.[250] And if EPA had looked at single-year cumulative levels as CASAC recommended (rather than averaging them out over 3 years), it would have found that numerous national parks and wilderness areas far exceeded even a 17 ppm-hours

[250] "Wells max4 w126 comparison memo" at 14 tbl.9 (EPA-HQ-OAR-2008-0699-4325).

threshold while meeting the health standard.[251]. These include national parks and Class I wilderness areas like Grand Canyon (maximum annual level of 21.7 ppm-hours), Petrified Forest (18.6 ppm-hours), Saguaro (20.2 ppm-hours), Mesa Verde (22 ppm-hours), Canyonlands (23.6 ppm-hours), Zion (19.8 ppm-hours), Carlsbad Caverns (26.7 ppm-hours), Wind Cave (20.6 ppm-hours), Chiricahua (19.8 ppm-hours), Superstition (19.6 ppm-hours), Maroon Bells-Snowmass (23 ppm-hours), Weminuche (20.8 ppm-hours), and Bridger (18.8 ppm-hours). 79 Fed. Reg. at 75,331-32, tbl.7.[252] Indeed, EPA's data show that areas in compliance with the 0.070 ppm 8-hour health standard experienced cumulative exposures that EPA agrees correspond to adverse effects on welfare. Worse, this has occurred in some of the nation's most iconic national parks, including Grand Canyon, Canyonlands, Mesa Verde, and Zion, as well as Maroon Bells-Snowmass and Weminuche wilderness areas. Monitors in each of these locations have recorded cumulative 3-year average levels higher than 17 ppm-hours during periods when a 0.070 ppm 8-hour level was met.[253]

Thus, EPA is mistaken when it claims that "virtually all" areas in compliance with a design value of 70 ppb do not exceed the target level of 17 ppm-hrs on the W126 index. *E.g.*, 85 Fed. Reg. at 49,911/3. EPA is also wrong to conclude, as the agency appears to do, that these elevated cumulative exposures that occur despite compliance with the health standard are insignificant or de minimis. EPA's own data shows that, since 2000, EPA's monitors have recorded 25 observations with 3-year average W126 in excess of 17 ppm-hrs despite compliance with a 70 ppb 8-hour standard, and 52 observations with annual W126 values exceeding 19 ppm-hours despite such compliance. Moreover, in its effort to dismiss this evidence that cumulative levels corresponding to adverse welfare effects in fact will occur despite compliance with the primary standard, EPA irrationally compares these recorded instances to the total number of ozone measurements. EPA fails to explain why this is the appropriate comparator. To evaluate the protection of welfare values provided by the health standard, EPA should rationally compare these problematic observations only to the subset of observations where ozone levels are close to the health standard, but compliant with it. When EPA's data are considered in proper context, they show a large and significant number of exceedances of harmful W126 thresholds in areas that meet the primary standard. That comparison, for both all sites and Class I area proximate sites, is presented in the tables below.

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[251] *See* Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (Aug. 2014) at 5-28 to -29 tbl.5-2; *see also* Class I Areas dvle75 w126ge15 July 2015 for Final Rulemaking; Dataset on which Table 3 in the Preamble to the 2015 Final Rule is based (Sept. 2015) (EPA-HQ-OAR-2008-0699-4249).
[252] *See* Class 1 area data at EPA-HQ-OAR-2008-0699-4249
[253] *See* Class I Area data at EPA-HQ-OAR-2008-0699-4249.

| All Sites | # Observations | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **3-yr W126 average | | | | | | | ***1-yr W126 average | | | | | | |
| ***Design Value (ppb)** | ≥ 19 (ppm-hrs) | % | > 17 (ppm-hrs) | % | > 7 (ppm-hrs) | % | Total | ≥ 19 (ppm-hrs) | % | > 17 (ppm-hrs) | % | > 7 (ppm-hrs) | % | Total |
| ≤ 70 | 2 | 0.02% | 21 | 0.26% | 3020 | 36.84% | 8197 | 50 | 0.56% | 117 | 1.30% | 3009 | 33.55 % | 8970 |
| 65-70 | 2 | 0.04% | 21 | 0.46% | 2744 | 60.60% | 4528 | 48 | 0.99% | 113 | 2.32% | 2546 | 52.34 % | 4864 |
| 68-70 | 2 | 0.08% | 21 | 0.89% | 1809 | 76.72% | 2358 | 41 | 1.63% | 93 | 3.69% | 1571 | 62.27 % | 2523 |

*ranges inclusive of boundaries

** Annual 4th Max Percent Complete ≥ 75; Annual W126 Percent Complete ≥ 75; 3-Year Average 4th Max Percent Complete ≥ 90; 3-Year Average W126 Percent Complete ≥ 90. Rows where 3-year average W126 values were not given were excluded from totals.

*** Annual 4th Max Percent Complete ≥ 75; Annual W126 Percent Complete ≥ 75. Rows where annual W126 index value was not given were excluded from totals.

| Class I areas | # Observations | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 3-yr W126 average | | | | | | | 1-yr W126 average | | | | | | |
| ***Design Value (ppb)** | ≥ 19 (ppm-hrs) | % | > 17 (ppm-hrs) | % | > 7 (ppm-hrs) | % | Total | ≥ 19 (ppm-hrs) | % | > 17 (ppm-hrs) | % | > 7 (ppm-hrs) | % | Total |
| ≤ 70 | 2 | 0.40% | 7 | 1.41% | 193 | 38.76% | 498 | 41 | 2.74% | 62 | 4.15% | 586 | 39.22% | 1494 |
| 65-70 | 2 | 0.30% | 7 | 1.07% | 160 | 24.35% | 219 | 41 | 6.24% | 62 | 9.44% | 477 | 72.60% | 657 |
| 68-70 | 2 | 0.58% | 7 | 2.03% | 102 | 29.57% | 115 | 36 | 10.43% | 54 | 15.65% | 295 | 85.51% | 345 |

*ranges inclusive of boundaries

As well as comparing monitors' compliance with the primary standard form with arbitrarily weak W126 thresholds over a 19-year period, EPA also examines the relationship between the primary standard and W126 values, finding it to be positive and nonlinear, at least based on the 2016-2018 period. 85 Fed. Reg. at 49,893/1. This comparison provides only limited information, as it is based on just three years' worth of data. Moreover, to the extent the relationship changes over time, EPA's assumption that it will continue to hold is baseless and thus arbitrary. Accordingly, EPA must make a rational examination of whether the relationship will continue to hold. Such an examination may be informed by studying how the relationship has changed over time. Regrettably, EPA's arbitrarily short comment period limits our ability to carry out the analysis.

Similarly, EPA characterizes the relationship between the long-term change in the DV metric and the W126 metric as positive and linear, measured over the 2000-2002 to 2016-2018 period. 85 Fed. Reg. at 49893/2. But, again, the relevant question is whether that relationship will continue to hold moving forward, and EPA's comparison ignores important considerations. For example, the relationship may be different over a somewhat narrower range of years. If it is different in recent years from what it was in earlier years, or overall, that may have implications for what the relationship is likely to be moving into the future. Particularly relevant date ranges are tied to implementation of standards using the DV metric. The DV metric only started being the focus of implementation in 2004, at the earliest, when designations for the 1997 NAAQS were made. Thus, a relevant question becomes what the relationship looks like from 2004-2006 to 2016-2018. Further, in most areas, implementation of the 1997 NAAQS has been superseded by implementation of newer, more stringent NAAQS. Implementation of the 2015 NAAQS is in its infancy still. Thus, what is the relationship from 2012-2014 (when the 2008 NAAQS started being implemented) to 2016-2018? Again, however, EPA's arbitrarily short comment period limits our ability to carry out the analysis.

Additional support for the lack of a necessary relationship between the two metrics comes from the regional differences in the relationship that EPA acknowledges in the policy assessment. EPA has failed to rationally address the importance of these differences and what they mean about the nature of the relationship moving forward.

EPA itself has shared these concerns about the mismatch between the primary standard and the actually protective W126 form. In 2014, it noted that there was no consistent relationship between 8-hour and W126 levels. 79 Fed. Reg. at 75,344 ("These known differences between urban and rural sites suggest that there is the potential for an inconsistent relationship between 8-hour daily peak $O_3$ concentrations and cumulative, seasonal exposures in those areas.").

Finally, we note once more that this is not the first time EPA has tried to force the secondary standard to fit into the primary standard. EPA's effort here is arbitrary for the same fundamental reason it was arbitrary before: the forms are not the same, and emissions control that affects one form does not necessarily affect the other. Because of the core repetition, we also

incorporate here by reference our comments on this point from the 2015 review. EPA-HQ-OAR-2008-0699-2720 at 194-99.

## VI. THE ADMINISTRATOR'S PUTATIVE ENVIRONMENTAL JUSTICE ANALYSIS IS ARBITRARY

EPA directly mentions "environmental justice" exactly once in the Proposal – to assert that it "believes that this action does not have disproportionately high and adverse human health or environmental effects on minority, low-income populations and/or indigenous peoples." 85 Fed. Reg. at 49,914. The Agency claims that since it has considered "at-risk groups," this fulfils its obligations under E.O. 12,898. The two terms are not necessarily synonymous, and at minimum, EPA has done nothing to indicate or explain that they are. Further, as discussed above, the Agency has entirely failed to analyze the susceptibility of communities of color and lower socioeconomic status to different levels of ozone pollution, and has done nothing to remediate the environmental justice issues that permeated the 2015 review.[254]

Executive Order 12,898 calls for agencies to "identify[] and address[], as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low income populations in the United States and its territories and possessions, the District of Columbia, the Commonwealth of Puerto Rico, and the Commonwealth of the Mariana Islands." EPA must assess whether its Proposal to "retain, without revision," the outdated ozone NAAQS harms human health or the environment, and whether those impacts will be disproportionately borne by communities of color and low-income communities.[255] EPA's own record in both the 2020 and 2015 reviews makes clear that the human health harms of maintaining the outdated standard are disproportionately distributed and, as already described above, EPA is already flouting the Clean Air Act's separate statutory mandate under the NAAQS Program to consider effects on these same populations.[256]

The analysis the Executive Order calls for is different from the analysis the Act calls for. Indeed, the 4th Circuit recently rejected an attempt to conflate the two. In *Friends of*

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[254] Comments of American Lung Association, et al., on EPA's Proposed Revisions to the National Ambient Air Quality Standards for Ozone, March 17, 2015, 79 Fed. Reg. 75,234, ID No. EPA-HQ-OAR-2008-0699-2720, at 240-57 (describing irrationalities of EPA's proposed environmental justice analysis). We incorporate here by reference the cited comments.

[255] Bell, Michelle L., Antonella Zanobetti, and Francesca Dominici. "Who Is More Affected by Ozone Pollution? A Systematic Review and Meta-Analysis." *American Journal of Epidemiology* 180, no. 1 (July 1, 2014): 15–28, *available at* https://doi.org/10.1093/aje/kwu115.

[256] The Proposal itself notes that "[a]mong populations of different races or ethnicities, black non-Hispanic children aged five to 14 have the highest prevalence, at 16.1%. Asthma prevalence is also increased among populations in poverty. For example, 11.7% of people living in households below the poverty level have asthma compared to 7.3%, on average, of those living above it (CDC, 2019, Tables 3–1 and 4–1; PA, Table 3–1). Population groups with relatively greater asthma prevalence might be expected to have a relatively greater potential for O3-related health impacts." 85 Fed. Reg. at 49,850.

*Buckingham v. State Air Pollution Control Board*, the Court explained, "'The purpose of an environmental justice analysis is to determine whether a project will have a disproportionately adverse effect on minority and low income populations.'" 947 F.3d 68, 87 (4th Cir. 2020) (quoting *Mid States Coal. for Progress v. Surface Transp. Bd.*, 345 F.3d 520, 541 (8th Cir. 2003)). Based on that understanding, the Court held that it was irrational for the government's environmental justice analysis to "merely fall[] back on NAAQS and state air quality standards not tailored to this specific EJ community." *Id.* at 90. The Court explained

> The Board's reliance on air quality standards led it to dismiss [environmental justice] concerns. Even if all pollutants within the county remain below state and national air quality standards, the Board failed to grapple with the likelihood that those living closest to the Compressor Station—an overwhelmingly minority population according to the Friends of Buckingham Survey—will be affected more than those living in other parts of the same county. The Board rejected the idea of disproportionate impact on the basis that air quality standards were met. But environmental justice is not merely a box to be checked, and the Board's failure to consider the disproportionate impact on those closest to the Compressor Station resulted in a flawed analysis.

*Id.* at 91-92.

EPA here is repeating the same irrationality. Its reliance on its overall analysis ignores precisely the disproportionate impacts that the Executive Order compels it to analyze and that EPA purports to have analyzed. EPA's approach reduces environmental justice analysis to "merely a box to be checked." That approach is not consistent with the Executive Order, is independently not rational, and is not in keeping with core principles of justice and equity.

Notwithstanding the Agency's attempt to characterize its Proposal as merely maintaining the status quo, the studies contained in EPA's own record both now and from 2015 are sufficient to trigger EPA's responsibility under E.O. 12,898 to assess whether health harms from maintaining the current ozone standard are disproportionately borne by vulnerable communities and, if so, how EPA should address this disparity. The fact that the status quo is inequitable is not a rational reason either to forego meaningful analysis of the inequities of the status quo or to avoid redressing those inequities. As the record notes, communities of color and lower socioeconomic communities—which can and often do overlap—are frequently disproportionately exposed to higher levels of ozone air pollution, to more types of elevated air pollution and to more chronic air pollution. And, perhaps not surprisingly, communities of color and lower socioeconomic communities suffer a disproportionately higher asthma burden in the United States—particularly Blacks, Puerto Ricans, and Native Americans. Further, and as discussed extensively in our 2015 comments, in many parts of the country, as air quality progressively worsens in an area, representation of Blacks and other communities of color in the population increases while representation of whites in the population decreases. It is critical to

consider the cumulative impacts of multiple stressors on these communities when assessing health impacts, including a population's exposure to multiple pollutants, exposure to higher levels of multiple pollutants, and chronic exposure to lower levels of multiple pollutants.

Further, in the midst of a pandemic that disproportionately harms communities of color and low-income communities, the mandates of E.O. 12,898 have never been more urgent. The Administrator signed this rule six months into a global pandemic, and yet the Proposal nowhere discusses the disproportionate impact that COVID-19 has on communities of color and low-income communities and how that informs setting the ozone standard. Doubly burdening these communities during a respiratory pandemic is unconscionable, and the Administrator's silence in the face of these disproportionate impacts further underscores the inadequacy of the Proposal's environmental justice review.

EPA's failure protect sensitive subpopulations is a violation of its legal requirement under E.O. 12,898 review and under the mandates of the Clean Air Act. It further is irrational. Contrary to EPA's assertion, Section II of its August 14, 2020 Federal Register notice does not document that this proposed action does not have disproportionately high and adverse human health or environmental effects on communities of color, low-income populations, or indigenous peoples, as specified in the Executive Order. *See* 85 Fed. Reg. at 49,914. If the 2020 Ozone NAAQS is to adequately address environmental justice issues, as it must, EPA must undertake a serious environmental justice review of the cumulative impacts these communities face, and set a standard using a precautionary approach to protect the health of these vulnerable populations.

## VII. THERE IS NO LAWFUL OR RATIONAL BASIS FOR WEAKENING THE OZONE NAAQS

As explained elsewhere in these comments, EPA has arbitrarily failed to explain how its review remotely justifies maintaining the outdated 2015 standard rather than strengthening it. *A fortiori*, the science available to the agency in no way justifies a weaker standard, notwithstanding EPA's attempt to redefine the relevant exposure level in the Schelegle study relied on by the Administrator in 2015.[257] To the extent EPA appears to consider relevant factors, its purported concerns about "uncertainty" in setting the standard seems only to drive it toward setting a less protective standard. That is precisely the opposite of the orientation of the Act and is thus unlawful and irrational. E.g., *Lead Indus. Ass'n*, 647 F.2d at 1155 ("orientation" of the Act is toward protection and precaution)

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[257] See, e.g., 85 Fed. Reg. 49,840, n. 29: "For the 70 ppb target exposure, Schelegle et al. (2009) reported, based on O3 measurements during the six 50-minute exercise periods, that the mean O3 concentration during the exercise portion of the study protocol was 72 ppb. Based on the measurements for the six exercise periods, the time weighted average concentration across the full 6.6- hour exposure was 73 ppb (Schelegle et al., 2009)." The 2015 review described this study as having a concentration of 72 ppb, and in the 2020 review, the Agency instead adorts the "weighted average concentration" of 73 ppb.

We also reiterate that EPA may not consider background ozone levels and their purported impact on the standards' attainability at all in setting the standard. The Proposal asserts the D.C. Circuit:

> rejected the argument that the EPA was required to take background $O_3$ concentrations into account when setting the NAAQS, holding that the text of CAA section 109(b) precluded this interpretation because it would mean that if background $O_3$ levels in any part of the country exceeded the level of O3 that is requisite to protect public health, the EPA would be obliged to set the standard at the higher nonprotective level []. Thus, the court concluded that the EPA did not act unlawfully or arbitrarily or capriciously in setting the 2015 NAAQS without regard for background $O_3$ [].

85 Fed. Reg. 49,836 (citing *Murray Energy Corp. v. EPA*, 936 F.3d 597 (D.C. Cir. 2019)) (internal citations omitted).

EPA falsely characterizes the Court's holding. Rather than holding merely that EPA was not required to consider background ozone's purported effect on attainability, the court made exceedingly clear that background levels may not be considered in setting the standard. It held that the Act makes only public health and welfare relevant considerations in standard setting, and thus that "'the agency is not free to trespass beyond the bounds of its statutory authority by taking other factors into account.'" *Murray Energy*, 936 F.3d at 623 (quoting *Lead Indus.*, 647 F.2d at 1150). It further held that, based on the structure of the Act, "Congress decided that EPA should account for background ozone during enforcement, not when setting standards." *Id.* It also held that its own binding precedent forecloses the polluters' argument: "Simply put, 'the question of attainability is not relevant to the setting of ambient air quality standards under the Clean Air Act.'" *Id.* at 623-24 (quoting *API*, 665 F.2d at 1190). And, capping it off with a clear, concise, to the point statement, the Court summarized its holding: "the Clean Air Act prohibits EPA from adjusting for background ozone in setting the NAAQS." *Id.* at 624. To the extent EPA's [258]is an attempt to re-introduce discussion of background levels into the consideration of the standards, this is a violation of the plain language of section 109, the Act's structure, and the D.C. Circuit's controlling precedent.[259] The D.C. Circuit has repeatedly chastised EPA for repeatedly violating its binding decisions in the same ways. *E.g.*, *NRDC v. EPA*, 643 F.3d 311, 322-23 (D.C. Cir. 2011); *Sierra Club v. EPA*, 479 F.3d 875, 884 (D.C. Cir. 2007). EPA must resist the temptation to go down that path yet again.

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[259] *See, e.g.*, 85 Fed. Reg. 49,838, "In such locations, the modeling suggests the potential for episodic and relatively infrequent events with substantial background contributions where daily maximum 8- hour O3 concentrations approach or exceed the level of the current NAAQS (i.e., 70 ppb). This contrasts with most monitor locations in the U.S. for which international contributions are predicted to be the lowest during the season with the most frequent occurrence of daily maximum 8-hour O3 concentrations above 70 ppb."

## VIII. CONCLUSION & SUMMARY OF RECOMMENDATIONS

For all of the reasons explained above, EPA must re-do its inadequate scientific review process, revise its Proposal for the primary ozone NAAQS to no higher than 60 ppb, propose a primary standard that targets long-term ozone exposure, revise its Proposal for the secondary NAAQS to no higher than 7 ppm-hours (measured as a single-year W126 metric), and then reopen the comment period. Only these actions would reflect the Clean Air Act's directives and binding case law, which make clear that EPA's responsibility is to protect public health with an adequate margin of safety and protect public welfare against any known or anticipated adverse effect, based on the best available science.

Sincerely,

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# Attachment 2

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON D.C. 20460**

**OFFICE OF THE ADMINISTRATOR**
**SCIENCE ADVISORY BOARD**

June 26, 2014

EPA-CASAC-14-004

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: CASAC Review of the EPA's *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*

Dear Administrator McCarthy:

The Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel met on March 25 - 27, 2014, to review the EPA's *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*, hereafter referred to as the Second Draft PA. This letter highlights the chartered CASAC's consensus advice, followed by consensus responses to the charge questions from the Agency. Individual review comments from the CASAC Ozone Review Panel are also attached.

Overall, the Second Draft PA is an excellent summary of information needed to judge the adequacy of the current National Ambient Air Quality Standards (NAAQS) for ozone and to consider alternative standards. The information on emissions, atmospheric chemistry and common patterns of ozone concentration is presented clearly and is appropriately characterized. "Background" ozone (i.e., ozone that originates from precursors from natural sources or anthropogenic international emissions) is extensively and appropriately characterized, although in our consensus responses to charge questions, we have some technical comments that should be addressed to improve the coverage of this issue. The Second Draft PA is not clear as to how background estimates might impact the primary and secondary standards and whether these impacts may differ regionally. The Second Draft PA cites a 2002 court decision (*American Trucking Associations, Inc. v. EPA, 283 F.3d at 379*) that allows the EPA to consider relative proximity to peak background levels when evaluating alternative standards but it also cites a case where the court said "attainability and technological feasibility are not relevant considerations in the promulgation of the NAAQS" (*American Petroleum Institute v. Costle*, 665 F. 2d at 1185). The Second Draft PA was silent as to how the EPA intends to navigate between these two legal guidelines when considering background ozone in a policy and standard-setting context. This question became an important issue in the CASAC deliberations as we listened to public comments regarding

high background levels in the intermountain Western United States.

In addressing the adequacy of the primary standard, the Second Draft PA presents scientifically sound information on the health effects evidence for each major effect category: lung function decrements, pulmonary inflammation, respiratory symptoms, respiratory morbidity and respiratory mortality. The CASAC finds scientific justification that current evidence and the results of the exposure and risk assessment call into question the adequacy of the current standard. Furthermore, there is clear scientific support for the need to revise the standard. The CASAC supports the scientific rationale presented in the Second Draft PA on these points.

The CASAC concurs with the staff's justifications in the Second Draft PA for retaining the current indicator (ozone), averaging time (maximum daily 8-hour average) and form (annual 4$^{th}$ highest maximum daily 8-hour average, averaged over three years) for the primary standard. The indicator of ozone is appropriate based on its causal or likely causal associations with multiple adverse health outcomes and its representation of a class of pollutants known as photochemical oxidants. The current 8-hour averaging time is justified by the combined evidence from epidemiologic and clinical studies referenced in Chapter 4. The CASAC concurs that the ozone standard should be based on the fourth highest, daily maximum 8-hour average value (averaged over three years). This averaging time provides programmatic stability by allowing for atypical meteorological conditions that can lead to abnormally high ambient ozone concentrations while providing health protection.

The CASAC further concludes that there is adequate scientific evidence to recommend a range of levels for a revised primary ozone standard from 70 ppb to 60 ppb. The CASAC reached this conclusion based on the scientific evidence from clinical studies, epidemiologic studies, and animal toxicology studies, as summarized in the Integrated Science Assessment (ISA), the findings from the exposure and risk assessments as summarized in the HREA, and the interpretation of the implications of these sources of information as given in the Second Draft PA. However, as noted below, we believe there is an important distinction in our finding and advice regarding the upper bound level of 70 ppb as compared to that of EPA staff as given in the Second Draft PA.

In reaching its scientific judgment regarding a recommended range of levels for a revised ozone primary standard, the CASAC focused on the scientific evidence that identifies the type and extent of adverse effects on public health. The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act. The CASAC advises that, based on the scientific evidence, a level of 70 ppb provides little margin of safety for the protection of public health, particularly for sensitive subpopulations. In this regard, our advice differs from that offered by EPA staff in the Second Draft PA. At 70 ppb, there is substantial scientific evidence of adverse effects as detailed in the charge question responses, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard, it may not meet the statutory requirement to protect public health with an adequate margin of safety. In this regard, the CASAC deliberated at length regarding advice on other levels that might be considered to be protective of public health with an adequate margin of safety. For example, the recommended lower bound of 60 ppb would certainly offer more public health protection than levels of 70 ppb or 65 ppb and would provide an adequate margin of safety. Thus, our policy advice is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your

judgment regarding the desired margin of safety to protect public health, and taking into account that lower levels will provide incrementally greater margins of safety.

With respect to the secondary standard, the CASAC concurs with EPA's identification of adverse welfare effects related to ecosystem services, food and fiber products from crops, and damage to resource use from foliar injury. The CASAC concurs that tree species relative biomass loss, foliar injury, and crop yield loss are appropriate surrogates of adverse welfare effects. The CASAC further supports the causality determinations of the ISA between exposure to ozone and adverse welfare effects. The CASAC supports the scientific conclusion in the Second Draft PA that the current secondary standard is not adequate to protect against current and anticipated welfare effects of ozone on vegetation. We recommend retaining the current indicator (ozone) but establishing a revised form of the secondary standard to be the biologically-relevant W126 index accumulated over a 12-hour period (8 a.m. – 8 p.m.) over the 3-month summation period of a single year resulting in the maximum value of W126 (henceforth W126). The CASAC recommends that the level associated with this form be within the range of 7 ppm-hrs to 15 ppm-hrs to protect against current and anticipated welfare effects of ozone. The CASAC does not support a level higher than 15 ppm-hrs. For example, at 17 ppm-hrs, the median tree species has 6% relative biomass loss, and the median crop species has over 5% yield loss. These levels are unacceptably high. These combinations of indicator, form, averaging time, and level are scientifically justifiable given evidence of current and anticipated welfare effects as captured in the Second Draft PA, and supported by the ISA and the second draft of the WREA.

In reaching its scientific judgment regarding the indicator, form, summation time, and range of levels for a revised secondary standard, the CASAC has focused on the scientific evidence for the identification of the kind and extent of adverse effects on public welfare. The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act. Specifically, the Clean Air Act grants discretion to the Administrator to specify a standard that is "requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air" (Section 302(h), 42 U.S.C., §7602(h)). As a policy recommendation, separate from its advice above regarding scientific findings, the CASAC advises that a level of 15 ppm-hrs for the highest 3-month sum in a single year is requisite to protect crop yield loss, but that lower levels provide additional protection against crop yield loss. Furthermore, there are specific economically significant crops, such as soybeans, that may not be protected at 15 ppm-hrs but would be protected at lower levels. A level below 10 ppm-hrs is required to reduce foliar injury. A level of 7 ppm-hrs is protective of relative biomass loss for trees and offers additional protection against crop yield loss and foliar injury. Therefore, 7 ppm-hrs is protective of ecosystem services. Thus, lower levels within the recommended range offer a greater degree of protection of more endpoints than do higher levels within the range.

The CASAC does not recommend the use of a three-year averaging period for the secondary standard. We favor a single-year period for determining the highest three-month summation which will provide more protection for annual crops and for the anticipated cumulative effects on perennial species. The scientific analyses considered in this review, and the evidence upon which they are based, are from single-year results. If, as a policy matter, the Administrator prefers to base the secondary standard on a three-year averaging period for the purpose of program stability, then the level of the standard should be revised downward such that the level for the highest three-month summation in any given year of the three-year period would not exceed the scientifically recommended range of 7 ppm-hrs to 15 ppm-

hrs. For example, if in a three-year period the highest three-month summation during a one year period is 15 ppm-hrs, and the corresponding lowest value associated with a three-year average of the highest three-month summations in each year is 13 ppm-hrs, then the appropriate level for the three-year average would be 13 ppm-hrs to protect against a peak one year level of 15 ppm-hrs. The final Policy Assessment should quantify the ratio of the three-year average of the highest three-month summations in each year to the highest three-month summation in the highest year. This ratio should be used to determine what downward adjustment from the three-month summation in one year recommended here is needed if a three-year form is selected.

The CASAC recommends that EPA facilitate research needed for the next review of the ozone NAAQS. For the health-based standard, we note that the Second Draft PA outlines key uncertainties and research that needs to be addressed for future reviews of the health-based standards. Specifically, we underscore the need for research to address the characterization of the exposure-response function; the identification of population thresholds; the role of co-pollutants and temperature in modifying or contributing to ozone effects; alternative modeling specifications; population-based information on human exposure for at-risk populations; time-activity data to improve population-based exposure and risk assessment; and the characterization of background levels.

For the secondary standard, the Second Draft PA also identifies uncertainties and needed research to develop data and better methods for extrapolating results to plant species for which exposure-response functions have not been developed; assessing the effects of ozone on climate (and the effects of climate on ozone); characterizing the effects of ozone on whole ecosystem structure and function; and evaluating how the public judges the adversity of various kinds of ecological effects including foliar injury and estimated reduced tree biomass growth. This policy-relevant research could be conducted in collaboration with other federal and non-governmental organizations to improve our understanding of ozone effects in support of the next review of the ozone NAAQS.

While these scientific research priorities will enhance future scientific reviews of the ozone primary and secondary standards, we also make clear that there is sufficient scientific evidence, and sufficient confidence in the available research results, to support the advice we have given above for this review cycle of the primary and secondary standards.

Although CASAC was not asked to comment about international transport of ozone, we would like to call your attention to this issue as a matter separate from our advice regarding the standard. North American background ozone is defined by the EPA as the ozone that would be present in U.S. surface air in the absence of North American anthropogenic emissions. North American background ozone can be estimated using global models by conducting simulations with North American anthropogenic emissions set to zero. Results indicate that background is only partly natural (lightning, biosphere, fires, stratospheric influence) and is enhanced by anthropogenic sources outside North America. Estimates of this external anthropogenic enhancement are fairly consistent across models [Fiore et al., 2009]. Zhang et al. [2011] estimated that during spring-summer 2006-2008 the mean enhancement from intercontinental pollution and anthropogenic methane is 9 ppb at low-altitude sites and 13 ppb at high-altitude sites (>1,500 m elevation), both roughly one third of the North American background ozone in the respective areas. The authors also indicated that the background ozone is higher than average when ozone concentrations exceed 60 ppb, particularly in the intermountain West. There is currently no international legal agreement on ozone or its precursors that would effectively deal with long-range transport, despite the recommendations by the National Academy of Sciences (2009) and the Task Force

on Hemispheric Transport of Air Pollution (2010) that such an agreement be sought. Given the significant portion of ozone coming from anthropogenic sources outside North America, the CASAC recommends that EPA seek opportunities for international cooperation to reduce long-range transport of ozone.

During the course of the review of the Second Draft PA, the CASAC received public comments focused on costs and implementation issues associated with a possible revised ozone standard, mainly focused on the primary standard. *Whitman vs. American Trucking Associations, Inc*. (2001) decreed that the EPA cannot consider implementation costs in setting the NAAQS. Furthermore, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards" (*American Petroleum Institute vs. Costle*, 665 F. 2d at 1185) and EPA need not tailor the NAAQS to fit each region or locale. Thus, cost and implementation issues are not relevant or allowable considerations in setting or revising a NAAQS. Therefore, CASAC did not consider such issues in its scientific review of the current standards or in developing its advice regarding revising the standards. However, the CASAC acknowledges that the Clean Air Act, section 109(d), states that the CASAC shall "advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards." Separate from the standard-setting process, the CASAC would be receptive to a request from EPA to review EPA analyses of "adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards" (42 U.S. Code § 7409). It should be noted, however, that not all of these effects will be "adverse" and any comprehensive assessment would include both adverse and beneficial effects. For example, positive economic effects accrue from implementation of national ambient air quality standards, such as the economic benefit of avoided morbidity and mortality. In response to such a request, the SAB Staff Office would form an *ad hoc* CASAC panel to obtain the full expertise necessary to conduct such a review.

The current approach to review and revision of the primary NAAQS is based on a one-pollutant-at-a-time approach. As the state of science regarding the joint effects of human exposure to multiple pollutants improves, the EPA should consider how review and revision of the NAAQS can be done synergistically for logical, scientifically relevant groupings of criteria pollutants. For example, $O_3$ and $NO_2$ are both criteria pollutants that are inter-related via atmospheric chemistry, and human exposure to these pollutants is often in the form of a mixture that includes both, and other pollutants such as particulate matter. The National Research Council and the North American Research Strategy for Tropospheric Ozone have both made detailed recommendations for multipollutant approaches to air quality management, and EPA has been exploring a multipollutant approach for the secondary standards for $SO_x$ and $NO_x$. CASAC encourages EPA to explore multipollutant approaches for review of the primary standards, and would be receptive to a request by EPA to review planning or methods documents for such approaches.

Overall, we find the Second Draft PA to be adequate for its intended purpose of providing a strong scientific basis for findings regarding the inadequacy of current primary and secondary ozone air quality standards; for scientifically justifiable indicators, averaging times, and forms for alternative revised primary and secondary standards; and for our advice regarding scientifically justifiable ranges of levels for each of the primary and secondary standards. The CASAC appreciates the opportunity to provide advice on the Second Draft PA and looks forward to receiving the agency's response.

Sincerely,

/signed/

Dr. H. Christopher Frey, Chair
Clean Air Scientific Advisory Committee

Enclosures

## NOTICE

This report has been written as part of the activities of the EPA's Clean Air Scientific Advisory Committee (CASAC), a federal advisory committee independently chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC provides balanced, expert assessment of scientific matters related to issues and problems facing the agency. This report has not been reviewed for approval by the agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies within the Executive Branch of the federal government. In addition, any mention of trade names or commercial products does not constitute a recommendation for use. The CASAC reports are posted on the EPA website at: http://www.epa.gov/casac.

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# CASAC Consensus Responses to Charge Questions On the Second Draft Policy Assessment for the Review of the National Ambient Air Quality Standards for Ozone

## *Introduction (Chapter 1)*

1. *Does the Panel find the introductory and background material (sections 1.1 and 1.2) to be appropriately characterized and clearly communicated?*

This chapter is an excellent introduction to the legislative requirements of the Clean Air Act as they apply to ozone. It also provides an excellent history of the standard-setting process; Table 1-1 does a good job summarizing the different NAAQS that have been set historically. The historical review of legal challenges to previous decisions and their eventual outcomes is well done. The chapter clearly delineates the scope and approach for the Second Draft PA. This review is especially informative about the ruling by the U.S. Court of Appeals for the District of Columbia concerning the failure of the CASAC to be clear in its recommendations on "whether it was providing scientific or policy recommendations…." which led to retention of the 75 ppb standard instead of a standard between 60 and 70 ppb.

2. *In section 1.3, we describe the general approach for the review. This includes the key aspects of the approach employed in the last review in judging the adequacy of the then-existing standards and in selecting revised standards. Does the Panel find this description of the approach in the previous review adequate and clear? Does the summary of the approach in the current review appropriately describe important considerations in this review?*

Sections 1.3.1 through 1.3.1.2 clearly delineate the Administrator's stated rationale for lowering the NAAQS in 2008 based on the weight of the evidence at that time. The process by which this decision was made is explained in a clear and lucid manner. Figure 1-1 is an excellent flow diagram that establishes the basis for the Second Draft PA on the primary standard. The description of the five-point hierarchical weight of evidence classifications and how they are used in the Second Draft PA (e.g., greatest weight placed on those effects deemed to be caused, or likely to be caused, by ozone) is clearly explained. The fact that the Second Draft PA focuses on at-risk populations for which the evidence is "adequate" is also made clear (see page 1-21). Stressed throughout is the EPA's concern about the uncertainty and likelihood of ozone effects at lower exposures, which is important for setting a lower end to the recommended range for the NAAQS. How the EPA deals with this type of uncertainty is very well explained throughout this chapter and the rest of the Second Draft PA.

How the EPA deals with controlled human exposure studies and epidemiologic studies is well delineated. There is considerable discussion about the possible existence of threshold effects, with the EPA concluding that there is no evidence for a sharp break point between exposures of 80 and 60 ppb.

There is an extensive discussion of how the welfare risks were evaluated in previous reviews (section 1.3.2.1) and why in the last review the secondary standard was set equal to the primary standard, even though the CASAC had recommended a different form and level from the primary standard (i.e., a cumulative exposure index, the W126; pg 1-30). The discussion of the weight of the evidence and how it was considered in the Second Draft PA is quite understandable and well written.

In several places (e.g., page 1-27, lines 7-10; page 1-36, lines 24-27) the document states that at low W126 exposures, the "magnitude of the response becomes increasingly uncertain." This statement is misleading; the exposure-response functions for seedlings of some tree species definitely show growth losses (decrements) at chronically low exposure levels, whereas other species show decrements only at higher exposures. Crop species show a similar range of responses. For both crop and tree species, there is strong evidence of adverse effects on common, ecologically and economically important species at exposure levels at and below 7 ppm-hrs (W126).

Overall, this is a well written introduction which sets the stage for the rest of the Second Draft PA.

***Ozone Monitoring and Air Quality (Chapter 2)***

1. *To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of $O_3$ concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?*

Chapter 2 is concise and well written. In sections 2.1 to 2.3, the discussions of monitoring, atmospheric chemistry and ozone patterns are well done. The chapter focuses primarily on the issues involving background ozone, which is an appropriate discussion, but it should further discuss the response of lower level ozone to controls (e.g., as an extension of the section on atmospheric chemistry or as a stand-alone section). As shown in the Second Draft HREA, this is a very important consideration. The Second Draft PA should be clear that controls designed to reduce the peak levels of ozone (e.g., the 4th highest annual MDA8) may not be effective at reducing lower levels of ozone on more typical days and may actually increase ozone levels on days where ozone concentrations are low. The EPA should consider showing the meteorologically adjusted ozone levels in the figures.

2. *With regard to information on estimating $O_3$ concentrations associated with non-anthropogenic sources or "background $O_3$" (section 2.4), to what extent is this information appropriately characterized and clearly communicated?*

The discussion of background ozone is extensive and generally clear though some pieces are missing. First, the method by which the various backgrounds are calculated or taken into account (e.g., models used) should be further described, and the uncertainties discussed. This section should discuss how the background might impact various standards (both health and welfare-based) and how that might differ regionally. The discussion of the source apportionment model estimates is too minimal to really understand what is being done and its importance is not evident; consequently, it should be moved to the appendix. The issues of using monitoring to estimate background should be discussed.

There appears to be confusion in the proper use of the zero-out approach. On p. 2-12, lines 23-26, and again on p. 2A-7, lines 231-241, the Second Draft PA indicates that removing $NO_x$ emissions completely and unrealistically could lead to inflated estimates of background ozone in urban areas where $NO_x$ titration of ozone is significant. The authors consider this a paradoxical result of the zero-out approach. It is not apparent what is meant by paradoxical in this case as the behavior is well known, and is part of the non-linearity in ozone chemistry (see above suggesting a further discussion of the increase in lower ozone levels from controls). Furthermore, the authors ran separate Community Multi-scale Air Quality (CMAQ) model runs for base case (designated as total), natural background (NB), North American Background (NAB) and United States Background (USB), and then took the ratios of one of the

background runs to the base case runs as the percent contribution of the background to the base case. This is inappropriate because it assumes ozone additivity; however, ozone chemistry is nonlinear. The zero-out approach is not intended for use in assigning relative contributions, and relative contribution is not a meaningful concept unless the perturbation due to some source emissions is small enough that linearity can be approximated. Based on the above discussion, in the case of the zero-out approach, it is best to change the text in the chapter from "percent contribution" (like in Fig. 2-11 on p. 2-18) to "ratio" when the background ozone is compared to the base case ozone.

***Adequacy of the Primary Standard (Chapter 3)***

1. *To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?*

Section 3.1 captures the important studies discussed in the ISA and integrates them into a logical narrative to summarize the important findings in each of the major effect categories: lung function decrements, pulmonary inflammation, respiratory symptoms, respiratory morbidity, and respiratory mortality. The adversity of the effects and their implications for public health are discussed in a straightforward and clear manner that leads the reader through the body of data.

The CASAC notes that Figure 3.1, which is intended to illustrate mode-of-action, does not present a logical sequence of steps leading to specific endpoints. The discussion of mode-of-action could be more clearly communicated as it has been in the Appendix. Various specific technical comments are included in individual panel member comments. In some cases, individual panelists suggest changes in the wording or thrust of some of the sentences and paragraphs. One such example is the discrepancy between epidemiological studies supporting anti-oxidants being partially protective of ozone-induced lung function decrements and controlled human studies showing no such protection.

The CASAC concurs with the findings of the Integrated Science Assessment, as summarized in the Second Draft PA, pertaining to the scientific evidence of the kinds of identifiable effects on public health that are expected from the presence of ozone in the ambient air.

For public health, these effects are health outcomes from short-term exposure to ozone that include respiratory effects, cardiovascular effects, central nervous system effects, and total mortality. Of these, the scientific weight of evidence of a causal relationship between short-term exposure and adverse effect is "causal" for respiratory effects, "likely to be causal" for cardiovascular effects and total mortality, and "suggestive of a causal relationship" for central nervous system effects. Given the stronger weight of evidence for several of these endpoints, EPA has appropriately focused its assessments of short-term exposure levels of concern to those most related to respiratory and cardiovascular effects, and its assessments of risk based on epidemiologic studies to mortality from short-term exposures. In the context of exposure and risk assessment, the CASAC concurs that estimation of $FEV_1$ decrements of $\geq$15% is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, whereas an $FEV_1$ decrement of $\geq$10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease.

For long-term exposures, the CASAC concurs with the findings of the ISA that the scientific weight of evidence for long-term exposure to ozone and adverse health effects is "likely to be causal" for respiratory effects and "suggestive of a causal relationship" for cardiovascular effects, reproductive and developmental effects, central nervous system effects, and total mortality. In terms of quantitative risk assessment, the most relevant scientific evidence available is with respect to epidemiologic estimates of the relationship between ambient concentration and mortality. Thus, EPA's risk assessment appropriately focuses on this particular heath end point for long-term exposure.

Furthermore, with regard to the exposure assessments, the CASAC concurs that children are an important at-risk group. In particular, school-age children spend an increased amount of time outdoors in relatively high levels of activity, which increases air intake, and include asthmatic children. Outdoor workers and other adults who engage in moderate exertion for prolonged periods or heavy exertion for shorter periods during the day also comprise at-risk groups. Therefore, the focus on estimation of $FEV_1$ decrements for asthmatic school age children and adult populations is appropriate. Asthmatic subjects appear to be at least as sensitive, if not more sensitive, than non-asthmatic subjects in manifesting ozone-induced pulmonary function decrements.

At the level of the current standard, 11% to 22% of school age children are predicted to experience at least one day with an $FEV_1$ decrement $\geq$10%, which is not protective of public health. The range of values represents variability among the analyzed cities. The proportion of school age children predicted to experience at least one day with an $FEV_1$ decrement $\geq$10% is 8% to 20% at a level of 70 ppb; 2% to 18% at a level of 65 ppb; and 4% to 13% at a level of 60 ppb. Concurrently, the proportion of school age children experiencing $\geq$ 6 days with $FEV_1$ decrements $\geq$10% decreases with level, at 1% to 6% for a level of 75 ppb; 1% to 5% at a level of 70 ppb; 0% to 4% at a level of 65 ppb; and 0% to 3% at a level of 60 ppb.

2. *With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?*

The major exposure and risk information requisite to assess the adequacy of the current standard is well presented for the adjusted air quality data, exposure-based considerations, and risk-based considerations. Overall, the salient points are clearly presented with enough detail to allow the reader to make judgments on how much weight to assign to any limitations or uncertainties. Individual panelist comments are provided that, if addressed, will strengthen these points. Major points are supported by reference to studies or data presented either earlier in the Second Draft PA or in the Second Draft ISA or Second Draft HREA, which leads to the conclusion that the points have been appropriately interpreted.

3. *In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection?*

Section 3.4 clearly articulates the findings and points that underpin the EPA staff's preliminary conclusion to call into question the adequacy of the current standard and the appropriateness of revising

it. The CASAC finds scientific justification that current evidence and exposure/risk information call into question the adequacy of the current standard. Furthermore, there is scientific support for the need to revise the standard to achieve additional public health protection.

The CASAC finds that the current NAAQS for ozone is not protective of human health. The HREA emphasizes the conclusion reached in the ISA that there is a causal relationship between short-term ozone exposure and a range of respiratory effects, including lung function decrements, respiratory symptoms, and inflammation—all of which are observed below the level of the current ozone NAAQS. As summarized in our advice on the HREA, the HREA presents ample scientific evidence from human controlled exposure and epidemiology studies that adverse health effects in young healthy adults occur with exposures to 72 ppb of ozone for 6.6 hours. For example, the combination of decrements in $FEV_1$ together with the statistically significant alterations in symptoms in human subjects exposed to 72 ppb ozone meets the American Thoracic Society's definition of an adverse health effect (American Thoracic Society, 2000). It is the judgment of CASAC that if subjects had been exposed to ozone using the 8-hour averaging period used in the standard, adverse effects could have occurred at lower concentration. Further, in our judgment, the level at which adverse effects might be observed would likely be lower for more sensitive subgroups, such as those with asthma.

While the scientific evidence supporting the finding that the current standard is inadequate to protect public health is strongest based on the controlled human exposure studies of respiratory effects, the CASAC also finds sufficient scientific evidence based on epidemiologic studies for mortality and morbidity associated with short-term exposure to ozone at the level of the current standard. Recent animal toxicological studies support identification of modes of action and, therefore, the biological plausibility associated with the epidemiological findings. The scientific evidence from multiple approaches including toxicology, clinical studies, and epidemiologic studies support an overall finding that the current standard is not adequate to protect public health. The Second Draft PA provides more detailed discussion on these and related points in the section on pages 3-118 to 3-123 in supporting the staff conclusion, which the CASAC supports, that the current standard is not adequate to protect public health. In particular, the scientific evidence provides strong support for the occurrence of a range of adverse respiratory effects and mortality under air quality conditions that would meet the current standard. Therefore, the CASAC unanimously recommends that the Administrator revise the current primary ozone standard to protect public health.

***Consideration of Potential Alternative Primary Standards (Chapter 4)***

1. *In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative standards?*

This chapter provides a comprehensive, clear, and carefully documented assessment of potential alternative primary standards for ozone. As discussed in some individual comments, it could be improved to minimize repetition within the chapter and with earlier chapters. The discussion could be more focused on the salient points such as in the discussion of studies conducted in locations that meet possible alternative standards (p. 4-12 to 4-13) and the cut-point analysis (p. 4-14 to 4-15). Figures 4.1 – 4.8 could use some cosmetic improvements.

2. *In the Panel's view, does the discussion in section 4.6 provide an appropriate and sufficient rationale, supported by the discussions in sections 4.1 through 4.4, to support staff's preliminary*

*conclusions regarding alternative primary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?*

Section 4.6 is well written with a clear rationale presented for each of the possible alternative standards. Scientific justification for retaining the current indicator (ozone), averaging time (maximum daily 8-hour average), and form (annual 4th highest maximum daily 8-hour average, averaged over three years) is provided, as well as the scientific basis for consideration of alternative levels.

The CASAC concurs with staff conclusions in the Second Draft PA that the current indicator, averaging time, and form be retained. The indicator of ozone is appropriate based on its causal or likely causal associations with multiple adverse health outcomes and its representation of a class of pollutants known as photochemical oxidants.

The current 8-hour averaging time is justified by the combined evidence from epidemiologic and clinical studies referenced in Chapter 4. Results from clinical studies, for example, show a wide range of respiratory effects in healthy adults following 6.6 hours of exposure to ozone, including pulmonary function decrements, increases in respiratory symptoms, lung inflammation, lung permeability, decreased lung host defense, and airway hyperresponsiveness. These findings are supported by evidence from epidemiological studies that show causal associations between short-term exposures of 1, 8 and 24-hours and respiratory effects and "likely to be causal" associations for cardiovascular effects and premature mortality. The 8-hour averaging window also provides protection against the adverse impacts of long-term ozone exposures, which were found to be "likely causal" for respiratory effects and premature mortality.

Regarding the form of the standard, the CASAC concurs that the ozone standard should be based on the fourth highest, daily maximum 8-hour average value (averaged over three years). This provides health protection while allowing for atypical meteorological conditions that can lead to abnormally high ambient ozone concentrations which, in turn, provides programmatic stability.

In considering the upper and lower bound of the range of levels that CASAC recommends for consideration by the Administrator, CASAC took into account the scientific knowledge of the kind and extent of identifiable effects on public health from exposure to ambient ozone, including scientific information on the nature and severity of the health effects, size of the sensitive populations at risk, and the kind and degree of uncertainties. While uncertainty is inherent in assessments of this type, the CASAC finds that there is sufficient weight of evidence and degree of confidence to reach the following scientific conclusions.

CASAC concurs with the summary of the public health significance of exposure benchmarks levels of concern as described in the Second Draft PA on Page 5-18, lines 15-21. The 80 ppb-8hr benchmark level represents an exposure level for which there is substantial clinical evidence demonstrating a range of ozone-related effects including lung inflammation and airway responsiveness in healthy individuals. The 70 ppb-8hr benchmark level reflects the fact that in healthy subjects, decreases in lung function and respiratory symptoms occur at concentrations as low as 72 ppb and that these effects almost certainly occur in some people, including asthmatics and others with low lung function who are less tolerant of such effects, at levels of 70 ppb and below. The 60 ppb-8hr benchmark level represents the lowest exposure level at which ozone-related effects have been observed in clinical studies of healthy individuals. Based on its scientific judgment, the CASAC finds that the 60 ppb-8hr exposure benchmark is relevant for consideration with respect to adverse effects on asthmatics.

The CASAC concurs with EPA staff regarding the finding based on scientific evidence that a level of 60 ppb corresponds to the lowest exposure concentration demonstrated to result in lung function decrements large enough to be judged an abnormal response by ATS and that could be adverse in individuals with lung disease. The CASAC further finds, as does EPA staff, that a level of 60 ppb also corresponds to the lowest exposure concentration at which pulmonary inflammation has been reported. Based on the exposure assessments conducted by EPA, a standard with a level of 60 ppb would reduce children exposures of concern of 60 ppb or higher over 8-hours by 96% and would allow virtually no children to experience two or more exposures in a year at this exposure of concern. Such a standard would allow 2% or fewer of children to have lung function $FEV_1$ decrements ≥15% one or more times per year, although it would allow 5 to 11% of children, including asthmatic children, to have ozone-induced lung function decrements ≥10%. A standard with a level of 60 ppb would be expected to reduce epidemiology-based mortality and morbidity risk for short-term exposures to ozone.

The Second Draft PA concludes that the scientific evidence and available information support consideration of a new primary ozone standard within the 60 ppb to 70 ppb range based on ozone as the indicator, an 8-hour averaging time, and annual 4th highest daily form of the standard (averaged over three years). The CASAC concurs that 60 ppb is an appropriate and justifiable scientifically based lower bound for a revised primary standard. This is based upon findings of adverse effects, including clinically significant lung function decrements and airway inflammation, after exposures to 60 ppb ozone in healthy adults with moderate exertion (Adams 2006; Schelegle et al., 2009; Brown et al. 2008; Kim et al., 2011), with limited evidence of adverse effects below 60 ppb. The CASAC further notes that clinical studies do not address sensitive subgroups, such as children with asthma, and that there is a scientific basis to anticipate that the adverse effects for such subgroups are likely to be more significant at 60 ppb than for healthy adults.

At a level of 70 ppb for the averaging time and form of the current standard, clinical and epidemiological studies show adverse effects to human health. As discussed in the Second Draft HREA and the Second Draft PA, approximately 1% of children are estimated to experience exposures of 70 ppb or more (daily maximum 8-hour exposures) in an ozone season, with 3% to 10% of children (depending on urban area) estimated to experience one or more exposures of concern at or above 60 ppb. Up to 5% of children are expected to experience ozone-induced lung function decrements greater than or equal to 15% in a "worst case" year with respect to meteorological conditions. Exposures of these magnitudes have been shown to result in significant adverse effects. For example, controlled human exposure studies show respiratory symptoms combined with clinically significant lung function decrements following ozone exposures to 60 ppb to 70 ppb in healthy individuals. On average over the years 2006 to 2010, a standard set at 70 ppb is estimated to allow about 11 to 17% of children to experience one or more moderate $O_3$-induced lung function decrements (i.e., ≥ 10%), which could be adverse for people with lung disease. This reflects an average reduction of about 15%, compared to current standard. A standard with a level of 70 ppb is also estimated to allow about 6 to 11% of children to experience two or more such decrements (17% reduction, compared to current standard). With regard to epidemiologic studies the CASAC concurs with the EPA staff finding in the Second Draft PA that, compared to the current standard, a revised standard with a level of 70 ppb would be more effective in maintaining short-term ambient $O_3$ concentrations below those present in locations that provided the basis for positive and statistically significant health effect associations. However, a level of 70 ppb offers only modest incremental reductions in short-term mortality risk compared to the current standard. Taken as a whole, these findings indicate that ozone exposures of 70 ppb pose reduced risk compared to the current standard but, nonetheless, are of significant concern, especially for children, asthmatics, the elderly and other at risk populations.

We also considered the adverse health implications of a level of 65 ppb. An alternative standard level of 65 ppb would reduce the frequency of occurrence of lung function decrements of 15% or higher, as compared to a level of 70 ppb, but does not eliminate such occurrences. Further, an alternative standard level of 65 ppb would lead to lower frequency of short-term premature mortality than the current standard or a level of 70 ppb. The frequency of lung function decrements and premature mortality from short-term exposure to ozone decreases even further when the alternative standard is lowered to 60 ppb. As noted earlier, based on results for clinical studies of healthy adults, and scientific considerations of differences in responsiveness of asthmatic children compared to healthy adults, there is scientific support that 60 ppb is an appropriate exposure of concern for asthmatic children.

In summary, based on the scientific evidence from clinical studies, epidemiologic studies, animal toxicology studies, as summarized in the ISA, the findings from the exposure and risk assessments as summarized in the HREA, and the interpretation of the implications of all of these sources of information as given in the Second Draft PA, the CASAC concludes that there is adequate scientific evidence to recommend a range of levels for a revised primary ozone standard from 70 ppb to 60 ppb. However, as noted below, we believe that there is an important distinction in our finding regarding the level of 70 ppb in contrast to that of EPA staff as given in the Second Draft PA.

In reaching its scientific judgment regarding a recommended range of levels for a revised ozone primary standard, the CASAC has focused on the scientific evidence for the identification of the kind and extent of adverse effects on public health. The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act. The CASAC advises that, based on the scientific evidence, at a level of 70 ppb, there is little margin of safety for the protection of public health, particularly for sensitive subpopulations. In this regard, our advice differs from that offered by EPA staff in the Second Draft PA. At 70 ppb, there is substantial scientific certainty of a variety of adverse effects, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard, it may not meet the statutory requirement to protect public health with an adequate margin of safety. In this regard, the CASAC deliberated at length regarding advice on other levels that might be considered to be protective of public health with an adequate margin of safety. For example, the recommended lower bound of 60 ppb would certainly offer more public health protection than levels of 70 ppb or 65 ppb and would provide an adequate margin of safety. Thus, our policy advice is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your judgment regarding the desired margin of safety to protect public health.

Other suggestions for improving the section were relatively minor, including better labeling, annotation, and discussion of tables and figures, such as Figure 4-13, and adding sub-headings for the consideration of 70, 65, and 60 ppb standard levels.

3. *Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?*

The chapter provides a cogent presentation of the rationale behind the Second Draft PA's conclusions and the key uncertainties and areas for future research (Section 4.7). The CASAC recommends future research to address key uncertainties related to ozone health effects. This research, which could be

conducted in collaboration with other federal and non-governmental organizations, will help to improve our understanding of ozone health effects in support of the next review of the ozone NAAQS.

The current approach to review and revision of the primary National Ambient Air Quality Standards (NAAQS) is based on a one-pollutant-at-a-time approach. As the state of science regarding the joint effects of human exposure to multiple pollutants improves, the EPA should consider how review and revision of the NAAQS can be done synergistically for logical, scientifically relevant groupings of criteria pollutants. For example, $O_3$ and $NO_2$ are both criteria pollutants that are inter-related via atmospheric chemistry, and human exposure to these pollutants is often in the form of a mixture that includes both, and other pollutants such as particulate matter. The National Research Council (NRC, 2004) and the North American Research Strategy for Tropospheric Ozone (Hidy et al., 2011) have both made detailed recommendations for multipollutant approaches to air quality management, and EPA has been exploring a multipollutant approach for the secondary standards for $SO_x$ and $NO_x$. CASAC encourages EPA to explore multipollutant approaches for review of the primary standards, and would be receptive to a request by EPA to review planning or methods documents for such approaches.

***Adequacy of the Secondary Standard (Chapter 5)***

1. *To what extent does the information in sections 5.1 through 5.5 capture and appropriately characterize the key aspects of the evidence for ozone welfare effects assessed and integrated in the ISA? To what extent does the information in section 5.1 (Nature of Effects and Biologically Relevant Exposure Metric) appropriately summarize the nature of ozone welfare effects and to what extent does it appropriately characterize the evidence with regard to biologically relevant exposures?*

This chapter does a nice job summarizing evidence for welfare effects of ozone exposure and for linking ecological effects to welfare effects. We support EPA's continued emphasis on Class I and other protected areas. The discussion of flux-based metrics is useful and appropriate, concluding that potential benefit may eventually derive from such metrics but that excessive uncertainty remains at this time. We note that when discussing the W126 metric, the phrase "Exposure-Response" (E-R) should be used in place of "Concentration-Response". The discussion regarding the reduction of uncertainty associated with Open Top Chamber (OTC) derived E-R relationships since the last review (page 5-10; page 5-31) is appropriate and clearly presented. It should be further emphasized in the revised chapter that the National Crop Loss Assessment Network (NCLAN) studies covered multiple locations in the U.S. and multiple crops, along with multiple ozone exposure levels, using consistent methods. All of these factors are important because they enhance the reliability of the results.

The secondary standard should be protective against known or anticipated ozone effects that are adverse to the public welfare. The CASAC concurs with EPA staff that adverse effects of interest are characterized as "damage," which are injury effects that reach sufficient magnitude as to reduce or impair the intended use or value of the plant to the public, and thus are adverse to public welfare.

The CASAC supports the concept of ecosystem services, which are the benefits that individuals and organizations obtain from ecosystems, as part of the scope of characterizing damage that is adverse to public welfare. For example, CASAC concurs that trees are important from a public welfare perspective because they provide valued services to humans, including aesthetic value, food, fiber, timber, other forest products, habitat, recreational opportunities, climate regulation, erosion control, air pollution removal, and hydrologic and fire regime stabilization. Damage effects to trees that are

adverse to public welfare occur in such locations as national parks, national refuges, and other protected areas, as well as to timber for commercial use. The CASAC concurs that biomass loss in trees is a relevant surrogate for damage to tree growth that affects ecosystem services such as habitat provision for wildlife, carbon storage, provision of food and fiber, and pollution removal. Biomass loss may also have indirect process-related effects such as on nutrient and hydrologic cycles. Therefore, biomass loss is a scientifically valid surrogate of a variety of adverse effects to public welfare.

The CASAC concurs that another important surrogate for damage that is adverse to public welfare is crop loss. Crops provide food and fiber services to humans. Evaluation of market-based welfare effects of ozone exposure in forestry and agricultural sectors is an appropriate approach to take into account damage that is adverse to public welfare.

The CASAC concurs that visible foliar injury can impact public welfare by damaging or impairing the intended use or service of a resource. Visible foliar injury that is adverse to public welfare can include: visible damage to ornamental or leafy crops that affects their economic value, yield, or usability; visible damage to plants with special cultural significance; and visible damage to species occurring in natural settings valued for scenic beauty or recreational appeal.

In summary, CASAC concurs that relative biomass loss for tree species, crop yield loss, and visible foliar injury are appropriate surrogates of a wide range of damage that is adverse to public welfare.

2. *To what extent is staff's consideration of the welfare effects evidence, including the implications of reported vegetation effects with regard to adversity to public welfare technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?*

The linkage of ecological effects of ozone to welfare effects is effective in this draft. The effort to monetize welfare impacts and benefits is appropriate although techniques for this monetization are not yet fully developed. Specifically, calculation of consumer and producer surpluses is a useful contribution to quantification of welfare effects. However, this national-level approach does not adequately account for negative effects on individual farmers and forest owners in high-ozone areas. Tabulating and discussing the number of counties in which yield loss is predicted to exceed a threshold of 5% for individual sensitive crops for alternative candidate standards should be added to Table 6-4 to help address this issue.

The interaction of agriculture and forestry as modeled by the Forest and Agricultural Sector Optimization Model with Greenhouse Gases (FASOM-GHG) is mentioned in both the Second Draft WREA and the Second Draft PA but not adequately explained.

The cottonwood data (Figures 5-1 and 5-3) receive too much emphasis. These results are from a gradient study that did not control for ozone and climatic conditions and show extreme sensitivity to ozone compared to other studies, as already noted in the text (page 5-14, line 5). Although they are important results, they are not as strong as those from other experiments that developed E-R functions based on controlled ozone exposure.

E-R functions for individual tree seedling species, supported by results from other methods such as

Free Air Carbon Dioxide/Ozone Enrichment (FACE) and naturally occurring gradients, demonstrate that some species are very sensitive to ozone and show decreased growth at very low chronic exposure levels, while other species show little response even at much higher levels. A similar result is found for crop species. Thus there is strong evidence of decreased growth and yield of sensitive tree and crop species at very low ozone levels.

The method used with FASOM for forest growth is based on individual species' E-R functions, but this is strictly accurate only for forest stands comprised of single species. For mixed-species forest stands, competition among species with different sensitivity will reduce overall stand growth losses, but also exacerbate effects on sensitive species. Some panel members were concerned about the difficulty of interpreting "median" response for both ozone-sensitive and relatively insensitive species. It should not be assumed that species of unknown sensitivity are tolerant to ozone. It is more appropriate to assume that the sensitivity of species without E-R functions might be similar to the range of sensitivity for those species with E-R functions.

The spatial extent and degree of impact on sensitive species expected at current ozone exposures, the current standard, and at alternate standards should be better quantified for different regions of the country. A county-level analysis will provide insights regarding the spatial extent and degree of impact. For example, rather than focusing solely on the median relative biomass loss (RBL), the number of counties containing sensitive tree species that are expected to have growth loss of greater than 2% should be quantified.

In addition, the Second Draft PA should clarify whether the denominator basal area in the calculation includes only the 12 species with available E-R functions, or rather includes all species. If it is all species, then there is a bias introduced by implicitly assuming that species without E-R functions are insensitive to ozone. If it only includes the species with E-R functions, then the interpretation will vary depending on what fraction of the basal area is represented by species without known E-R functions. In either case this requires explicit consideration.

3. *With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?*

This chapter makes a strong case that the current secondary standard fails to protect vegetation and ecosystem services from adverse effects. The form of the current standard is inadequate to provide such protection. From correlation analysis based on the Higher Order Direct Decoupled Method (HDDM), the EPA suggests that a W126 level of 15 ppm-hrs may in many cases be similar to the current standard. However, as noted in the CASAC's review of the Second Draft WREA (EPA-CASAC-14-003), the CASAC finds that a W126 level of 15 ppm-hrs may not be similar to the current standard, since the actual approaches that would be used to achieve such a level are likely to be different than those assumed in the HREA air quality scenarios for just meeting the current standard. Specifically, and quoting from our review of the Second Draft WREA:

> "The currently reported finding of only small differences in risk between just meeting the current standard and a W126-based level of 15 ppm-hrs must not be interpreted to mean that just meeting the current standard will be as protective as meeting a W126-based standard at 15 ppm-hrs. There are two key factors that must be considered when

making this comparison. First, air quality was simulated in the Second Draft WREA based on the magnitude of across-the-board reductions in NOx emissions required to bring the highest monitor down to the target level. Meeting a target level at the highest monitor requires substantial reductions below the targeted level through the rest of the region. This artificial simulation does not represent an actual control strategy and may conflate differences in control strategies required to meet different standards and different targets. As a result, there may be a number of monitors that meet the current standard but would not meet an alternative W126 standard. Second, and equally important, the current form of the standard is much less biologically relevant for protecting vegetation than is a seasonal, peak weighted index such as the W126, which was designed to measure the cumulative effects of ozone exposure"

Because injury is clearly observed at and below 15 ppm-hrs, the chapter demonstrates that the current standard is inadequate to protect against welfare effects due to ozone. Despite the paucity of data in certain areas, the Second Draft PA makes appropriate statements about causality and risk with which to evaluate the adequacy of the current welfare standard.

The uncertainties are well described and appropriately interpreted. As mentioned previously, there is some confusion that should be clarified regarding increasing uncertainty of responses at lower ozone levels versus smaller magnitudes of response. There is adequate evidence for effects in sensitive species at levels of W126 well below 15 ppm-hrs. In Figure 5-5 some information is needed about the referenced sites. Uncertainties do not weaken the case for a more stringent standard. The paucity of data on ozone sensitivity of most U.S. plant species should not prevent the Second Draft PA from discussing "anticipated" effects on a number of unidentified sensitive species. As in the Second Draft WREA, the consideration of uncertainty is repetitive to the point of detracting from the considerable strength of the analyses and the evidence on which they are based.

The discussion of economic losses due to bark beetles and fire perpetuates the confounding of spatial association with causation in the Second Draft PA. As stated, this does not contribute much to the assessment of risk nor evaluation of the adequacy of the current or alternative standards.

4. *In the Panel's view, does the discussion in section 5.7 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public welfare protection?*

The CASAC concurs with the justification in this section that the form of the standard should be changed from the current 8-hr form to the cumulative W126 index and finds that the discussion provides an appropriate and sufficient rationale.

This section clearly demonstrates that ozone-induced injury may occur in areas that meet the current standard. As noted above, the correlative similarity between the current standard and a level of the W126 index of 15 ppm-hrs must not be interpreted to mean that just meeting the current standard is equivalent to just meeting a W126 level of 15 ppm-hrs. Most of the analyses found effects below 15 ppm-hrs (many at 10 or even 7 ppm-hrs). Based on review of relevant science, the CASAC concludes that the upper bound of the range that should be considered for the W126 standard should not exceed 15 ppm-hrs. The CASAC does not support a level higher than 15 ppm-hrs. Levels above 15 ppm-hrs should not be included in the revised PA as options for an alternate secondary standard. For example, at

17 ppm-hrs, the median tree species has 6% relative biomass loss, and the median crop species has over 5% loss. These levels are unacceptably high.

The CASAC does not recommend the use of a three-year averaging period. We favor a single-year averaging period, which will provide more protection for annual crops and for the anticipated cumulative effects on perennial species. The scientific analyses considered in this review, and the evidence upon which they are based, are from single-year results. If a 3-year averaging period is established, then the upper limit will need to be reduced to protect against one-year ozone peaks. We consider this further in the response to charge questions for Chapter 6.

In summary, the CASAC concurs with the Second Draft PA that the current secondary standard is inadequate with respect to form, level and averaging time. Only the current indicator (ozone) should be retained. The potential revised standard is considered further in the response to the charge questions for Chapter 6 below.

***Consideration of Potential Alternative Secondary Standards (Chapter 6)***

1. *In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering levels of protection and potential alternative standards?*

2. *In the Panel's view, does the discussion in section 6.5 provide an appropriate and sufficient rationale, supported by the discussions in sections 6.1 through 6.4, to support staff's preliminary conclusions regarding alternative secondary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?*

3. *Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?*

Charge Questions 1, 2, and 3 are all closely related and are being addressed together in this summary response.

The Second Draft PA makes a very strong case, consistent with previous CASAC judgment, for changing the secondary metric to the W126 averaged over the highest three-month interval. Accumulation over the 08:00 a.m. – 08:00 p. m. daytime 12-hour period is a scientifically acceptable and recommended means of generalizing across latitudes and seasons.

The suggestion in Section 6.2 to use a 3-year averaging period is not supported by the available data. We have not supported it in the past nor do we support it here. The primary justification for a 3-year averaging period is to improve the program stability of the classification of regions as being in or out of compliance. The proposed form includes a 3-month period, so it is not nearly as sensitive to extreme events as an hourly or 8-hour averaging period. The case has not been made that welfare benefits from the stability of a 3-year average are greater than those from using the biologically relevant 1-year value. If a 3-year averaging period is implemented, it should be at a lower level than a single-year standard to protect against single unusually damaging years that will be obscured in the average.

The key issue in the Second Draft PA with respect to welfare effects is the level of the standard. If protection of the most sensitive members of the community is extended to components of ecosystems that impact public welfare, then several potential levels of the standard should be considered. A 2% biomass loss is an appropriate scientifically based value to consider as a benchmark of adverse impact for long-lived perennial species such as trees, because effects are cumulative over multiple years. For example, a 2% annual RBL fully explains the observed the biomass loss of 21% over 7 years in the study of pure stands of aspen at the Rhinelander, WI FACE site (Wittig et al. 2009). The CASAC considers it significant that a similar value of 1% to 2% for tree seedling biomass loss was recommended previously by a consensus meeting of experts on ecological effects of ozone (Heck and Cowling 1997). In our scientific judgment, it is appropriate to identify a range of levels of alternative W126-based standards that includes levels that aim for not greater than 2% RBL for the median tree species.

The CASAC considered carefully the data presented in Figure 5-2 and Table 6-1 of the Second Draft PA. The Monte Carlo analysis (red dots, Fig. 5-2) should not be used in evaluating the effect of ozone on RBL of tree seedlings. This analysis overemphasizes the species for which relatively few E-R functions are available, is biased toward the few less sensitive response functions available for some individual species, makes unsupported assumptions regarding the representativeness of available response functions, and confounds intra- and inter-species variability in unquantifiable ways. We favor using a measure of central tendency of the data, specifically the median across species (the green line in Fig. 5-2). This analysis provides the median of best available estimates within each species, and the median across species with all species treated equally. Table 6-1 presents the RBL results for individual species for different levels of W126. This table demonstrates that a range of 7 ppm-hrs to 15 ppm-hrs will protect against RBL of 2% for at least 5 of the 12 species. We do not consider a value of 17 ppm-hrs from Table 6-1 because even though only 5 of 12 tree species are estimated to have relative biomass loss of 2 percent or less at this level, the median species has relative biomass loss of 6.0 percent, which is unacceptably high. With compounding over the harvest cycle or life span of these species, this will result in considerably greater cumulative RBL as discussed above. For the more sensitive tree seedlings, a value closer to the lower end of the range (7 ppm-hrs) would be more appropriate. The level of 7 ppm-hrs is the only level analyzed for which the relative biomass loss for the median tree species is less than or equal to 2 percent. At 7 ppm-hrs, 7 of the 12 analyzed species have relative biomass loss of less than 2%.

Visible foliar injury is even more sensitive than RBL of 2%, with W126 values below 10 ppm-hr required to reduce the number of sites showing visible foliar symptoms.

The range of 7 ppm-hrs to 15 ppm-hrs is protective of median crop loss of 5% or less, with lower values within the range offering more protection than higher values. Crop loss appears to be less sensitive than these other indicators, largely because of the CASAC judgment that a 5% yield loss represents an adverse impact, and in part due to more opportunities to alter management of annual crops. At a W126 level of 15 ppm-hrs, the median species crop yield loss is less than 5%, with 6 of the 10 analyzed species having crop yield loss less than 5%. At a level of 7 ppm-hrs, all analyzed crop species are estimated to have crop yield losses less than 5%.

This discussion, like that in the Second Draft WREA and Second Draft PA, focuses on annual values for W126, and lower values should be considered for a multi-year average.

The spatial region for which a standard is intended to be protective should be specified. Some analyses are done for large regions of the country, some for counties, etc. A county scale is appropriate for assessing crop yield loss. Calculating producer and consumer surpluses at national or large region scales does not

provide adequate protection. Farmers growing sensitive crops in high ozone locations can be considered a "sensitive population" for welfare impacts, and crop yields under these conditions should be protected.

Care should be taken not to overstate uncertainties. For example, there is quite a lot of certainty in estimates of biomass loss for forest tree seedling species and crop species for which E-R functions have been developed. Because several dominant crop species have E-R functions, there is a quite a lot of certainty about impacts of ozone on crop yield across most annual cropland in the U.S..

There is considerable uncertainty in extrapolating from the 12 forest tree species to all forest tree species in the U.S. It should be anticipated that there are species of vegetation that are highly sensitive to ozone that do not have E-R functions, and others that are insensitive. It is scientifically justifiable to extrapolate from the known E-R curves, assuming that they are representative of the un-sampled population.

Thus, based on identification of known or anticipated ozone effects that are adverse to public welfare, taking into account the weight of evidence for causality of exposure to ozone and adverse welfare effects as given in Table 2-4 of the *Integrated Science Assessment*; results of the Second Draft WREA with regard to assessment of relative biomass loss for tree species, foliar injury, and crop yield loss; and the breadth of adverse welfare effects for ecosystem services, foliar injury, and crop loss, the CASAC recommends that the secondary standard for ozone be revised as follows: (1) ozone should be the indicator; (2) the form and summation time of the standard should be the W126 index summed over the highest three-month interval during a year, based on accumulation over the 08:00 a.m. – 08:00 p.m. daytime 12-hour period; and (3) the level of the standard should be between 7 ppm-hrs and 15 ppm-hrs. These recommendations are based on scientific evidence of adverse effect associated with the presence of ozone in ambient air. Note that these levels are based on an annual form of the standard.

In reaching its scientific judgment regarding the indicator, form, averaging time, and range of levels for a revised secondary standard, the CASAC has focused on the scientific evidence for the identification of the kind and extent of adverse effects on public welfare. The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act. Specifically, the Clean Air Act grants discretion to the Administrator to specify a standard that is "requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air" (Section 302(h), 42 U.S.C., §7602(h)). As a policy recommendation, separate from its advice above regarding scientific findings, the CASAC advises that a level of 15 ppm-hrs is requisite to protect crop yield loss, but that lower levels provide additional protection of crop yield loss. Furthermore, there are specific economically significant crops that may not be protected at 15 ppm-hrs but that would be protected at lower levels. Based on scientific judgment of CASAC, a level of 10 ppm-hrs is required to reduce foliar injury. A level of 7 ppm-hours is protective of relative biomass loss for trees. Furthermore, 7 ppm-hours offers additional protection against crop yield loss and foliar injury. Therefore, 7 ppm hours is protective of ecosystem services. Thus, lower levels from the recommended range offer a greater degree of protection of more endpoints than do higher levels from the range.

If, as a policy matter, the Administrator prefers to base the secondary standard on a three year averaging period for the purpose of program stability, then the level of the standard should be revised downward such that the annual level in any given year of the three year period would not exceed the scientifically recommended range of annual levels of 7 ppm-hrs to 15 ppm-hrs. For example, if in a three year period the highest annual W126 value is 15 ppm-hrs, and the lowest W126 value associated with a three year average is 13 ppm-hrs, then the appropriate level for the three year average would be 13 ppm-hrs to

protect against a peak annual level of 15 ppm-hrs. The final Policy Assessment should quantify the ratio of the annual to three year average W126 values to determine what downward adjustment from the annual levels recommended here is needed if a three year form is selected.

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# Appendix A

## Individual Comments on the Policy Assessment
## For the Review of the Ozone NAAQS (Second Draft)
## CASAC Ozone Review Panel

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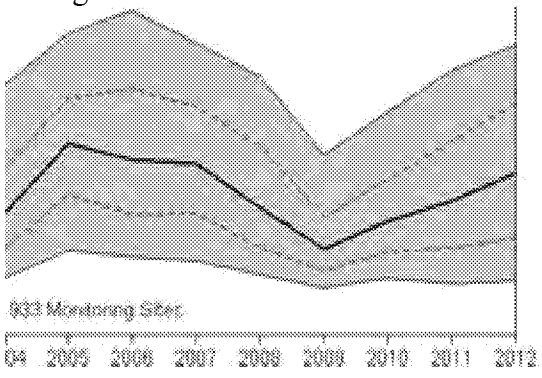
**George Allen**

Charge Questions on O3 Monitoring and Air Quality (Chapter 2).

Ch. 2, Q #1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of O3 concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

Section 2.1, Monitoring. National trends of annual 4th highest max 8-hour values are plotted in Figure 2-2, page 2-4. Section 2.1 appropriately notes the distinct drop between 2002 and 2004, consistent with the drop in summer NOx emissions due to the "NOx SIP call", and notes the decreasing trend between 2000 and 2009. While that time period does appear to have a distinct downward trend, it is also informative to look at this same plot constrained to the period from 2004 through 2012:




This 9-year time period starting after the NOx SIP call drop in O3 shows no indication of a trend, and leads to a very different conclusion. While both this time window and EPA's interpretation of O3 trends over 2000 through 2009 are valid, the latter is totally driven by a one-time intervention; since then there does not appear to be any progress in reducing O3 concentrations. Year to year variations in summer meteorological conditions can play a large role in "raw" trends of less than 15 to 20 years duration. In the past EPA has presented trend estimates that include adjustments for meteorology; see: http://www.epa.gov/airtrends/weather.html and references therein. It may be helpful to present such "adjusted trend" data to better assess progress since the NOx SIP call; these adjustments tend to pull "high" years down and "low" years up in concentration. 2013 O3-season data is now in AQS; even though those data will not be "certified" for another 3 months, it would be informative to add that data for 2013 to this trend plot.

Section 2.2, Emissions and Atmospheric Chemistry. This section is a clearly written and concise summary of this topic. It makes the interesting point regarding the co-benefit from NOx emission reductions for O3, NO2, and PM2.5.

Section 2.3, Air Quality Concentrations. This section is a clearly written and concise summary of this topic. Footnote 7, page 2-10, makes the sometimes overlooked point that since O3 is measured seasonally in most areas, the 4th highest day's value is similar to the 98th percentile annual metric form used for some other criteria pollutants.

Section 2.4, Background O3.

Ch. 2, Q #2. With regard to information on estimating O3 concentrations associated with nonanthropogenic sources or "background O3" (section 2.4), to what extent is this information appropriately characterized and clearly communicated?

This section is the core of this chapter. Estimates of background O3 now play a minimal role in the REA document given the new approach to estimating risk under various emission reduction scenarios using the HDDM rollback method and total O3 concentrations.

Background O3 is still a factor in the Policy Assessment however, since a 2002 court decision allows EPA to consider background levels when evaluating risk for alternative (lower) standards (section 1.3.1, page 1-26, lines 17-19). But case law also states that "that attainability and technical feasibility are not relevant considerations in the setting of a NAAQS" (section 1.2.1, page 1-4 lines 19-21, API v. Costle, 1981). It is unclear how EPA might navigate between these two legal guidelines in terms of how background O3 would be used in a policy and standard-setting context.

EPA performed new 2007 base "year" (7-months) zero-out and CAMx source apportionment modeling that is presented in this section. Section 2.4.2 (page 2-16, lines 6-14) introduces the concept of "apportionment-based US background" O3 (AB-USB?) as the most relevant metric for estimation of a "fractional background" metric. Overall this chapter is difficult to follow. It seems the new modeling's utility is to confirm earlier outcomes using these improved modeling approaches. It would be helpful if the chapter could better focus on these specific issues.

Section 2.4.3: The discussion on page 2-17, lines 1-12, is helpful in understanding the fractional contribution of background O3 on days with elevated O3.

Figures 2-13 and 2-14 on page 2-19 could benefit from the addition of "N" (# of site-days) to each bin. Figure 2-13 is difficult to interpret without this information.

Section 2.4.4 presents background O3 in the context of the 12 urban case study areas. Table 2-2 (page 2-21) seems to be the most relevant presentation, but is only for site-days > 60 ppb; it would be helpful to also include this information for site-days >65 and > 70.

Section 2.4.5 presents background O3 in the context of a W126 secondary standard form for four locations (2 are large urban areas). Page 2-22 lines 10-12 refer to figure 2-7 (page 2-7) as showing high observed 2010-2012 W126 values for these four sites. These sites can not readily be identified on this map, so these values also need to be provided in a text form.

Other Comments.

Chapter 1, Section 1.2.2. (History of O3 NAAQS reviews)

This section is a useful summary of recent actions and court rulings regarding the O3 NAAQS review process. There are two topics regarding the 2008 NAAQS revision and subsequent reconsideration process that I would like to expand on that may be relevant to the current review.

First is the "Reconsideration" of the 2008 O3 primary NAAQS, discussed on page 1-9. It is not widely known that in the summer of 2011, EPA sent a final rule to OMB/ORIA with 65 ppb as the standard. This and the role that ORIA played in the process was detailed in a New York Times

article on Nov. 17, 2011:

www.nytimes.com/2011/11/17/science/earth/policy-and-politics-collide-as-obama-enters-campaign-mode.html

It is worth noting that EPA proposed this standard (in the middle of the CASAC range of 60 to 70 ppb) based on the scientific literature used for the 2008 rule – e.g., new studies since 2006 could not be considered in this reconsidered rulemaking. EPA subsequently posted the full preamble of what was to be the final Summer 2011 rule, as well as the draft impact analysis at:http://www.epa.gov/glo/actions.html

While this background material is not directly relevant to the current review process, it provides some useful context for the decisions the agency made in 2011 during the reconsideration process, and may be of interest to the current O3 panel.

Second, this section is a useful summary of the court's 7/23/2013 decision (reissued 12/11/13) regarding the 2008 O3 NAAQS rule. While this ruling upheld the 2008 primary NAAQS of 75 ppb, it did so based on an unusual interpretation of CASAC's intent in saying a range of 60 to 70 ppb was appropriate to consider. This may have implications on how future CASAC advisory reviews are written. Although this issue is not part of the PA review, it would be helpful if EPA staff could provide some guidance to CASAC on how to avoid future perceived ambiguity in its recommendations.

On page 1-10 lines 10-14, the court's rationale for the 0.075 ppm not being inconsistent with CASAC advice is correctly explained. However it is informative to look more closely at the detailed wording of this argument, especially since it may require the CASAC to be more explicit in future letters regarding this issue.

The court decision is summarized at:

http://www.lawandenvironment.com/2013/07/mississippi-v-epa-support-of-the-clean-air-science-advisory-committee-is-not-necessary-to-affirm-epas-naaqs/

The decision itself:

http://www.lawandenvironment.com/wp-content/uploads/2013/07/08-1200-1447980.pdf

The essence of the decision, on page 41:

"...in order for EPA to explain adequately its reasons for disagreeing with CASAC, CASAC itself must be precise about the basis for its recommendations. Because in this case CASAC failed to specify whether the 0.070 ppm level it recommended as a maximum rested on a scientific conclusion about the existence of adverse health effects at that level, EPA's invocation of scientific uncertainty and more general public health policy considerations satisfies its obligations under the statute."

Additional excerpts from the decision relevant to CASAC follow.

Pages 38-39:

EPA did not make such a specific scientific determination about the 0.070 ppm level that served as

the ceiling of CASAC's recommendation; instead, EPA referred generally to declining certainty below 0.075 ppm. Had CASAC reached a scientific conclusion that adverse health effects were likely to occur at the 0.070 ppm level, EPA's failure to justify its uncertainty regarding the existence of adverse health effects at this level would be unacceptable. Indeed, it is a familiar principle that agencies may not "merely recite the terms 'substantial uncertainty' as a justification for [their] actions"; instead, they "must explain the evidence which is available, and must offer a rational connection between the facts found and the choice made." State Farm, 463 U.S. at 52 (internal quotation marks omitted). In other words, EPA must explain why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it. This is especially true given the added layer of stringency imposed by EPA's obligations under section 307(d)(6).

But we are unable to determine whether CASAC reached any such scientific conclusion. Although CASAC stated that "overwhelming scientific evidence" supported its recommendation that the standard be set no higher than 0.070 ppm, Mar. 2007 CASAC Letter, at 2, it never explained whether this proposal was based on its scientific judgment that adverse health effects would occur at that level or instead based on its more qualitative judgment that the range it proposed would be appropriately protective of human health with an adequate margin of safety. Indeed, although CASAC concluded that "there is no longer significant scientific uncertainty regarding [its] conclusion that the current 8-hr primary NAAQS must be lowered," given the "large body of data clearly demonstrat[ing] adverse human health effects at the current level," CASAC recognized that "[s]cientific uncertainty does exist with regard to the lower level of ozone exposure that would be fully-protective of human health." Oct. 2006 CASAC Letter, at 5.

To be sure, EPA's statutory obligation to respond to CASAC does not evaporate whenever CASAC exercises judgment amidst scientific uncertainty. Quite to the contrary, had CASAC acknowledged uncertainty in the scientific evidence but explained that, based on its expert scientific judgment, it nonetheless believed adverse health effects were likely to occur at the 0.070 ppm level, then section 307(d)(6) would have required EPA to explain why it disagreed with this scientific conclusion. Put differently, to the extent that CASAC has exercised scientific judgment, EPA must respond in kind. But because CASAC never made clear the precise basis for its recommendation, all we know for certain is this: both CASAC and EPA believed the existence of adverse health effects to be certain at the 0.08 ppm level and reached differing conclusions about what level below 0.08 ppm was requisite to protect the public health with an adequate margin of safety. [end quote]

Page 41:
Absent a definitive scientific conclusion from CASAC that adverse health effects would occur at the 0.070 ppm level, we must assume that it too took these same considerations into account and simply exercised its judgment to recommend a standard set at a lower level. Although both CASAC and EPA must exercise public health policy judgment when confronted with scientific evidence that does not direct it to a specific outcome, it is to EPA's judgment that we must defer. And (as noted earlier):

But in order for EPA to explain adequately its reasons for disagreeing with CASAC, CASAC itself must be precise about the basis for its recommendations. Because in this case CASAC failed to specify whether the 0.070 ppm level it recommended as a maximum rested on a scientific conclusion about the existence of adverse health effects at that level, EPA's invocation of scientific uncertainty and more general public health policy considerations satisfies its obligations under the statute.

Consideration of Potential Alternative Primary Standards (Chapter 4). These are general comments regarding this chapter.

Section 4 of the draft Policy Assessment is a concise summary of the science presented in the ISA and the health REA with regard to evaluating the health impacts of the current and alternative ozone NAAQS. I agree that all aspects of the form of the current ozone NAAQS are appropriate to retain. It is worth noting that in much of the country, ozone is monitored for 6 or 7 months of the year; this makes the 4th-highest 8-h daily mean form similar to the 98th percentile form used in other NAAQS with a daily form.

When choosing ozone concentrations to consider for alternative (lower) values of a standard, there is a continuum of decreased risk along with increased uncertainty of the quantitative assessment of that risk as ozone exposures decrease. Thus there are no "bright risk lines" at any one ozone concentration when considering values for a revised standard. However, the risk and exposure assessment process creates bright lines at intervals of 5 ppb, ranging from 80 to 60 ppb, focusing on health risks at standards of 70, 65, and 60 ppb in this review. This approach is appropriate since there is no meaningful value in attempting to characterize differences in risk between standards of 70 and 69 ppb for example; the supporting science simply isn't that precise, and we are working from a starting point of 75 ppb (the current ozone NAAQS).

Section 4.6 of the draft Policy Assessment summarizes the reduction in risk for various health endpoints associated with alternative standards of 70, 65, and 60 ppb. 70 ppb is the upper end of the range recommended in this assessment. I agree with the many panel members who expressed concern during the March 27, 2014 CASAC meeting that 70 ppb was not sufficiently protective of vulnerable populations. In that context, EPA's discussion of risks and the science supporting those risks for 65 ppb (starting on page 4-52) is informative to this process. Lines 3-13 on that page provide a framework for this value, noting 65 ppb is "somewhat below" the 70 ppb level where health effects "judged adverse" by the ATS were reported, and higher than the level where lung function decrements "that could be adverse in individuals with lung disease." 65 ppb is also above the 60 ppb level where "pulmonary inflammation has been reported."

Risk is not eliminated at 65 ppb, but this is a concentration where the science behind the reported health effects of concern can be considered to be sufficiently robust for the NAAQS process. Thus I recommend that EPA consider setting a revised ozone standard that is no higher than 65 ppb. This is consistent with the CASAC letter of March 30, 2011 regarding the ozone "reconsideration" review process, which says that 70 ppb "would provide little margin of safety". This review was based on the science available to the panel in the 2008 NAAQS revision, and thus does not reflect new research since 2006. It is also consistent with the "first version" of EPA's final rule for the reconsideration process, which went to OMB in 2011 with a standard of 65 ppb (see my comments on Chapter 1 of this document).

Finally, although not directly relevant to this process, it is worth noting that a new Canadian Ambient Air Quality Standard (CAAQS) for ozone was approved in 2012; this replaces the existing Canada Wide Standard of 65 ppb. The ozone CAAQS of 63 ppb (same form as the current ozone NAAQS) goes into effect in 2015, followed by a standard of 62 ppb in 2020. More information on the ozone CAAQS can be found at:

http://gazette.gc.ca/rp-pr/p1/2013/2013-05-25/html/notice-avis-eng.html#d106

**Ed Avol**

CHAPTER 1 INTRODUCTION

1. P1-2, line 16 and Footnote 5: not clear that this footnote or caveat are needed; there could be other reasons, including substantive technical as well as basic grammatical or textual, reasons that might lead to a request for a 2nd draft document.
2. P1-14, line 4: With all due respect, there was considerable controversy over the Administrator's recommendation of a 0.075 ppm ozone standard. One cannot "know" what the Administrator "relied" on to make his determination. It would be more appropriate (and accurate) to say that "…the Administrator *was provided* the available scientific evidence…*He subsequently* revised the level of the 8-hour primary O3 standard…"
3. P1-14, line 21: We cannot know what "The Administrator *believed*…" This should be changed to something like "In the opinion of the Administrator…"
4. P1-19, Figure 1-1: A more accurate presentation of the review of the primary standard would suggest that the **Averaging Time** box in the figure be re-worded to allow for the possibility of either a longer *or shorter* -term averaging time.
5. P1-21, lines 8-12: This is a pretty convoluted and wordy sentence, almost obscuring the message. The point here is that based on available research, there is no evidence of a biological threshold for ozone health effects (…and that's a lot shorter and more understandable sentence!).
6. P1-27, lines 21 forward: Why is so much time and effort spent in this document discussing what a former Administrator did or did not do with regard to the last review? While it's appropriate to refer to this, it seems like there is an inordinate amount of text devoted to revisiting (or arguably, attempting to re-formulate) the historical record with regard to what a former Administrator did or did not rely on to make his prior determination. The issue before the current CASAC is NOT what the prior review did or did not decide; the issue before the current CASAC is the strength of the cumulative current evidence regarding ozone exposure and protection of the public's health, and the clarity and appropriateness of proposed staff recommendations to the current Administrator.
7. P1-27, line29: We do not and cannot know to what extent the Administrator *carefully considered the public comments*…or to what *degree he further recognized that several additional lines of evidence had progressed sufficiently since the 1997 review to provide a more complete and coherent picture*… (p1-28, lines 1-3); this phrasing should be removed. The comments and information were provided, the Administrator had access to them, and he made a determination. (This PA is not the place to justify or re-interpret previous Administrator's actions, but rather to present current data and judgments).
8. (typographical error; p1-35, line 35, "evidence")
9. P1-40, lines 25 to 34: this is a useful paragraph describing the organization of the overall document, but it is completely out of place at the end of Chapter 1. This should be moved to the first few pages of Chapter 1, prior to the Background section, and an overview sentence could be added describing the presentation in Chapter 1.

CHAPTER 2 OZONE MONITORING AND AIR QUALITY

10. P2-8, line 13: This is an important point but is awkwardly phrased. Recommend re-wording to say, "…contributes to subsequent $O_3$ formation further downwind."
11. P2-9, line 7: replace "high" with "elevated", so that sentence reads "…result in a higher frequency and duration of days with elevated $O_3$ conditions."
12. P2-9, line16: replace "high" with "higher" and "low" with "lower"
13. P2-10, lines 26 to 27: The lower rates of chemical scavenging in downwind rural areas can often result in characteristically broader, more gradual hourly ambient $O_3$ concentrations, rather than the more"peaky" $O_3$ spikes often seen in urban areas with substantive rush-hour-type combustion NO contributions. This observation helps to clarify why locations such as Lake Arrowhead downwind of Los Angeles can exhibit elevated eight-hour levels compared to surrounding reporting locations.
14. P2-11 forward, Section 2.4Background $O_3$: Although I appreciate the figures, depth, and discussion regarding background ozone levels, this presentation seems to conflict with the prior determination that background levels are less important, since total ozone concentrations are being used in the current document to assess risk. This section might be valuable as a supplement or Appendix, but if total ozone is the perspective and approach being used, this whole section seems overly detailed, out of scope, and a diversion from keeping the presentation focused and crisp. If staff were to consider every possible question that might be asked of them and seek to develop and provide as complete an answer to every other possible question, the resulting document would be several times larger than it already is and considerably less accessible to the Reader. In my opinion, this document should focus on the approach, implications, and process put into place by the related ISA and HREA, and not delve off into addressing every possible corollary or potential derivative consideration.

CHAPTER 4 CONSIDERATION OF ALTERNATIVE PRIMARY STANDARDS

(No specific comments on specific sections)

This chapter provides a useful and carefully documented assessment of alternative primary standards for ozone. Although I personally found it wordy and a bit indirect, it does provide a comprehensive evaluation of the anticipated health implications of alternative ozone standards in the 60 to 70ppb range. The figures and tabular summaries regarding assorted health indices should be of particular utility to the Administrator in her assessment.

**Joe Brain**

**O3 Monitoring and Air Quality (Chapter 2):** This chapter provides a description of the current O3 monitoring network and recent concentrations, information on emissions and atmospheric chemistry, common patterns and variability in O3 concentrations, as well as, discussion of current information on estimating O3 concentrations associated with non-anthropogenic sources.

**1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of O3 concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?**

I believe that to a great extent, the most relevant information on monitoring, emissions, atmospheric chemistry, and resulting patterns of ozone concentration are presented in Chapter 2. A great deal of information is presented concisely. Especially the figures are helpful in understanding the geographic distribution of the network and the ozone concentrations that have been measured.

A key question is not answered. How does the information collected – the geographic distribution of monitoring stations – correlate with the distribution of humans throughout the United States. It's clear that information is more densely collected in the northeast and in coastal California. We know that that makes sense. But overall, if one simply designed a system of monitoring sites that was solely based on accurately measuring exposure of as many inhabitants as possible, would it be the same or would it be different?

For example, one can imagine that the monitoring sites were selected decades ago. To what extent does the current network operating today represent recent changes in population, such as dramatic declines in Detroit and growth in Las Vegas. There should be a paragraph or so defending the network or at least explaining the extent to which it resembles an ideal, unbiased network. This same discussion should be made not only in relation to all people, but in relation to more responsive populations. What's the distribution of children? What's the distribution of people with preexisting disease and/or the elderly? To what extent do these distributions resemble the current ozone monitoring network?

Ozone, as we all know, is not a primary emission from cars, trucks, factories, or other anthropogenic sources. As we know, ozone comes from two primary precursors, oxides of nitrogen and volatile organic compounds. When they combine in the presence of sunlight, ozone is produced. Carbon monoxide and methane may modulate these chemical reactions.

Shouldn't we also have a map showing the distribution of sites that monitor these precursors or perhaps a map showing the relative quantitative importance of these precursor emissions? Should we then comment on the extent to which ozone creation is produced from local sources to ones that contribute because of long distance transport mechanisms? Of course, these issues are perhaps more related to control strategies than to the focused mandate of this report.

**2. With regard to information on estimating O3 concentrations associated with nonanthropogenic sources or "background O3" (section 2.4), to what extent is this information appropriately characterized and clearly communicated?**

I am delighted at the well-developed Section 2.4, which deals with background levels of ozone and their contributions from natural sources, as well as from anthropogenic emissions outside our borders. The PRB or the NAB (North American background) is important. (There is also the USB, US background.) The text and the figures are extremely useful, and clearly demonstrate that these background levels are appreciable.

Figures 2-8 through 2-10 include the phrase "zero-out modeling." The text, especially 2-12, has a thorough discussion of the limitations of this strategy. But what approaches to dealing with this background are rational and how have they been incorporated into this document? This clearly affects the magnitude of attributable outcomes to ozone and to the nature of the dose-response curves at low and realistic levels. It also calls into question pivotal clinical studies. For example, when examining the responses of exercising human chamber subjects to 60, 70, 80, or 100 ppb ozone, should their measurements be compared to 0 ppb or is it more relevant and appropriate to compare that to background ozone levels? That has rarely been done, but would clearly diminish the magnitude of the changes reported. Again, I would be interested in variability in ozone levels in these geographic areas. The hypothesis that greater variability is associated with heightened responses, even if the average values are the same, is a hypothesis worth exploring. I also think there should be more discussion of co-exposures such as ozone and PM or ozone and heat stress.

**David Chock**

CHAPTER 2: OZONE MONITORING AND AIR QUALITY

Charge questions:
1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of ozone concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

2. With regard to information on estimating ozone concentrations associated with non-anthropogenic sources or "background ozone" (section 2.4), to what extent is this information appropriately characterized and clearly communicated?

This Chapter provides a very clear and concise picture of the monitoring network, the recent observed ozone concentration trends, both spatially and temporally, and a very brief but relevant and credible description of the emissions and atmospheric chemistry. It also provides a clear description of the different definitions of background ozone concentrations.

There appears to be a confusion in the proper use of the zero-out approach. On p. 2-12, lines 23-24, and again on p. 2A-7, lines 231-241, the authors indicate that removing NOx emissions completely and unrealistically could lead to inflated estimates of background ozone in urban areas where NOx titration of ozone is significant. The authors consider this result as a paradoxical result of the zero-out approach. The implication is that background ozone should not be higher than when anthropogenic precursor emissions are involved. This is erroneous, and in fact contradictory to the acknowledged notion that ozone chemistry is nonlinear. Furthermore, the authors ran separate CMAQ runs for base case (designated as total), NB, NAB and USB, and then took the ratios of one of the background runs to the base case runs as the percent contribution of the background to the base case. This is again erroneous, because it assumes ozone additivity, which violates chemistry's nonlinearity. The zero out approach is not intended for use to assign relative contributions, and relative contribution is not a meaningful concept unless the perturbation due to some source emissions is so small that linearity can be approximated. The source-apportionment method can be used to assign relative background contributions when base case (total) emissions are run, but the resulting relative background contributions are valid only for these particular base case conditions, and the contributions cannot be converted to absolute concentrations to represent background ozone for other emission scenarios including the background emissions alone. Note also that the source apportionment methodology used in CAMx is an approximate tool taking some ozone nonlinearity (local identifications of NOx-limited and VOC-limited environments) into consideration. Its general applicability to a wide range of conditions remains to be established.

Based on the above discussion, in the case of the zero out approach, it is best to change the text in the Chapter from "percent contribution" (like in Fig. 2-11 on p. 2-18) to "ratio" when the background ozone is compared to the base case ozone. Here two model results are compared, and the ratios need not be less than 100%. In the case of source apportionment, "percent contribution" can be used, but is applicable only to the base case run. A separate model run still has to be made to determine the background-only ozone concentrations. So if the authors are willing to replace

"percent contribution" by "ratio", the zero-out approach is actually more straightforward and does not involve the additional assumptions in the source-apportionment methodology.

In the case of W126, the EPA uses a counterfactual assumption by determining the ozone concentrations by separately zeroing out different background emissions based on the definitions of NB, NAB and USB. The procedures are more complicated but are presented in the Appendix. The resulting estimates of background fractions for different definitions of background are generally consistent with but slightly lower than those for the MDA8. This is partly due to the definition of W126 which has a higher weighting for higher ozone concentrations.

One very minor comment: Since seasonal means have been used quite extensively, it is better to incorporate the definition of season in the text rather than leaving it in the footnote (footnote 8 on p. 2-13).

Overall, other than the misstatements about the zero out approach and the erroneous implications that background ozone cannot become greater than when anthropogenic emissions are involved, this is an outstanding chapter in terms of clarity, conciseness, and scientific credibility. The authors should be congratulated for a job well done.

**Ana Diez Roux**

**Chapter 3. Adequacy of the Primary Standard**

*1. To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?*

Overall section 3.1 appropriately describes key aspects of the evidence. I found the consideration if the evidence to be technically sound, and the information appropriately interpreted for the purpose of assessing the adequacy of the current standard. My main comment is that the section would benefit from synthesis and emphasis of the most important facts relevant to assessing the adequacy of the current standard. There is also some repetition within sections (for example the section on at risks populations repeats the key message several times).

*2. With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?*

Section 3.2 also contains abundant repetitions from the REA and could be synthesized.

The section refers to two important issues in estimating the health impact of alternative standards:

1. It is noted that the simulations used to estimate Ozone levels under alternative standards result in spatial patterns different than those observed in the epidemiologic studies on which the health effects measures are based. This would result in different health impacts than those predicted from the epidemiologic studies if one or both of the following conditions are met (a) factors associated with space modify the effects of ozone on heath or (b) spatial mobility of persons within the area is a key driver of individual-level exposures. If we are confident that the impact of these two conditions is absent or negligible then we can be confident in the expected health benefits as predicted despite the change in the spatial pattern.

2. It is noted that based on the approach used to model ozone reductions under alternative standards, ozone levels may actually rise in some areas when meeting lower overall standards. This is because of the dynamics used to model ozone reductions. It should be noted that as a consequence the estimates of the health effects are not precisely the health impacts of reducing ozone to a certain level, but rather the health impact of meeting an alternative standard *through a postulated set of changes to precursors* (some of which results in reductions and some of which result in increases in ozone). This is a subtle but important difference I think. It may be useful to at least note this. Also, is the approach used to model meeting alternative standards (which results in increases in some locations but decreases in others) realistic?

Pg 3-106 lines 23-28 suggest that since approximately 30-60% of the average daytime O3 is attributable to US anthropogenic sources, then 30-60% of total 03- associated health risks in the urban case studies is attributable to US anthropogenic sources. I don't think this statement is accurate: if the reductions in ozone exposure necessary to eliminate or sharply reduce ozone associated health effects can be achieved through redctions in US anthropogenic sources alone, then much more than 30-60% in health effects can be attributed to anthropogenic sources.

*3. In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection?*

Overall I though this section was adequate but could benefit from synthesis and emphasis.

**Chapter 4. Consideration of Potential Alternative Primary Standards**

1. *In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative standards?*

   Overall I found the chapter to be very well written and to the point. The point regarding ozone serving as an indicator for a standard meant to provide protection against photochemical oxidants is well taken. The discussion regarding averaging times is focused and supported by appropriate evidence. The discussion regarding the form was also very well written. The points supporting he use of an nth highest daily maximum (as opposed to an expected excedance or percentile-based form) were well stated, however I found the justification of the 4$^{th}$ highest daily max (as opposed to the nth highest) incomplete.

   The section on controlled human exposures studies is an excellent summary although it loses focus in the latter part (pg 4-10 line 19 through pg 4-11 line 6 ). For example it is not clear why panel studies are discussed here as they are not controlled human exposures studies. The section on page 4-11 lines 6-20 should be consistent with and avid repetitions with pg 4-10 lines 1-18.

   The approach of summarizing associations in cities meeting various alternative standards may be informative but the point of this analysis is not stated clearly and the overall conclusion is not well stated (pg 4-13 ). What can we conclude then from table 4-1? If studies conducted in areas that have met lower standards do not show an effect do we conclude then that the standard produces appropriate health protection? But if they do does this suggest that an even lower standard is necessary? The logic of this analysis needs to be clarified.

   The subsequent section (on associations below various cutpoints) is clearer but the conclusion could also be summarized more clearly. Is the key point that a standard of 60 ppb is protective whereas a standard of 65 or 70 is not because studies for which all exposures were below 65-70 still reported associations whereas those at levels below 60 did not? I also found Table 4-2 confusing. The main point needs to be summarized. The

reference to the table in the text was confusing.

The section on protection from long term exposures is well done and convincing.

Section 4.4.2.1 would benefit from a final statement of the key conclusions derived from figure 4-1 to 4-4. The same applies to section 4.4.2.2. the bullets are useful but an overall summary statement of what we can conclude from these bullets taken together would be very helpful.

Section 4.4.2.3. The reason for the large difference in the % reduction in mortality associated with meeting a standard of 70 ppb for areas with area wide concentrations > 40ppb and >60ppb is not clear (the footnote does not help clarify). This also applies to other health outcomes. Also the rationale for reporting these two particular estimates is not presented. These types of estimates are repeated later in the chapter so their meaning needs to be clarified.

I'm not sure I would characterize a 9% reduction in ozone associated mortality as a "small " change (pg 4-41 , top of page). In any case it is larger than the effect observed with a standard f 70 ppb so it is not clear why it is considered small.

The chapter also does a reasonable job of grappling and acknowledging the complex issue of uncertainties.

Minor comment: avid using the word mortality ( a rate) when you mean total number of deaths (as in Figure 4-10).

2. *In the Panel's view, does the discussion in section 4.6 provide an appropriate and sufficient rationale, supported by the discussions in sections 4.1 through 4.4, to support staff's preliminary conclusions regarding alternative primary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?*

The section provides an appropriate and sufficient rationale. Overall he section is very well organized and the arguments are laid out n a clear and compelling way. A few clarifications, particularly of the data presented, would make this an outstanding chapter.

Tables 4-4 and 4-5 are clear but I found figure 4-13 cryptic. It is not clear exactly what is shown on the Y axis. Is it the ratio of deaths attributable to ozone for alternative standards compared to the 75 ppb standard ? Maybe label the x axis : total ozone attributable deaths, ozone attributable deaths at ozone levels > 20, >40 and >60.

It is difficult to follow the calculations reported on page 4-51 lines 14-21. "For days with area wide concentrations at or above 20ppb a standard with a level of 70….". Is this derived from figure 4-13? But if so isn't this the reduction in deaths attributable to ozone above 20ppb (**not** on days with area wide concentrations at or above 20 ppb??)

3. *Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?*

   No additional recommendations. Overall this is an excellent chapter. The final section in particular is very well done.

**David Grantz**

***Chapter 5. Adequacy of the Secondary Standard.***
*1. To what extent does the information in sections 5.1 through 5.5 capture and appropriately characterize the key aspects of the evidence for ozone welfare effects assessed and integrated in the ISA? To what extent does the information in section 5.1 (Nature of Effects and Biologically Relevant Exposure Metric) appropriately summarize the nature of ozone welfare effects and to what extent does it appropriately characterize the evidence with regard to biologically relevant exposures?*

This chapter does a nice job off summarizing evidence for welfare effects of ozone exposure. The paragraph (page 1-37, lines 4-14) provides an excellent rationale for considering the range of available studies, and how they might be assessed. Similarly, lines 30-36 on page 1-37 provide an excellent rationale for emphasis on Class I and other protected areas.
The discussion of flux based metrics is useful and appropriate, concluding that potential benefit may eventually derive from such metrics but that excessive uncertainty remains at this time. The discussion regarding reduced uncertainty associated with OTC derived C-R relationships (page 5-10; page 5-31) is appropriate and clearly presented.
The reference to EPA 2013 (page 5-13, line 5) is curious. Meta-analysis has demonstrated that reduced carbon transport to roots is a generally observed phenomenon, though exceptions exist. This sentence needs to be reviewed, for accuracy and for syntax.

*2. To what extent is staff's consideration of the welfare effects evidence, including the implications of reported vegetation effects with regard to adversity to public welfare technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?*

The linkage of ecological effects to welfare effects is clearly and appropriately explained, and in sufficient detail.
The cottonwood data (Figures 5-1 and 5-3) receive too much emphasis. These data are clearly outliers, as already noted in the text (page 5-14, line 5) and require further confirmation.
The effort to monetize welfare impacts and benefits is appropriate, though techniques for this are not yet fully developed. Specifically, calculation of consumer and producer surplus data is a useful contribution to quantification of welfare effects. The interaction of agriculture and forestry as modeled by the Forestry and Agricultural Sector Optimization Model with Greenhouse Gases (FASOM-GHG) is mentioned in both the WREA and the PA but not adequately explained.

*3. With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?*

Given that a W126 of 15 ppm hr is in many cases approximately equivalent to the current standard, and that injury is clearly observed below 15 ppm hr, the chapter demonstrates that the current standard is inadequate to protect against welfare effects due to ozone. The consideration of uncertainty (page 5-22, line 23 on) represents an appropriate level of concern and level of

interpretation. A similar tone should be adopted in the WREA. However, as in the WREA, the periodic consideration of uncertainty is again accumulated and repeated later (e.g. Page 5-27). Consolidation near the end of the chapter would enhance the impact of the evidence, reduce redundancy, and substantially shorten the document.
It is unclear why the information on foliar injury in four National Wildlife Refuges (Table 5-6) did not appear in the Risk Assessment.
The discussion at the top of page 5-55, related to economic losses due to bark beetles and to fire, perpetuates the questionable discussion in the WREA, confounding association with any evidence of causation. As stated these effects do not contribute much to the assessment of risk due to ozone nor to the adequacy of the current or alternative standards.
In Table 5-8 the ranges for Normal and Dry Palmer Z indices overlap. Is this intentional?

*4. In the Panel's view, does the discussion in section 5.7 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public welfare protection?*

This section can be made more concise and impactful. It clearly demonstrates that ozone induced injury may occur in areas that meet the current standard. It systematically justifies the conclusion that the form of the standard should be reconsidered, and begins to build the case for levels that should be considered.
There is a wrong word/typographical error at page 5-62, line 2, which alters the meaning.

***Chapter 6. Consideration of Potential Alternative Secondary Standards.***

*1. In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering levels of protection and potential alternative standards?*

It is well justified and consistent with previous CASAC judgment, that a cumulative, non-threshold metric, such as W126 is an appropriate form for the standard. Accumulation over the 08:00 – 20:00 daytime 12 hour period is an acceptable means of generalizing across latitudes and seasons. The compromises involved in this selection are clearly explained.
It is not convincing to argue that a multi-year averaging period is superior to a single year standard. Many cultivated and un-managed species are annuals, or cultivated as annuals. Perennials including trees may compound annual effects, but the effects are inherently single year impacts. Potential differences in soil moisture do not really bear on this question, as there are many factors that vary between years. The only significant reason provided in the chapter to consider a three year average is for increased statistical stability (page 6-11, lines 14-27). This may be sufficient reason, but this should be clearly stated. If a three year averaging period is implemented, it should be at a lower level than a single year standard to protect against single unusually damaging years that will be obscured in the average.
The key issue in the PA with respect to Welfare Effects is the level of the standard. It is surprising to find the statement at page 2-20, line 17-18, that "we are not able to identify a range of appropriate W126 index values". If protection of the most sensitive members of the community is extended to components of ecosystems that impact public welfare, then several potential levels of the standard suggest themselves. Both visibility and seedling biomass exhibit identifiable

thresholds at around 10 ppm hr (though visibility is more of a slope change than a decline to low injury level) and for relative biomass loss it is closer to 7 ppm hr. Crop loss appears to be less sensitive than these other indicators from the current analysis.

There is substantial redundancy in this chapter that could be consolidated for clarity and brevity.

*2. In the Panel's view, does the discussion in section 6.5 provide an appropriate and sufficient rationale, supported by the discussions in sections 6.1 through 6.4, to support staff's preliminary conclusions regarding alternative secondary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?*

Given the apparent break points around 7-10 ppm hr for various endpoints, it is difficult to understand how staff comes to suggest a standard as high as 17 ppm hr. In many cases, 15 ppm hr is nearly equivalent to the current standard, which is considered here to be inadequate to protect against ozone induced welfare effects. If uncertainty is invoked to prevent over-protection, then 15 ppm hr is the highest justifiable level for the revised standard based on the internal logic of the WREA and PA. If, as seems more likely given patchy species and spatial data coverage, the uncertainty results in potential underestimation of risk, then a lower level should be considered.

*3. Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?*

None.

**Daniel J. Jacob**

***Introduction (Chapter 1)*:**
*1. Does the Panel find the introductory and background material (sections 1.1 and 1.2) to be appropriately characterized and clearly communicated?*

Yes. My only confusion is in the use of "We" at various points in the text. It isn't clear to me who "We" refers to.

On page 1-9 lines 3-4, "a causal relationship between O3 and 8-hour exposures" doesn't seem to make sense. Probably a typo.

*2. In section 1.3, we describe the general approach for the review. This includes the key aspects of the approach employed in the last review in judging the adequacy of the then-existing standards and in selecting revised standards. Does the Panel find this description of the approach in the previous review adequate and clear? Does the summary of the approach in the current review appropriately describe important considerations in this review?*

It is generally fine. I only have a few concerns:

1. Page 1-38: The choice of the W126 index as metric for the secondary standard is not revisited as part of the current review. Why is it not?
2. Page 1-40: It's not clear if the analysis of the background contribution to ozone is to have solely a scientific purpose or also a policy purpose.
3. Page 1-40, lines 22-24: the notion that background ozone does not significantly impact the W126 index has been challenged by recent work, particularly for the Intermountain West where the background is high.

**Steven Kleeberger**

Chapter 4: Consideration of Potential Alternative Primary Standards

*1. In Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative standards?*

I believe the information has been appropriated characterized and interpreted.

*2. In the Panel's view, does the discussion in section 4.6 provide an appropriate and sufficient rationale, supported by the discussions in sections 4.1 through 4.4, to support staff's preliminary conclusions regarding alternative primary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?*

In my opinion, the rationale and discussion that lead to preliminary conclusions are appropriate. For more clear presentation, staff may wish to consider sub-headings for the consideration of 70, 65, and 60 ppb standard levels. Conclusions (p 4-57) are clearly stated, and the rationale for not considering levels below 60 ppb is appropriate. However, in general, the table and figure legends should provide more detail to enable the reader to understand better what is presented. Specifically, legends for Figures 4.1 – 4.4 and 4.5 – 4.8 are good examples where more detail in the figure legends would help the reader understand all of the included information.

*3. Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?*

I do not have additional interpretations or conclusions to add to the chapter. However, I would like to commend the staff for including the key uncertainties and areas for future research (4.7). This is very helpful for the reader to understand that the 'ozone field' still requires much additional effort/studies to fully understand all of the consequences of exposure to this pollutant.

**Fred Miller**

**Introduction (Chapter 1):**

1. Does the Panel find the introductory and background material (sections 1.1 and 1.2) to be appropriately characterized and clearly communicated?
2. In section 1.3, we describe the general approach for the review. This includes the key aspects of the approach employed in the last review in judging the adequacy of the then-existing standards and in selecting revised standards. Does the Panel find this description of the approach in the previous review adequate and clear? Does the summary of the approach in the current review appropriately describe important considerations in this review?

***Response:*** The introductory and background material provides the reader with a synopsis of the evolution of the NAAQS review process for photochemical oxidants together with insights into major litigation actions that have occurred over the last 30 years. The description of the approach in the previous review is clearly presented, and the summary of the current review approach captures the salient features of the review process.

**O3 Monitoring and Air Quality (Chapter 2):**

1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of O3 concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?
2. With regard to information on estimating O3 concentrations associated with nonanthropogenic sources or "background O3" (section 2.4), to what extent is this information appropriately characterized and clearly communicated?

***Response:*** My comments address the layout of the figures and tables in this chapter and do not address the charge questions. The authors should consider a different color scheme for some of the figures -- it is hard for the reader to sometimes discern differences (e. g., Figure 2-1). Since figures and tables should stand alone, the legends sometimes need to be expanded so the reader does not have to refer to the text to interpret the table or figure (e. g., Figure 2-2).

**Adequacy of the Primary Standard (Chapter 3):**

1. To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?

***Response:*** This section captures the important studies discussed in the ISA and integrates them into a logical narrative of what the important findings were in each category of effect such as lung function decrements, pulmonary inflammation, respiratory symptoms, and respiratory mortality.

The adversity of the effects and their implications for public health is discussed in a straightforward and clear manner that leads the reader through the body of data that has been amassed for this ubiquitous pollutant. The level of detail used is appropriate for the task at hand. Most importantly, the studies have been appropriately interpreted and discussed in Section 3.1.3 in the context of assessing the adequacy of the current standard. Section 3.1.3 presents the discussion of adversity in a manner that one might find in a legal briefing document, which speaks to the clarity of the points raised and supported by facts brought forward from the ISA and the HREA.

On page 3-15, the statement is made that the group mean decrements in various controlled human exposure studies at 60 ppb $O_3$ are not consistently statistically significant. While a correct statement, the authors should add that this is due to a lack of consistency in statistical power among the studies reflecting an inadequate number of subjects in some of the studies. There are places where paragraphs are duplicated almost verbatim on the same page, such as on page 72 for the first 2 paragraphs. On page 3-81, there is a reference to Table 3-12 but no such table appears in the chapter.

2. With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?

**Response:** The exposure and risk information pertinent to assessing the adequacy of the current standard is presented for 3 main categories: the adjusted air quality data, exposure-based considerations, and risk-based considerations. The salient points are clearly presented, and enough detail is provided so the reader can ascertain how much weight to assign to any limitations or uncertainties. Major points being made are always supported by reference to studies or data presented either earlier in this draft of the PA or in the ISA or HREA, which leads one to conclude that the points have been appropriately interpreted.

Consideration might be given to having the Y-axis on each of Figures 3-7 to 3-10 all be from 0 to 30 percent. This would allow the reader to better understand the importance of the different points that are being made in this body of figures.

3. In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection?

***Response:*** Absolutely! – Section 3.4 is a "slam dunk". This section, which is just slightly over 5 pages in length, clearly articulates the findings and points that underpin Staff's preliminary conclusion to call into question the adequacy of the current standard and the appropriateness of revising it.

**Consideration of Potential Alternative Primary Standards (Chapter 4):**

1. In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of

considering potential alternative standards?
2. In the Panel's view, does the discussion in section 4.6 provide an appropriate and sufficient rationale, supported by the discussions in sections 4.1 through 4.4, to support staff's preliminary conclusions regarding alternative primary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?
3. Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?

***Response:*** The evidence and exposure/risk information together with an acknowledgement of the inherent limitations and uncertainties is presented in a logical manner and the data have been appropriately interpreted. The discussion in section 4.6 is well constructed and the case for considering alternative standards is articulated clearly. However, the CASAC $O_3$ Panel should discussion meeting the summary paragraphs for the 3 alternative levels considered by staff as the arguments/discussions presented in the PA have this reviewer inclined to want to revisit the upper level of 70 ppb based upon scientific body of evidence considerations and not on any policy recommendations.

**Howard S. Neufeld**

**Chapter 1: Introduction**

1. This chapter is an excellent introduction to the history of the standard setting process and the legal challenges to previous decisions and their outcomes. It also clearly outlines the goals of the PA. This was a well-written and well organized chapter.

2. Yes and yes. I have no other substantive comments.

**Chapter 2: Monitoring and Air Quality**

*First item here deleted as it was incorrect – the 8 hr standard should be expressed in units of concentration. I had previously confused it with an exposure index that has hours of ppb*hrs.*

1. The discussion on background ozone is satisfactory and clearly explains how staff is dealing with this concept.

**Chapter 3: Adequacy of the Primary Standard**

1. The analysis of the ISA conclusions is well done. The particular emphasis placed on studies on the low end of ozone concentrations is commendable. Staff has done a careful and thorough analysis of respiratory effects purportedly caused by ozone. The writing is clear and understandable to the general public.

2. I thought staff did an excellent job of translating the ISA and Risk Assessment results into a statement of adequacy with regards to the current standard. Their analysis of the uncertainty and variability is both thorough and complete and serves to strengthen their conclusions reached about the adequacy of the current standard.

3. As noted above, staff has properly interpreted the new scientific studies and reached a logical conclusion that the current standard is not adequately protecting human health. This chapter was one of the strongest of all in the document: well synthesized, well justified, and with appropriate conclusions drawn from the analyses. I feel, therefore, that they are justified in proposing that the current standard should be revised.

**Chapter 4: Consideration of Potential Alternative Primary Standards**

1. The analyses of the various standard attributes (indicator, averaging time, form, and level) are well done. The conclusions that follow are appropriately stated and thoroughly justified.

2. I agree in all respects with the conclusions in section 4.6. I think the analyses preceding this section clearly justify the proposals in this section. I found nothing with which to disagree. In particular, staff's analysis of the difficulties in setting the standard too low are much appreciated and their detailed consideration of alternative metrics are to be commended. They clearly justify why the current indicator, averaging time and form of the standard should be retained, but that the level should be lowered.

3. I have no additional recommendations here.

**Chapter 5: Adequacy of the Secondary Standard**

1. Staff make a strong case (perhaps stronger than in any previous reviews) both that the current secondary standard fails to protect vegetation and ecosystem services from adverse effects, and that the form of the standard is inadequate to provide such protection. Sections 5.1 through 5.5 clearly lay out the argument for the impacts of ozone on ecological processes and ecosystem services. Their descriptions and analyses of the uncertainties are refreshingly clear and unbiased. Despite the paucity of data in certain areas, staff is still able to make statements of causality and risk with which to evaluate the adequacy of the current welfare standard.

2. Staff did an excellent job regarding technical soundness and providing clarity to the public. I might note that during the risk analysis, and also here, staff compares changes in seedling growth under ozone exposure to adult tree changes in circumference, expressed as percent losses. However, circumference as a surrogate for growth is somewhat questionable since growth in diameter would imply an increase in area, which is related to changes in circumference by the square (and total growth, i.e. volume, would increase by the cube). A 10% reduction in circumference would translate into a 19% reduction in trunk area. How this might affect the conclusions drawn I don't know, but it suggests that using circumference underestimates the effects.

   With regard to adequately interpreting the data for the purpose of assessing the adequacy of the current standard, I am satisfied with the analyses presented and agree with staff's interpretations.

3. The uncertainties are well laid out and explained and place the interpretations into proper perspective. It appears both in this section, and in the previous chapter, that staff has gone to great lengths to justify the conclusions reached from their analyses of the ISA and REA documents as well as making sure to follow the requirements of the Clean Air Act. I was very impressed with this aspect of the current PA.

4. I agree with most of the conclusions in section 5.7. I support moving from the 8-hr standard form to the cumulative W126 index, and I agree with using the maximum 3 month interval. I think a strong case can still be made that the timing should be for an individual year, rather than averaged over three years. I am concerned about the level and at what upper limit it should be set. Most of the analyses seemed to find effects below 15 ppm*hrs (many at 10 or even 7), so it would seem reasonable to set it lower than 15 ppm*hrs, and not as high as 17 ppm*hrs. Also, in many cases 15 ppm*hrs is approximately equivalent to the current standard, so keeping it that high would engender little benefit.

**Chapter 6: Consideration of Alternative Secondary Standards**

1. Staff make a very strong case for switching the secondary form to the W126 and for averaging it over three months and using the highest three month interval as the metric that is evaluated. The lack of an arbitrary threshold and the higher weightings for higher ozone concentrations are the appealing aspects of this ozone metric. I also support the use of daylight hours for this metric, from 8 am to 8 pm. There could be some quibbling about whether this time interval is shifted too late in the day, and misses some uptake early in the morning, but as staff notes, ozone at low elevations rarely rises to high values before 8 am.

However, in mountain regions, ozone is high over a 24 hour period, and as such, starting the metric at 8 am instead of 7 am or even 6 am, may miss some aspects of the exposure impacts. However, given that only one time interval can be selected, and that most areas across the country are not at high elevations, I can support using the 8 am to 8 pm interval.

2. I am less convinced that the three year average form is better than a single year form. I fully understand staff's arguments about stability but remain to be convinced that this would provide superior protection (requisite protection) given the comments from CASAC on this topic from earlier reviews. And if the increased statistical stability is that important, then the level should be reduced in order to protect the most sensitive vegetation.

   There seems little justification for allowing the increased flexibility of setting the level of the W126 above 15 ppm*hrs. See comments above in the Chapter 5 section. Most of the tree data show 2% annual growth losses at up to 14 ppm*hrs. It would seem prudent to take out the statement that the Administrator could consider exposure values above 15 ppm*hrs.

3. I have no further recommendations except one: the PA document contains many redundancies, which take away from its ability to clearly transmit its message to the public. This is especially so for Chapters 5 and 6. If there is any prudent way to shorten these chapters some, I think that would improve this document.

In conclusion, I would like to commend EPA Staff for their due diligence and hard work in putting these documents together. I was much impressed by the analyses and conclusions. They represent a real step forward from the first drafts.

**Armistead (Ted) Russell**

Overall, I found the PA informative and providing much of the information needed to inform the Administrator in regards to potentially modifying the ozone NAAQS. It generally has a good discussion on the adequacy of the current health and welfare standards, and potential revisions. Further, the preliminary revisions are in line with the evidence provided in the ISA and the analyses in the two REAs. The current presentation, for the most part, picks a reasonable balance between the desire to make the PA readable, concise and to the point, and providing sufficient information. The greatest need has to deal with issues involving the increases in lower levels of ozone in response to controls designed to reduce higher ozone levels. This issue impacts the risk and exposure assessments and the form of the standard.

**Chapter 2: O3 Monitoring and Air Quality**

1. To what extent is the most relevant information on monitoring, emissions and chemistry, and common patters of ozone concentrations is presented, etc.:

The current Chapter 2 is very streamlined; too much so. At present, it focuses primarily on the issues involving background ozone, which is an appropriate discussion, but there is at least one larger issue that needs to be addressed here in some detail, that being the response of lower level ozone levels to controls. As shown in the Health REA this is a very important consideration, and should be discussed in more detail in Chapter 2 as it is an important consideration in the potential form of a standard, and the possible limitations of the current form. As such, the PA should provide a discussion of how the observed ozone levels at various percentiles have been found to be evolving, e.g., the decreases in higher levels and increases in lower levels. This should be augmented with results from the modeling. The PA should provide the Administrator with a firm understanding that controls oriented at reducing the peak levels of ozone (e.g., the 4$^{th}$ highest annual MDA8) may not be that effective at reducing more typical levels and may actually increase ozone levels on lower ozone levels and also increase 24 hour levels on a broader range of days. Chapter 2 needs an overall summary. What are the major take-home points for the Administrator (and others) from Chapter 2?

2. Is the discussion of Background Ozone appropriately characterized and adequately communicated?

The discussion of background ozone is much more extensive than any other part of the air quality characterization. None-the-less, there are some missing pieces. First, the method by which the NB is calculated (e.g., models used) should be further described. The discussion of the source apportionment model estimates is much too minimal to really understand what is being done. Provide an extra sentence or two. The sentences beginning on 2-16, line 9 going to line 14 are not clear. The potential use of monitoring to estimate background should be discussed. I would also include a bit more on the range of controversy surrounding this issue. This should be recapped later on as well. In general, however, the discussion does provide a good and reasonably thorough assessment of the "background ozone" issue on setting a standard.
In the PA, I would also bring forward more of the results on the levels of controls needed to just meet various levels of the standards being assessed, both for the health and welfare standards. One

could use the two tables from the Appendices for the H-REA (Table 2 of Appendix 4) and the W-REA (Table 4A-2). This could be part of a synthesis as well.
Page 2-16, line 16: It is not apparent that the difference between 66 and 59 is due to the definitional approach versus the difference in model .
2-17, l21-23: What exactly does this mean? In particular, does "but for" mean if background sources were not present, there would not be an exceedance, or does it mean, if only background sources were present, there would be an exceedance?
2-9, l34: When discussing specific metrics, be very careful as to what is being said as to not be ambiguous.
2-9 l 14. I think you mean "intrusions" not "inversions"

Chapter 4: Form of the health based standard. Given the potential for controls to increase lower levels of ozone, one might consider a different form of the standard that would be protective at lowering high levels of ozone and also decreasing mid and lower levels. This should at least be discussed at a level that could lead the Administrator/reader to confidently say that the current form is appropriate. Indeed, one might come to the conclusion that another form would be better.

Chapter 6. One of the conclusions of the W-REA was that just meeting the current standard (75 ppb) leads to very similar ozone levels as a W126 of 15. This should be brought out more. Indeed, I am not sure that the difference is beyond the uncertainties in the approaches used. Given that a W126 of 15 roughly corresponds to a 75 ppb standard, the rationale for considering a W126 of 17 should be further discussed.

The PA could use a synthesis as well. The Synthesis should include how the health and welfare standards might work together. Further, it could identify the critical findings that would likely drive the decision to keep or revise the standards, including the characterization of the likely benefits of various choices of the standards and the uncertainties that are key. Maybe this will be included as part of the Executive Summary in the next draft. At present, the Executive Summary is a bit too short and weak. For example, it currently uses the phrase "call in to question", which might be stated as finds that the current standard is inadequate to protect health, and provide the specific evidence to suggest so. One thing that the synthesis could provide is the similarities in ozone fields at different levels of the health and welfare standards under consideration. It could also include tables showing the levels of control to meet those levels.

Executive Summary:
As noted above, the ES is rather short, and appears to be a work in progress. Compared to the ES's for the two REAs, this one does not stand up. It really does not do the PA justice. An important point from the W-REA should be made here, that being that a W126 of 15 ppm-hrs is very similar to just meeting the current standard. The ES could also use a synthesis.

**Helen Suh**

**Adequacy of the Primary Standard (Chapter 3)**

1. *To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?*

The section is comprehensive. While this comprehensive summary is accurate and clear, it does appear in other documents. Further, its volume is overwhelming. As a result, the Chapter is somewhat unfocused, and evidence supporting its conclusions regarding the adequacy of the primary standard are not sufficiently targeted. As one suggestion to increase the clarity of the Chapter, Section 3.4 could be moved to the beginning of the Chapter, with the summaries of findings and other sections used to support the conclusions of Section 3.4. Other comments and suggestions are discussed briefly below:

- Figures need additional annotation, better titles and a better color scheme (for example Figures 3-7 to 3-10).
- The discussion of the policy-relevant background risks should be removed or moved to the discussion of the history.
- Subsection 3.1.2
  - The subsection 3.1.2, which addresses the nature and strength of conclusions, could be more targeted, focused less on a summary of all findings but instead on findings contributing to the adequacy determination. In this way, it can provide an introduction to the topics discussed in later subsections, including adversity of effects and concentrations associated with observed impacts, with these later subsections being at the heart of Section 3.1.
  - While causal determinations were stated at relevant places in the text, it would be helpful to include at the beginning of Section 3.1.2 a table that lists the causal determinations made in the 2006 and current ISA. This table should be accompanied by a brief discussion that explains how health outcomes were selected for further discussion in Section 3.1.2.
  - Summary figures and/or tables should be added to Subsection 3.1.2 in place of text for the major outcomes. While summary figures of epidemiological studies were included (such as Figure 3-2), a preferable model for summarizing findings may be to include tables, such as Tables 4-23 and 5-19 from the NOx ISA, which summarize information succinctly across evidence and study types to support causality determinations. It may also be helpful to note in these summary figures and tables studies or findings that show ozone impacts at standard-relevant ozone levels.
  - The summary of ozone-attributed health outcomes in epidemiological studies should include a brief discussion of the potential for confounding of the observed effects, since is it is relevant to causal determinations.
  - Page 3-53, line 29-33 The statement beginning "Generally, the epidemiologic studies used nearest air monitors to assess ozone concentrations…explained by the different exposure assignment methods used…" relates not only to this subsection but also to previous

subsections. It should be mentioned in earlier subsections, if only to say that significant associations were found despite the presence of exposure error resulting from the use of ambient ozone concentrations to assess exposures.

- Section 3.1.3: It seems that much of this section is a repeat of earlier discussions, although with a different focus. To reduce repetition, it may make sense for this discussion to be incorporated into section 3.1.2, possibly using the following outline
    - Health outcome 1
        - Summary of findings (including causality determination and whether it has changed)
        - Adversity of impacts
        - Ozone concentrations associated with health effects
    - Health outcome 2 (etc.)

- Section 3.1.4: Important discussion that summarizes information across health effects. The summary tables 3-1 and 3-2 were very helpful. This subsection would be improved with further organization and integration of the findings across health effects, as this would help to demonstrate coherence with regard to the lowest ozone concentration at which key health impacts have been observed. The discussion of coherence doesn't begin for many pages (page 3-71) and is consequently buried. It would be better to summarize the earlier discussion more concisely to highlight the key points of the section.

2. *With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?*

Again, this section is comprehensive and accurate. The discussion on page 3-94 was clear, to the point, and clearly related to standard-setting considerations. Similarly, the discussion of uncertainties was well written and concise. However, in other areas, the section was overly repetitive and should be summarized more concisely to highlight discussions that focus more specifically on standard-relevant issues.

3. *In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection.*

Section 3.4 was a terrific synthesis of the current health and exposure/risk information. In some ways, the chapter should lead with this section, as it captures the key points, summarizes the evidence clearly and concisely in a manner that keeps the focus on standard-setting considerations.

**Consideration of Potential Alternative Primary Standards (Chapter 4)**

1. *In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative standards?*

This Chapter was well written, comprehensive, clear, and focused. It was a pleasure to read. Suggestions to improve the chapter are rather minor. They include:

- In general, the figures and tables need further descriptions, better titles and better annotation. For example, several figures, such as Figures 4-1 and 4-2 and Figures 4-3 and 4-4, seem extremely similar (with the same title) and it is not clear what the graphs are depicting.
- The question on page 4-8 (and following text) should be reworded to focus on lung function decrements and airway hyperresponsiveness rather than controlled human studies given the inclusion of panel study results in this section. Correspondingly, the title of the subsection "epidemiological evidence" to hospital admissions and mortality should be reworded to focus on health outcomes rather than study type.
- The discussion on page 4-14 of the cut-point analysis is a repeat of that in Chapter 3. Rather than repeat the discussion, instead reference it and draw conclusions relative to the level of the standard.
- The interpretation of Figure 4-10 is unclear from the text and the figure.
- Figure 4-9 (and other figures), the y axis should be labeled as "deaths" and not "mortality". In the text, it may be helpful to explain reasons for the observed between-city variability in figures such as Figure 4-9. Is this between-city variability important?

2. *In the Panel's view, does the discussion in section 4.6 provide an appropriate and sufficient rationale, supported by the discussions in sections 4.1 through 4.4, to support staff's preliminary conclusions regarding alternative primary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?*

Yes. The section was clear, well-written, and effective.

3. *Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?*

The chapter was a cogent presentation of the rationale behind the report's conclusions.

**James Ultman**

*To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?*

The chapter does an excellent job of summarizing the current evidence-based considerations of short-term and long-term $O_3$ health effects and placing them in the contexts of adversity to the individual as well as public health implications.

**Section 3.1.1**

I believe that appendix 3A describes specific modes of action much better than current text in section 3.1.3. I would go so far as to replace the latter by the former.

Regarding figure 3-1 (copied from figure 5-8 in the ISA), the mode-of-action pathways for specific adverse effects do not necessarily follow from the hierarchy in the figure. For example, inflammation and cell remodeling are both placed on the second level while epithelial metaplasia appears on the third level. I would argue that a more accurate sequence for the metaplastic changes that have been observed in toxicological studies might be: inflammation (second level)→cell repair and remodeling (third level)→ metaplasia (fourth level not currently on figure).

The mode-of-action discussion implies that secondary oxidation products rather than ozone itself drive the respiratory responses. This point of view is based on well-accepted dosimetry analyses indicating that ozone is almost completely reacted during its transit through the mucous layer in conducting airways. However, these analyses are not directly supported by experimental observations. Furthermore, it is still quite possible that ozone quantitatively penetrates the thin surfactant layer in alveoli distal to the conducting airways.

The first step in the respiratory response is described as oxidant stress, but this catch-all term does not tell the whole story. While ozone and some of its reaction products are oxidants that can be detoxified by endogenous antioxidants, other reaction products (e.g., aldehydes) cause cell damage by non-oxidative processes.

Page 3-13 (line 6) gives a literal interpretation of the McDonnell and the Schelegle models in terms of a specific mechanism (i.e., oxidant stress). Although this is a reasonable hypothesis, one should recognize that both models are simply two-stage mathematical constructs that include a build-up of inhaled *ozone* dose by continuous inhalation in competition of a reduction in biologically-effective dose by some clearance or metabolic process. It is also possible that such a reduction is the result of absorption of ozone in airways regions (such as the nose and mouth) that are proximal to the airway sites where dysfunction actually occurs.

**Section 3.1.2.2**

Entry is missing from the table of contents.

*With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?*

I think that the document is quite effective in presenting risk reduction information between recent conditions and just meeting the current standard.

*In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection?*

This section provides a sufficient rationale for staff's conclusion the current standard does not provide adequate health protection.

**Sverre Vedal**

Ch. 3. Adequacy of the current standard

*Adequacy of the Primary Standard (Chapter 3)*
*1. To what extent does section 3.1 (Evidence-based Considerations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA? To what extent is staff's consideration of the health effects evidence, including the adversity of reported respiratory effects and public health implications technically sound and clearly communicated at an appropriate level of detail? In the Panel's view has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?*

- Although there is some evidence from epi studies that anti-oxidants partially protect from lung function declines due to ozone exposure (3-15), the more direct evidence from human clinical studies does not support this.
- Toxicologic morphologic changes do not provide evidence of bronchial hyperresponsiveness – these changes occur at the level of the respiratory bronchiole and alveoli, which probably does not influence larger airways effects such as those in asthma. Perhaps there is some problem with the wording or intent here (3-40, lines 28-32).
- Observations on three endpoints (and conclusions on 3-119):
  - Long-term exposure effects on lung-function: valiant attempts are made to provide evidence for this using relatively weaker studies, whereas the best study (CHS) showed no effects.
  - Short-term exposure effects on symptoms in asthmatic children: arguments to justify not considering the two multi-city (multi-site, actually) studies that find no evidence of associations. I wonder if this same effort would have been made if these were the only two studies in which evidence for associations was found?
  - New onset asthma: argument is presented as to why the lack of a confirming main effect of long-term ozone exposure in the CHS is ok in light of the interesting gene polymorphism interaction analysis.
- In "Pulmonary Structure and Function" (3-44) there is no mention of the CHS study that provides the strongest evidence against long-term exposure effects of ozone on lung function.
- Does Section 3.1.3, Adversity of Effects, really require so much exposition? It's very repetitious of earlier material.
- Is compression of the ozone distribution due to model-based air quality adjustments realistic, i.e., decreases in high ozone concentrations and increases in low concentrations? (3-86)
- It is difficult to accept, if I'm understanding this correctly, that the percentage of children experiencing lung function declines is approximately the same as the percentage of children exposed (Figures 3-7 through 3-14). For example, in Atlanta, 14% of children are estimated to experience at least one exposure of concern at or above 60 ppb (Fig. 3-7) and 17% of children are estimated to experience at least one day of >10% decline in $FEV_1$ (Fig. 3-11).
- In addition to the sensitivity of epidemiologic-based risk on C-R functions due to choice of study region, e.g., large vs. small (3-114), there was also seeming substantial sensitivity to choice of regional vs. national C-R functions.
- Missing references detected: Rojas-Martinez 2007 (3-44, line 11), Joad 2006 (3-45, line 16), NRC 2008 (3-85), US EPA 2007 (3-98).

- [Refs to check: Kim 2011 AJRCCM re: inflamm at 60 ppb, Lin EHP 2008 on first asthma admission; Fanucchi 2006 infant rhesus]

*2. With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?*

I found this section to be among the best sections of Chapter 3.

*3. In the Panel's view, does the discussion in section 3.4 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public health protection?*

Most definitely. It's well done.

**Peter Woodbury**

***Executive Summary***

Page ES-2, line 26. I don't think suggesting that values "somewhat above" 15 ppm-hrs is appropriate. If the EPA staff judge that a value above 15 ppm-hrs for W126 should be considered, then the analysis throughout the WREA and the PA should include a specific value above 15 ppm-hrs so that this suggestion can be reviewed by CASAC and others.

***Introduction (Chapter 1)*:** This chapter provides context for the review, including the background of past reviews, as well as the scope and approach for the current review. This includes discussion of the basis for the current standard.

**1.** Does the Panel find the introductory and background material (sections 1.1 and 1.2) to be appropriately characterized and clearly communicated?

Yes, this material is important and the coverage is appropriate.

**2.** In section 1.3, we describe the general approach for the review. This includes the key aspects of the approach employed in the last review in judging the adequacy of the then-existing standards and in selecting revised standards.

Does the Panel find this description of the approach in the previous review adequate and clear?

Yes, this material is important and the coverage is appropriate.

Does the summary of the approach in the current review appropriately describe important considerations in this review?

Overall, this summary is cogent and useful. However, regarding the secondary standard, certain important conclusions are misleading and require revision. For example, on page 1-27, lines 7-10 states that the "magnitude of the response becomes increasingly uncertain". A similar statement is made on page 1-36, lines 24-27. This is somewhat misleading. Data such as the concentration-response functions for individual tree seedling species, supported by results from other methods such as FACE and naturally occurring gradients demonstrate that some species are very sensitive to ozone and show decreased growth at very low chronic exposure levels, while other species show little response to much higher levels. A similar result is found for crop species. Thus there is strong evidence of decreased growth and yield of some common tree and crop species at very low ozone levels. The more important source of uncertainty at these low levels is determining what degree of growth decrement should be considered unacceptable to protect public welfare. This issue extends throughout the PA, and the PA could be strengthened by more specifically quantifying the spatial extent and degree of impact expected at current ozone exposures, the current standard, and at the alternate standards. For example, rather than focusing on the "median RBL", quantify the number of counties containing sensitive tree species that are expected to have growth loss of greater than 1%, 2%, etc.

***O3 Monitoring and Air Quality (Chapter 2)*:** This chapter provides a description of the current O3 monitoring network and recent concentrations, information on emissions and atmospheric chemistry, common patterns and variability in O3 concentrations, as well as, discussion of current information on estimating O3 concentrations associated with non-anthropogenic sources.

1. To what extent does the Panel agree that the most relevant information on monitoring (section 2.1), emissions and atmospheric chemistry (section 2.2), and common patterns of O3 concentrations (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

**2.** With regard to information on estimating O3 concentrations associated with non-anthropogenic sources or "background O3" (section 2.4), to what extent is this information appropriately characterized and clearly communicated?

The large difference in "counterfactual" vs "source apportionment" methods for estimating backgrounds, is important for W126 (p. 2-23 and elsewhere). This issue is challenging to describe, but is done reasonably well. In particular, the summary on Page 2-26 and 2-27 is helpful..

"Anthropogenic" emissions of VOCs are distinguished from "natural" sources. However, as mentioned on Page 2-7 (lines 19-20) and 2-8 (lines 1-4), "natural" emissions can include human-influenced emissions from fire, agriculture, forestry, and other land management practices. This issue of definitions should be further clarified (see my further comment below). Even more importantly, the extent to which such human-influenced emissions are included in "natural background" or other "background" ozone scenarios, should be clarified, and preferably quantified since it could affect interpretation of what portion of ozone is potentially controllable.

On a more minor but related point, the terms "anthropogenic", "man-made" and "manmade" all seem to be used to mean the same thing, with "anthropogenic" being the most commonly used term. Perhaps the term "man-made" should be used throughout for emissions directly from human activity, with the term "anthropogenic" used more broadly to include indirect human-influenced emissions such as from agriculture, forestry, and other land management practices. Or if the term "anthropogenic" is used throughout then, make it clear that this narrower and I believe non-standard definition is being used.

***Adequacy of the Secondary Standard (Chapter 5)***: This chapter discusses key aspects of the welfare effects evidence and exposure/risk information, particularly relevant to consideration of adequacy of the current secondary standard and specifically describes staff's consideration of this information in reaching preliminary conclusions about the adequacy of the current standard.

**1.** To what extent does the information in sections 5.1 through 5.5 capture and appropriately characterize the key aspects of the evidence for ozone welfare effects assessed and integrated in the ISA?

In general, the information from the ISI is presented appropriately. The brief quotes are particularly helpful, as are the references to specific portions of the ISI.

To what extent does the information in section 5.1 (Nature of Effects and Biologically Relevant Exposure Metric) appropriately summarize the nature of ozone welfare effects and to what extent does it appropriately characterize the evidence with regard to biologically relevant exposures?

In general, Section 5.1 is useful and appropriate, and the use of questions and answers is a good format. However, I suggest rearranging the order of material within each subsection such that the question is answered at the end of the section discussing each question. For example, the current section on page 5-1, lines 21-33 should be placed just before Page 5-3, line 9. Furthermore, each question should be clearly answered. For example, Page 5-7, before Line 1, there should be a short paragraph that directly answers the question about appropriate paradigm posed on Page 5-5, lines 29-30.

Page 5-2, line 25. Replace "vegetative species" with "many species of vegetation".

Page 5-13, line 5. Delete "although"

**2.** To what extent is staff's consideration of the welfare effects evidence, including the implications of reported vegetation effects with regard to adversity to public welfare technically sound and clearly communicated at an appropriate level of detail?

In general, the draft is appropriate and substantially improved from the previous draft, with some caveats. First, it is important to appropriately address the fact that the sensitivity of most tree species and many crop species has not been quantified in terms of a C-R function. It should not be assumed that species of unknown sensitivity are not sensitive to ozone. For example, on page 5-18, lines 28-29, discusses "if present in these specially protected areas", referring to 7 of the 12 tree species for which C-R functions are available. More appropriately, it should state that "if ozone-sensitive species are present". This may sound like a minor point about language, but I believe it is actually an important point about how to apply the available scientific data to ecosystems, and it has large implications. For example, stating that "Half (6/12) of species with known C-R functions would have growth decreases greater than 5%, and of these species are representative of responses of unmeasured species, this degree of impact would occur in [state percentage of studied locations with this level of response]. In brief, it is important not to assume that unmeasured species are not sensitive to ozone, it is much more appropriate to assume that the sensitivity of species without C-R functions might be similar to the range of sensitivity for those species with C-R functions.

**In the Panel's view** has the information been appropriately interpreted for the purpose of assessing the adequacy of the current standard?

Please see comments above.

**3.** With regard to the presentation of the exposure and risk information for the purpose of assessing the adequacy of the current standard, to what extent is the information, including associated limitations and uncertainties, sufficiently characterized, appropriately interpreted and clearly communicated?

The choice of the word "paradigm" seems odd in question on p. 5-5, but I don't have a suggestion of a better term.

Make sure not to define "adverse" effects too narrowly (p. 5-6), loss of biomass growth could be important even if the species is not harvested for timber or fiber. This topic is mentioned elsewhere, and on Page 5-12 this issue is appropriately broadened, but perhaps on p. 5-6 some mention of other effects could be made, or a reference to other locations that address these broader impacts.

p. 5-13, line 5 delete "although"

Figure 5-1 should be improved by moving the legend to the right of the main figure panel and arranging the legend species in the same order (top to bottom) as in the main figure panel.

p. 5-14, line 16 and elsewhere. As I mentioned in comments on the previous drafts, it is difficult to interpret a "median" response for both ozone-sensitive and relatively insensitive species. Instead, it makes sense to characterize the expected impacts on the sensitive species, and quantify the spatial extent and effect on biomass growth for (1) known sensitive species (i.e., those that are shown be particularly sensitive with their C-R functions, and (2) the same result assuming that the 12 species with known C-R functions represent all tree species. A more complex scheme could be developed to try to extrapolate known species to unknown species based on physiological characteristics, as was done for crops in the FASOM analysis, but there would be substantial uncertainty in such extrapolation.

p. 5-21. I think that the "modeling regions" in Table 5-4, are the 9 large US climate regions shown in Fig. 4-6, but this should be made explicit (the term "modeling region" doesn't seem to be defined in the text currently).

p. 5-24. As in my comments on the first draft WREA and PA, and second draft WREA (Section 6.8) I still have a question about the RBL values weighted by basal area. Does the denominator basal area in the calculation include only the 12 species with C-R functions or does it include all species? If the latter, it is biased. If the former, the interpretation will vary depending on what fraction of the basal area is for species without C-R functions. Furthermore, if the goal is to assess ozone effects on total biomass growth of a mixed-species forest, then this value is not very informative because it will overestimate impacts in mixed species forests because of not including competition between sensitive and insensitive species (see previous comments on competition). If the purpose is to assess ozone impacts on sensitive species, this value is also not informative because it underestimates impacts on sensitive species for the same reason. A comparatively small growth decline in a sensitive species (e.g. 2%) based on a seedling study may translate into a larger effect at the stand scale.

Page 5-25. The method used with FASOM for forest growth is based on individual species C-R functions, but that is only appropriate for mono-specific stands. For mixed-species stands, overall forest growth will not be affected as much as would be implied by a weighted average of the growth rates (or yield losses) from individual C-R functions. This is because of competition among species with different sensitivity to ozone. This is a serious limitation in the approach for mixed-species forests that are common in many parts of the USA.

I still don't agree about ignoring impacts on farmers and forest owners in high ozone areas just because national assessments include winners and losers. An example of such a calculation is presented on page 5-32, line 9-12 for soybean for 2 counties in Kansas. The number of counties in which yield loss is predicted to exceed 1, 2% or 5% could be tabulated for alternative standards. See comment for Chapter 6 of the WREA related to this topic. Summaries of county-scale information could be added to Table 6-4.

p. 5-30 line 31 etc. Clarify that NCLAN covered multiple locations in the USA and multiple crops, with multiple O3 exposure levels using consistent methods – all of these factors are very important because they mean that the results are highly valuable for national risk assessments.

Check for occurrences of "PSDI", should be "PDSI" throughout.

p. 5-41, line 6. Change "by of" to "by".

Figure 5-5 (page 5-48). In figure legend, provide some information about the sites.

EPA should assure that uncertainties are not suggested or implied to always weaken the case for a more stringent standard. For example, the paucity of data on ozone sensitivity of most US plant species should be considered as "anticipated" that there are a large number of unidentified sensitive species, as well as of course many less sensitive species.

Page 5-62, replace "commiserate" with "commensurate".

Page 5-63, beginning line 31. Rephrase the sentence on line 31 to be more definite (replace "might be" with "are").

Page 5-65, lines 20-23. Replace "likelihood and magnitude of a response become increasingly uncertain" with "magnitude of effects become smaller". As discussed above, the evidence is very strong for tree biomass loss and crop yield loss for sensitive species at W126 values of 5-10. It is the magnitude of the effect that is smaller. And for less sensitive species, there will be little or no biomass loss at low ozone exposure values. Again the important uncertainty is determining what magnitude of an effect is important for welfare, not whether there are any effects at lower ozone exposure levels. This is an important distinction.

4. In the Panel's view, does the discussion in section 5.7 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that the current evidence and exposure/risk information call into question the adequacy of the current standard and that it is appropriate to consider revising the standard to achieve additional public welfare protection?

In general, this section is appropriate. However, because it is a summary section, many comments on other sections of this chapter should also be applied to this section. Also, note my specific comments above for this section (i.e. Pages 5-59 through 5-65).

***Consideration of Potential Alternative Secondary Standards (Chapter 6)***: This chapter discusses key aspects of the welfare effects evidence and exposure/risk information particularly relevant to consideration of potential alternative secondary standards and specifically describes staff's

consideration of this information in reaching preliminary conclusions on alternative standards appropriate to consider.

**1.** In the Panel's view, has the evidence and exposure/risk information, including associated limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering levels of protection and potential alternative standards?

In general, yes, except for a few points. First, I don't understand the suggestion of values "somewhat above" 15 ppm-hrs. If the EPA staff judge that a value above 15 ppm-hrs for W126 should be considered, then the analysis throughout the WREA and the PA should include a specific value above 15 ppm-hrs so that this suggestion can be reviewed by CASAC and others. Second, there needs to be greater attention paid to sensitive species. While there is analysis of both sensitive crop and tree species, much of the focus is on a median response, for example for tree species. And even when sensitive species are discussed, it is with statements such as 7 of 12 species had a relative yield loss of X below an ozone exposure value of y. However, with trees, the two most sensitive species had a substantial yield loss well below this value. Thus more attention should be paid to including information about commonly occurring sensitive species. Third, more attention should be paid to crop yield loss and tree biomass growth losses at smaller spatial scales such as counties. If yield of a sensitive crop such as soybean is greater than 5% in a county, it affects the farmers in that county, even if at larger regional or national scales there are smaller impacts on yield or on producer surpluses. Fourth, the suggestion to use a 3 year averaging period is not supported by the available data, nor has it been supported by CASAC. The only justification for a 3-year averaging period is to improve the stability of the classification of regions as being in or out of compliance. Greater attention should be paid to accounting for cumulative impacts of a 1% or 2% loss in growth of tree species and other impacts if a 3-year averaging period is to be used. Specifically, a lower value of the standard would be appropriate for a longer averaging period than 1 year. See also detailed comments below.

Additionally it seems to me that there is likely to be a strong bias effect of using across-the-board NOx reductions (see comments for Chapter 4 of WREA). For the large climate regions used, there is a wide variation in ozone exposure values throughout the region. If "across-the-board" cuts are used to reduce ozone exposure in the highest locations, then ozone exposure in locations where it is lower to start with will tend to become very low. But an actual targeted control strategy would likely only reduce NOx in the locations necessary to bring the high ozone-exposure locations into compliance, thus having much less effect on other locations than would across-the-board cuts. If this bias is large, then it strongly affects all of the risk analyses based on the alternate standards, because impacts of ozone under the alternate standards would be underestimated because ozone exposure values are underestimated for much of each region. If this bias is substantial it could mean that the ozone exposure is underestimated and thus the benefit of the alternate standards might all be underestimated. This could mean that the benefits of any of the alternate standards compared to "just meeting" the current standard and are underestimated as well.

Page 6-8, line 4-5. Change to "extremely highly correlated metrics, with Pearson correlation coefficients of 0.99".

Page 6-9, line 16-17. I don't find that this conclusion is warranted – the data support an annual time frame. There should be some compelling reason to use a multi-year time frame. Note

that the proposed form already includes a 3-month period, so it is not as sensitive as an hourly or 8-hour period to extreme events.

Page 6-9, lines 18-36. As in my comments in the previous 1st draft PA, it is not appropriate to assume that the only welfare effect of crop yield loss is total producer and consumer surpluses. I think that a goal of avoiding yield losses of sensitive crops of 5% or greater for each county would be appropriate to protect welfare. Farmers growing sensitive crops in high ozone locations can be considered a "sensitive population" for welfare impacts, and their crop yields should be protected. Furthermore, I do not find any support herein for the idea that the data do not support an annual time period for yield losses in annual crops.

Page 6-12. The argument that stability of compliance is of value is stated on this page. I agree with the previous CASAC statement (lines 26-29) that if a multi-year period is chosen for stability purposes, the level of the standard should be lowered to prevent exceedences of a threshold of impact. This is a very important point as it affects the choice of a level depending on the averaging time (1 versus 3 years).

Page 6-17 and 6-18. This discussion of individual species responses to different W126 levels is very helpful and informative, as is Table 6-1. However, I think Table 6-1 could be reformatted to make it easier to read by moving much of the text into column headings, and increasing the number of columns. For example "ppm-hrs" should appear at the top of the first column, under the column heading rather than be repeated on every row. And "median species" could be a column heading for both tree seedlings and crops, as could "loss". These changes would make it easier to see the actual values in the table. Also, it is not clear to me what "varying lower" means in the table.

Page 6-24, lines 10-24. See previous comments herein and for the first draft PA regarding a question with the weighted RBL scheme.

Page 6-25, line 14. Change "great" to "greater".

Page 6-30, lines 14-18. It would be helpful to include here and elsewhere the fraction of US forests represented by the species with C-R functions (probably using basal area) as well as the fraction of US crop area covered by the crop species with C-R functions. This helps quantify the uncertainty, which is quite different for crops and forest tree species. This information is available in the REA and could be summarized here as well.

Beginning page 6-30 line 6 and onward. While it is useful to list the various uncertainties, it would be more helpful to give some idea of how the uncertainty might affect the interpretation. I realize that this is challenging, but my concern that it is important to communicate what is known with reasonable certainty versus what is really unknown. I commend the staff for accomplishing this challenging task well in the REA in Table 7-23. There is quite a lot of certainty in estimates of biomass loss for forest tree seedling species and crop species for which C-R functions have been developed. Because several dominant crop species have C-R functions, there is a quite a lot of certainty about impacts of ozone on crop yield across most annual cropland in the USA. But it is much more uncertain to extrapolate from the 12 forest tree species to all forest tree species in the US. For uncertainty in ozone exposure, while it is true that the sparseness of rural monitors means

that in many regions there is uncertainty, there are large portions of the US where monitors are dense enough, and where there are not large mountains or other features that make interpolation more difficult, such that regional estimates of ozone exposure are pretty certain, even if there are somewhat larger uncertainties for individual locations.

Page 6-39, lines 29-31. This is a non-sequitur. The difficulty in determining the degree of impact that is important for welfare is not related to the question of averaging the standard across 1 or 3 years. Also, as quoted in the PA (page 6-36, line 19), the CASAC said "averaging across years in not recommended".

Page 6-43, line 13-14. As for the tree species, crop results should focus on both a group (such as median) response and also individual species response. This is important because sensitive species such as soybean are very widespread and important crops. Also, there is little attention given in the PA and WREA to non-crop annual species. The results for annual crops can be considered as also surrogates for a very large number of annual non-crop species that may have many welfare values. While I appreciate the much greater attention to effects on crop yield in this second draft compared to the first draft, I still think a bit more attention to crops is warranted given the strength of the database on crop yield response to ozone.

Page 6-43, line 35 and elsewhere. While the EPA chose to focus on 2% biomass loss for forest species, greater acknowledgement should be made that CASAC recommended 1 to 2%. This is particularly important in conjunction with the decision by EPA to focus on a 3-year rather than annual averaging time as recommended by CASAC.

Page 6-44, line 21. I think it is worth discussing the implications of focusing on sensitive tree species in addition to the existing focus on median and majority species. I think it is misleading for example on line 14-15 to say "less than 9 or 10" without including that the 2 remaining species have much higher predicted biomass losses. I am not suggesting that these sensitive species should be the primary focus, but rather including them for consideration rather than not including them, as happens with the current emphasis. As for sensitive crop species, these sensitive tree species are ecologically important and widespread. Furthermore, they may also serve as surrogates for the high likelihood that there are other sensitive tree species for which C-R functions have not been developed. As an example of how information on sensitive species might be included, the human health section of this PA includes estimates of the number of not just all children, but also asthmatics for example in Table 4-45, to better represent sensitive populations.

Page 6-45, lines 21-23. I don't understand why these lines are here. The EPA has selected a range of appropriate alternate values for the standard, and it is in accord with many previous CASAC recommendations. But this sentence says that the Administrator can reasonably choose a value beyond this range. This is a very open ended statement, and I don't understand what it is based on. If the EPA staff judge that a value above 15 ppm-hrs for W126 should be considered, then the analysis throughout the WREA and the PA should include a specific value above 15 ppm-hrs so that this suggestion can be reviewed by CASAC and others.

Page 6-45 lines 24-35. This is very helpful, pointing out the implications of choosing different values for the standard among the values put forward by EPA and by CASAC.

Page 6-46, lines 3-5 and 13-14. As mentioned above for the previous page, I don't understand the suggestion of values "somewhat above". If the EPA staff judge that a value above 15 ppm-hrs for W126 should be considered, then the analysis throughout the WREA and the PA should include a specific value above 15 ppm-hrs so that this suggestion can be reviewed by CASAC and others.

Page 6-48, lines 12-13. The only support that I find in the PA for a 3-consecutive-year time frame is stability of compliance among years. As discussed in the PA and in my prior comments, CASAC specifically recommends NOT averaging across years, so I think this recommendation should be reconsidered or at least further qualified.

Page 6-48, line 18, Again I find the usage of "somewhat above" to be vague and misleading and impossible to evaluate, see comments above.

**2.** In the Panel's view, does the discussion in section 6.5 provide an appropriate and sufficient rationale, supported by the discussions in sections 6.1 through 6.4, to support staff's preliminary conclusions regarding alternative secondary standards (including the indicator, level, averaging time and form) that it is appropriate to consider?

For the most part yes, except for the issue of mentioning values "somewhat above 15 ppm-hrs (see comments above). Also, I think more attention needs to be paid to suggesting a lower value for the standard if using a 3-year rather than a 1-year averaging time.

**3.** Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?

Please see comments above.

**Ronald E. Wyzga**

***Introduction (Chapter 1):***
Charge questions:

1. Does the Panel find the introductory and background material (sections 1.1 and 1.2) to be appropriately characterized and clearly communicated?

I believe that these sections are extremely well-written. I especially commend the Agency's intent to provide a document "written to be understandable to a broad audience". With respect to the latter, there are a few places where jargon and/or technical terms have crept in that could be clarified for a more naïve audience. For example, p. 1-7, l. 19: "certoriori", p. 1-21: "Controlled Human Exposure Studies"; p. 1-36: "OTC", which I believe refers to open-topped chambers.
In other places legal references could be placed in a footnote as they are distracting from the text; e..g, p. 1-3, ll. 24-28.

2. In section 1.3, we describe the general approach for the review. This includes the key aspects of the approach employed in the last review in judging the adequacy of the then-existing standards and in selecting revised standards. Does the Panel find this description of the approach in the previous review adequate and clear? Does the summary of the approach in the current review appropriately describe important considerations in this review?

This is well-written and provides an important introduction.
A minor comment is that some of the material in section 1.3.1.2.3 is repetitious of material in section 1.2.2.

Some comments on Chapters 3 and 4:

**Does the currently available scientific evidence and exposure/risk information ...support or call into question the adequacy of the current $O_3$ primary standard?**

The studies of Schelegle et al. (2009) clearly demonstrate that there are adverse health effects among a subpopulation of healthy young subjects after a 6.6 hour expsoure of 72ppb, a level below the current standard; hence there is clear scientific evidence that exposures at the current standard could lead to adverse effects and alternative standards are appropriate for consideration. It should be noted that lung function results from clinical studies at exposure levels at or below 72ppb also demonstrate a clear response. Whether these are "adverse" depends upon the definition of "adverse"; the Schelegle et al study clearly statisfies the definition of "adverse" as defined by the American Thoracic Society, which defines adversity as a combination of lung functions changes accompanied by symptoms. If an alternative definition of "adverse" is used, it should be clearly defined. There is also epidemiological support that finds adverse health responses at contemporary ozone levels in the US.

**What is the range of potential alternative standards that are supported by the currently available scientific evidence….?**

Clearly, from the above, the upper end must be at or below 72ppb. The Schelegle et al. (2009) study was conducted using healthy volunteers 18-25 years of age for an exposure of 6.6 hours. At issue is how to compensate for the shorter exposure time and the possible impacts among a more sensitive or less healthy population. Figure 2 from the Schelegle et al. (2009) study shows that at higher exposure levels lung function and symptom scores tend to increase with longer exposures. This increase is less apparent for the 70 and 80 ppb protocol exposures; nevertheless prudence suggests that some compensation could be made to adjust for the 6.6 hour exposure period. Panel studies also suggest that more sensitive individuals can respond to levels at or below 70ppb. There is no easy way to extrapolate from exposure levels at which healthy adults respond to comparable levels among sensitive populations, such as asthmatics and children; hence there is uncertainty associated with the lower end of the proposed range.

# Attachment 3

**Index of Scientific Studies included in Footnote Citations**


1. Archer, Cristina L., Joseph F. Brodie, and Sara A. Rauscher. "Global Warming Will Aggravate Ozone Pollution in the U.S. Mid-Atlantic." *Journal of Applied Meteorology and Climatology* 58, no. 6 (June 2019): 1267–78. https://doi.org/10.1175/JAMC-D-18-0263.1.

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# Scientific Studies

# Attachment 1

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# Global Warming Will Aggravate Ozone Pollution in the U.S. Mid-Atlantic

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(Manuscript received 1 October 2018, in final form 4 March 2019)

ABSTRACT

The goal of this study is to evaluate the effects of anthropogenic climate change on air quality, in particular on ozone, during the summer in the U.S. mid Atlantic region. First, we establish a connection between high ozone (HO) days, defined as those with observed 8 h average ozone concentration greater than 70 parts per billion (ppb), and certain weather patterns, called synoptic types. We identify four summer synoptic types that most often are associated with HO days based on a 30 yr historical period (1986 2015) using NCEP NCAR reanalysis. Second, we define thresholds for mean near surface temperature and precipitation that characterize HO days during the four HO synoptic types. Next, we look at climate projections from five models from phase 5 of the Coupled Model Intercomparison Project (CMIP5) for the early and late midcentury (2025 34 and 2045 54) and analyze the frequency of HO days. We find a general increasing trend, weaker in the early midcentury and stronger in the late midcentury, with 2 and 5 extra HO days per year, respectively, from 16 in 2015. These 5 extra days are the result of two processes. On one hand, the four HO synoptic types will increase in frequency, which explains about 1.5 2 extra HO days. The remaining 3 3.5 extra days are explained by the increase in near surface temperatures during the HO synoptic types. Future air quality regulations, which have been successful in the historical period at reducing ozone concentrations in the mid Atlantic, may need to become stricter to compensate for the underlying increasing trends from global warming.

## 1. Introduction

The most recent report of the Intergovernmental Panel for Climate Change (IPCC) indicates that an average global warming of about 2°C is likely by the end of the century, based on medium- to high-emission scenarios (IPCC 2013). Along the U.S. East Coast, the warming is projected to be even stronger with an increase of 2.5° 5.5°C (Maloney et al. 2014). Heat waves are expected to be more frequent and more intense and to last longer. For example, the number of days above 90°F (32°C) may increase by 50 days yr $^{1}$ in the mid-Atlantic region by the middle of the century if $CO_2$ emissions continue on their current trajectory (Melillo et al. 2014). Such increases in extreme temperatures are likely to have a negative impact on public health all along the mid-Atlantic, as high temperatures are associated with increased mortality. This temperature mortality link appears to be strongest in the eastern United States compared to other parts of the country (Curriero et al. 2002; Anderson and Bell 2009).

Global warming may exacerbate indirect health impacts via near-surface ozone ($O_3$) pollution (Monks et al. 2015). Ozone is a summer pollutant, regulated by the U.S. Environmental Protection Agency (EPA), that forms in the atmosphere as a result of photochemical reactions between nitrogen oxides ($NO_x$) and volatile organic compounds. Ozone has large negative impacts on health, especially affecting the cardiopulmonary and respiratory systems (EPA 2018b). In Delaware, ozone is the only regulated pollutant that exceeds national and state standards regularly [Delaware Department of Natural Resources and Environmental Control, Division of Air Quality (DNREC-DAQ) 2016], as will be discussed in detail later (section 2a). We focus on Delaware as representative of the mid-Atlantic region because of its central location. Further, since Delaware is a small state, even a few stations can represent ozone conditions over the state well.

Ozone is expected to reach higher concentrations (i.e., increase in intensity) and/or exceed national and state standards more often (i.e., increase in frequency)

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because of climate change via several mechanisms. First, higher temperatures enhance photochemical reactions that form ozone. Second, high-ozone (HO) episodes tend to occur during certain synoptic conditions, such as a high pressure system (e.g., the Bermuda high). These synoptic conditions may occur more often in the future, leading to more frequent HO events (Shen et al. 2015; Leibensperger et al. 2008). This paper will focus on this second indirect mechanism, that is, changes in the frequency of HO events in the future caused by changes in synoptic conditions. Since Delaware is a state with low local emissions and its ozone pollution is dominated by transport from upwind states (Moghani et al. 2018), it is a region where ozone tends to be dominated by synoptic, more than local, weather conditions.

How can we make projections of whether or not HO events may occur more frequently in the future? The most common tool used to create projections of future climate is coupled atmosphere ocean models, such as the models included in phase 5 of the Coupled Model Intercomparison Project (CMIP5; Taylor et al. 2012). The results of these model simulations form the basis of the papers that are used in the IPCC Assessments, for example, IPCC (2013). However, most models (unless specifically outfitted with complex chemistry models) do not include ozone as a prognostic variable. Therefore, to make projections of how HO days may change in the future, we must relate ozone concentrations to variables that all coupled atmosphere ocean climate models simulate, like pressure and temperature. Then we can determine how those variables are changing and the implications of their changes on the frequency of HO days.

Here we make use of CMIP5 simulations to project how the number of HO days may change over the mid-Atlantic region (and more specifically, Delaware), for two midcentury periods, 2025 34 and 2045 54, and compare this to the frequency of ozone days for the present day (1986 2015). Section 2 gives an overview of the observed and model data sources, while section 3 details the synoptic typing and other criteria used to classify days as "high ozone." Section 4 discusses the results, while section 5 offers conclusions and directions for future research.

## 2. Data sources

### a. Delaware ozone data

The period of interest for this study is 1986 2015. The DNREC DAQ operates a network of air quality stations throughout the state, recording a number of parameters, including ozone. The first three ozone monitoring sites (Claymont, Lums Pond, and Bellefonte) became

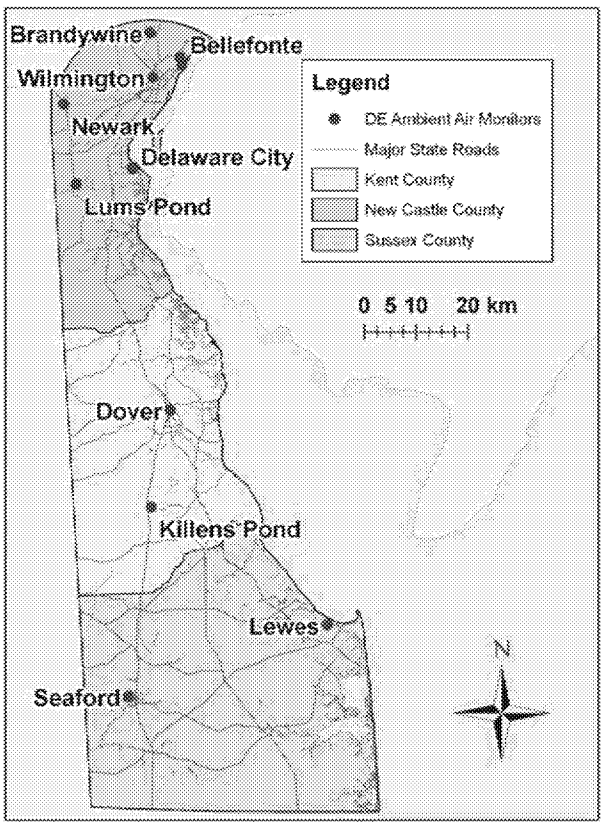


FIG. 1. Map of the air quality monitoring stations in the state of Delaware from DNREC DAQ (2018). Dover, Delaware City, and Newark do not record ozone.

operational in 1982, with additional stations being added, removed, or replaced since then. Since 2011, there are seven stations that record ozone with 1-h frequency (DNREC-DAQ 2018). The locations of these seven ozone monitoring stations are depicted in Fig. 1 and listed in Table 1. Since Delaware is a small state composed of only three counties, these seven stations provide a reasonable spatial coverage, with two stations in southernmost Sussex County, one station in central Kent County, and four stations in the more heavily populated northernmost New Castle County. These data are archived by DNREC and made available via the U.S. EPA Air Data portal (EPA 2018a).

Even though hourly values are recorded, the daily maximum 8-h average ozone concentration is used in this analysis to represent the daily value of ozone at each station. These 8-h averages have been error checked by DNREC and EPA. For example, an 8-h average is considered valid if at least six of the 8-hourly concentrations for the 8-h period are available and a daily maximum 8-h average ozone concentration is considered valid if valid 8-h averages are available for at least 13 of the 17 consecutive 8-h periods starting from 0700 to 2300

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TABLE 1. Details of the seven ozone monitoring stations located in Delaware and reporting to the EPA's air quality system as of 2018 (DNREC DAQ 2018). The station values that exceed the ozone standard are in boldface. Two additional monitoring stations, in Dover and Claymont, collected ozone data during 1982 94.

| AQS ID | Location | Lat (°) | Lon (°) | Since | Design value (ppm) |
|---|---|---|---|---|---|
| 10 001 0002 | Killens Pond | 38.986 70 | 75.5568 | 1995 | 0.066 |
| 10 003 1010 | Brandywine | 39.817 22 | 75.5639 | 1994 | **0.074** |
| 10 003 1013 | Bellefonte | 39.773 89 | 75.4965 | 1982 | **0.071** |
| 10 003 2004 | Wilmington (MLK) | 39.739 50 | 75.5575 | 2011 | **0.072** |
| 10 003 1007 | Lums Pond | 39.551 30 | 75.7320 | 1982 | 0.067 |
| 10 005 1002 | Seaford | 38.653 90 | 75.6106 | 1983 | 0.065 |
| 10 005 1003 | Lewes | 38.779 10 | 75.1632 | 1997 | 0.067 |

LT (EPA 2015). The daily maximum 8-h average ozone value is used to calculate the so-called design value of each station, which is the 3-yr average of the annual fourth-highest daily maximum 8-h average ozone concentration at each station. The National Ambient Air Quality Standard (NAAQS) for ozone is met when the design value is less than or equal to 0.070 ppm and it is violated when the design value is greater than 0.070 ppm (EPA 2015). In Delaware, three of the seven ozone monitoring stations were in violation of the NAAQS in 2018 (Table 1).

### b. *NCEP–NCAR reanalyses*

Reanalysis data used for the synoptic typing come from the NCEP NCAR reanalysis, version 1 (Kalnay et al. 1996). Reanalysis datasets are produced by assimilating various quality-controlled observations, including rawinsondes, surface marine data, aircraft data, surface land synoptic data, satellite sounder data, special sensing microwave imager, and satellite cloud drift winds, into a numerical weather prediction model (Parker 2016). The result is a gridded product that provides four-times daily "snapshots" of the atmosphere. The horizontal resolution of the NCEP NCAR reanalysis products is about 2.5° latitude × 2.5° longitude. Here we use the variables sea level pressure (SLP), surface air temperature, 500-hPa height, and precipitation rate. Data are available for the period from 1948 to the present, but again we focus on the period of 1986 2015.

### c. *CMIP5 climate model data*

The CMIP5 archive contains model output from a plethora of models worldwide, run for dozens of experiments, as discussed in section 1. Here we focus on the historical experiment simulations for the period 1986 2005 and the RCP8.5 scenario for 2006 15 (1986 2015 will be referred to as the "historical" period hereafter). Several different scenarios based on the radiative forcing by the end of the twenty-first century were used to generate projections of future climate in the CMIP5 project. The scenarios range from a low of 2.6 W m $^{2}$ to a high of 8.5 W m $^{2}$. The RCP8.5 scenario explores a world in which population increases to 12 billion by 2100 along with income inequality. Meanwhile, limited technological advances mean that there is no concomitant increases in energy efficiency (Riahi et al. 2011). This scenario thus represents a "business as usual" trajectory for the future (van Vuuren et al. 2011; Taylor et al. 2012) that is realistic given the failure of countries to so far meet the goals of the Paris Agreement (Masson-Delmotte et al. 2018). Regardless of the choice of scenario, the sign of most changes in the future projections is consistent between the different scenarios, meaning if temperature increases in one scenario with more radiative forcing, it increases in another simulation with less radiative forcing, but to a lesser extent (Giorgi and Mearns 2002). Two future RCP8.5 10-yr periods are considered: the early (2025 34) and late (2045 54) midcentury. Both periods are close enough in time to be directly affected by policy decisions made today. In the early midcentury period, however, the underlying climate is not too different from today's, while the late midcentury period is likely to show stronger effects from global warming.

We used output from five different coupled atmosphere ocean global circulation models in the CMIP5 archive (listed in Table 2) based on their performance over eastern North America, horizontal grid spacing, and availability of the relevant fields at daily and subdaily time scales. The horizontal grid spacing of the five models (degrees latitude by degrees longitude) is reported in Table 2. Pierce et al. (2009) have shown that using five models is sufficient to represent the behavior of the ensemble as a whole. Daily gridded data for the following variables were used for the analysis: SLP, surface air temperature, and precipitation. Because of Delaware's small size, all or most of the state is contained in a single grid cell of the CMIP5 models used, and thus the values for this single cell are used when local data are needed for temperature and precipitation. Additionally, the full gridded data for SLP over the eastern United States is used for spatial correlations with the NCEP reanalyses.

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TABLE 2. Details of the five selected CMIP5 models and trends (number of additional HO days yr $^{-1}$) over the 30 yr historical period (1986–2015) and the 10 yr early (2025–34) and late (2045–54) midcentury periods.

| Model abbreviation and resolution (° lat × ° lon) | Full model name | Institution and country | Historical | Early midcentury | Late midcentury |
|---|---|---|---|---|---|
| HadGEM2 (1.25° × 1.875°) | Hadley Centre Global Environmental Model, version 2 | Met Office Hadley Centre, United Kingdom | 0.369 | 0.091 | 0.448 |
| MIROC5 (1.401° × 1.406°) | Model for Interdisciplinary Research on Climate (MIROC), version 5 | MRI, Japan | 0.048 | 0.606 | −0.036 |
| CCSM4 (0.942° × 1.25°) | Community Climate System Model (CCSM), version 4 | National Center for Atmospheric Research (NCAR), United States | 0.113 | 0.394 | 0.388 |
| CNRM CM5 (1.401° × 1.406°) | Centre National de Recherches Meteorologiques (CNRM) Coupled Global Climate Model, version 5 | CNRM Centre Européen de Recherche et de Formation Avancée en Calcul Scientifique (CERFACS), France | 0.180 | −0.521 | 0.430 |
| MRI (1.122° × 1.125°) | Meteorological Research Institute (MRI) Coupled Atmosphere–Ocean General Circulation Model, version 3 | MRI, Japan | 0.040 | 0.588 | 0.321 |
| Ensemble median | | | 0.225 | 0.230 | 0.582 |

## 3. Methods

### a. High-ozone days from observations

The NAAQS for ozone would be the most obvious choice to assess observed high-ozone days, but this metric has not been constant over the years. For example, the 8-h average standard for ozone was changed from 0.080 ppm in 1997 (EPA 1997) to 0.075 ppm in 2008 (EPA 2008) and then further reduced to 0.070 ppm in 2015 (EPA 2015). In addition, the NAAQS for ozone is based on a rather complicated formula, including the calculation of the fourth-highest percentile each year and its average over three consecutive years (EPA 2015). Therefore, following the Air Quality Index (AQI; EPA 2017), a day is classified here as an HO day when the 8-h average ozone concentration at any station in Delaware exceeds the threshold of 70 ppb. In contrast to a large state, which would require multiple stations to identify observed high-ozone events, even just a single station is reasonable for a small state like Delaware.

Based on these criteria, we counted the frequency of observed HO events during the 30-yr observational record of ozone from 1986 to 2015. As shown in Fig. 2, the number of observed HO days decreased over the 30-yr period. For example, during the 1980s the average number of HO days was approximately 75, whereas by 2015 it had decreased to less than 20. On average, each year during the study period had about 2 fewer days of high ozone per year (as the trend line in Fig. 2 has a slope of −1.82 HO days yr $^{-1}$). This steady decline resulted from stricter regulations (such as federal and state air quality standards) and decreases in the emissions of ozone-forming pollutants.

### b. Synoptic typing

Episodes of high ozone are associated with certain synoptic weather conditions, such as the passage of midlatitude cyclones and the western expansion of the Bermuda high (Shen et al. 2015). Because of climate change, the synoptic weather conditions conducive to high ozone concentrations may occur with greater frequency, therefore increasing the potential for more HO episodes.

The synoptic weather conditions present on any given day can be classified by the use of synoptic typing. Synoptic typing uses an assortment of meteorological variables, including temperature, humidity, sea level pressure, precipitation, cloud cover, and wind velocity, to investigate common trends in the synoptic conditions, in order to identify a limited number of types that explain the underlying synoptic-scale variability. The origins of these techniques can be traced to visual classifications by Lamb (1972) and computer-assisted statistical relationships of sea level pressure by Lund (1963).

The synoptic typing used in this study was originally developed in Siegert et al. (2017), using an eigenvector-based approach (Kalkstein and Corrigan 1986; Yarnal 1993). Siegert et al. (2017) employed synoptic typing to assess hydroclimate in the mid-Atlantic states, with the same dataset expanded and used by Suriano and Leathers (2017) in evaluating lake-effect snowfall in the

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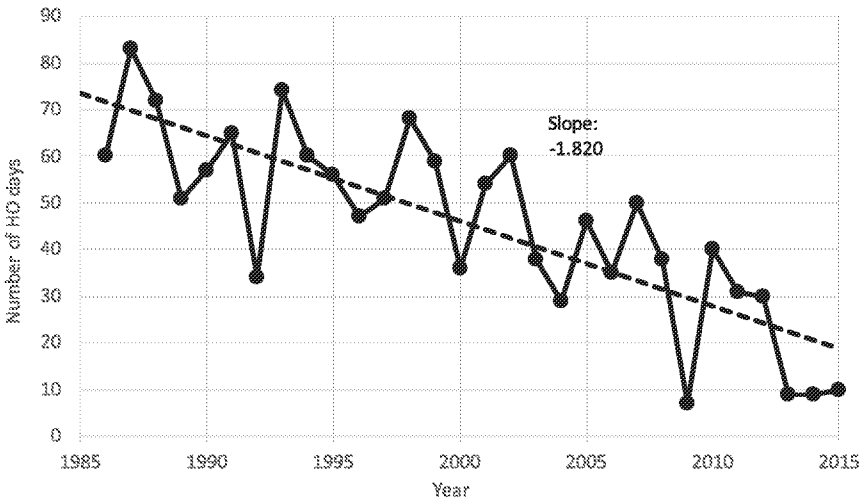


FIG. 2. Number of observed HO days per year from air quality monitoring sites in Delaware during the 30 yr period of 1986 2015.

Great Lakes region. Siegert et al. (2017) describe the procedure used to create the synoptic types as follows. Weather data from the period from 1948 to 2015 (temperature, dewpoint temperature, $u$ and $v$ wind components, atmospheric pressure, and cloud cover) taken four times daily (0900, 1500, 2300, 0300 UTC) at the Philadelphia International Airport Station were input into an unrotated R-mode principal components analysis. They then identified the five principal components explaining at least 75% of the variance in the mid-Atlantic region of the United States (i.e., Pennsylvania, New Jersey, Maryland, and Delaware) for winter, spring, summer, and autumn. Within-group average linkage clustering analysis was used on the seasonal component loadings to produce clusters, or synoptic types. Initially 20 clusters were retained and composite maps were developed for each cluster representing SLP, 500-hPa geopotential height, surface air temperature, and surface precipitation rate using the NCEP NCAR reanalysis (Kalnay et al. 1996). Because some of the clusters showed similar characteristics in the composite maps, they were combined based on expert assessment. This resulted in a variable number of synoptic types for each season: 12 in winter, 13 in spring, 9 in summer, and 11 in autumn. This research focuses on the nine synoptic types from the summer identified in Siegert et al. (2017), listed in Table 3, since the vast majority of high-ozone events in Delaware take place during the summer months.

Each summer day of the 30-yr record evaluated here (1986 2015) was assigned to one of the nine summer synoptic types, as defined by (Siegert et al. 2017), and to an ozone category (HO or non-HO), as described in section 3a. In this way, the frequency distribution of synoptic types associated with HO days could be determined (Fig. 3). The nine types and their frequencies are shown in yellow in Fig. 3; the distribution of HO days by synoptic type is shown in blue.

The four most common synoptic types for the entire 30-yr period are southwesterly flow (SW), New England low (NELOW), overhead high (OHHI), and weak pattern (WEAK); the two synoptic types with the highest number of HO days are SW and NELOW (Table 3). Several synoptic types have spatial patterns that are highly correlated with each other, as shown in Table 4. The spatial pattern correlation $\rho_{A,B}$ between two SLP maps $A$ and $B$ representing either two synoptic types or an individual day's map and a synoptic type was calculated as follows:

TABLE 3. Summer synoptic types and their frequencies during the 30 yr historical period of 1986 2015 in terms of the number of days that each synoptic type occurred and the number of HO days within each synoptic type based on at least one observing station exceeding the 70 ppb threshold. In boldface are the synoptic types that will be later associated with HO days based on the climate models.

| ID | Original ID | Description | Frequency | |
|---|---|---|---|---|
| | | | All days | HO days |
| **HBLOW** | 3006 | Hudson Bay low, frontal activity | 189 | 63 |
| **WEAKSW** | 3010 | Weak southwesterly flow | 224 | 29 |
| NEHI | 3013 | New England high | 70 | 0 |
| NNW | 3020 | North northwest flow | 62 | 15 |
| OFFHI | 3031 | Offshore high | 247 | 54 |
| WEAK | 3032 | Weak pattern | 305 | 68 |
| **NELOW** | 3033 | New England low | 445 | 163 |
| **SW** | 3034 | Southwest flow | 876 | 522 |
| OHHI | 3035 | Overhead high | 310 | 99 |

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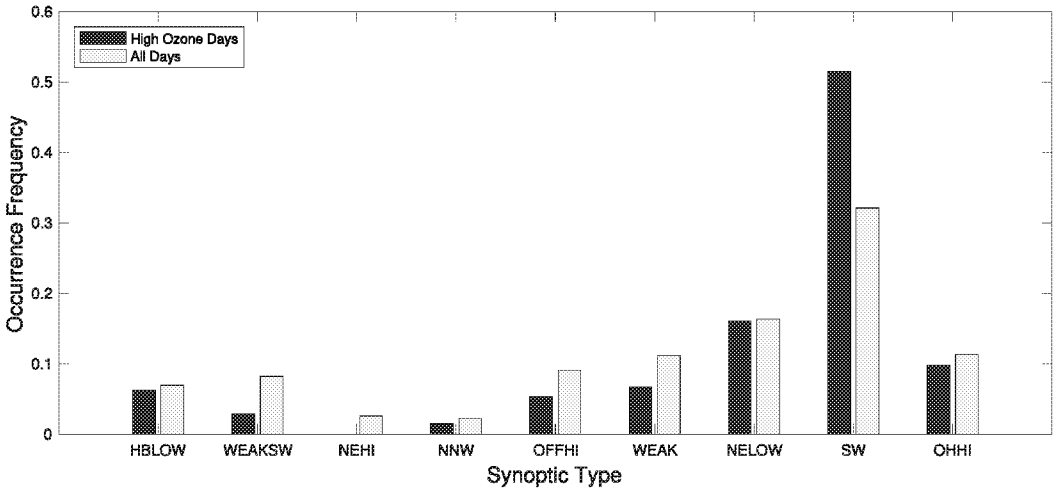


FIG. 3. Frequency distribution of observed (from NCEP NCAR reanalyses) synoptic types during the summer season for the 30 yr study period of 1986 2015.

$$\rho_{A,B} = \frac{\sum_{i=1}^{n}(A_i - \overline{A})(B_i - \overline{B})}{\sqrt{\sum_{i=1}^{n}(A_i - \overline{A})^2}\sqrt{\sum_{i=1}^{n}(B_i - \overline{B})^2}}, \quad (1)$$

where $\overline{A}$ and $\overline{B}$ represent the mean SLP for maps $A$ and $B$, respectively; $A_i$ and $B_i$ represent the SLP at grid point $i$ in maps $A$ and $B$, respectively; and $n$ represents the number of grid points. For example, both types HBLOW and WEAKSW are highly correlated (above 0.93, Table 4) with type SW, since all share a generally southwesterly flow associated with the presence of the Bermuda high located around 30°N, 50°W, which advects high temperatures and ozone precursors over the mid-Atlantic (Fig. 4). In contrast, the NELOW type is characterized by northwesterly flow that would advect precursors from the upper Midwest. The near-surface air temperature patterns between all four of these synoptic types are extremely similar (Fig. 5), with mean temperatures exceeding 25°C over the mid-Atlantic, except for the NELOW pattern, which has slightly lower temperatures. Additionally, many of the OHHI HO days occurred in the first decade (50 days in 1986 95, not shown), and both the frequency of HO days that occurred during OHHI and the overall number of days of the OHHI synoptic types trended downward during the two subsequent decades (from 50 days in 1986 95 to 34 days in 1996 2005 to 15 days in 2006 15), reducing the influence of this type in more recent years. Therefore, we classified Hudson Bay low (HBLOW) and weak southwesterly flow (WEAKSW) as high-ozone types as well. Thus, our four HO synoptic types are: NELOW, SW, HBLOW, and WEAKSW.

### c. *High-ozone days from the CMIP5 climate models*

Once the synoptic types associated with observed HO days have been determined, this information is used to classify which climate model days (historical and future simulations) have the potential to be HO days.

First, for each model day $t$ we calculated its spatial correlation $\rho_{t,j}$ with each of the nine summer synoptic

TABLE 4. Spatial pattern correlations between the summer synoptic types based on SLP. In boldface are the synoptic types that will be later associated with HO days based on the climate models.

| Synoptic type | HBLOW | WEAKSW | NEHI | NNW | OFFHI | WEAK | NELOW | SW | OHHI |
|---|---|---|---|---|---|---|---|---|---|
| **HBLOW** | 1 | 0.964 | 0.562 | 0.718 | 0.844 | 0.849 | 0.915 | 0.963 | 0.835 |
| **WEAKSW** | 0.964 | 1 | 0.672 | 0.656 | 0.860 | 0.914 | 0.872 | 0.934 | 0.827 |
| NEHI | 0.562 | 0.672 | 1 | 0.428 | 0.869 | 0.866 | 0.400 | 0.706 | 0.786 |
| NNW | 0.718 | 0.656 | 0.428 | 1 | 0.575 | 0.725 | 0.876 | 0.745 | 0.802 |
| OFFHI | 0.844 | 0.860 | 0.869 | 0.575 | 1 | 0.912 | 0.658 | 0.939 | 0.927 |
| WEAK | 0.849 | 0.914 | 0.866 | 0.725 | 0.912 | 1 | 0.781 | 0.912 | 0.931 |
| **NELOW** | 0.915 | 0.872 | 0.400 | 0.876 | 0.658 | 0.781 | 1 | 0.858 | 0.783 |
| **SW** | 0.963 | 0.934 | 0.706 | 0.745 | 0.939 | 0.912 | 0.858 | 1 | 0.938 |
| OHHI | 0.835 | 0.827 | 0.786 | 0.802 | 0.927 | 0.931 | 0.783 | 0.938 | 1 |

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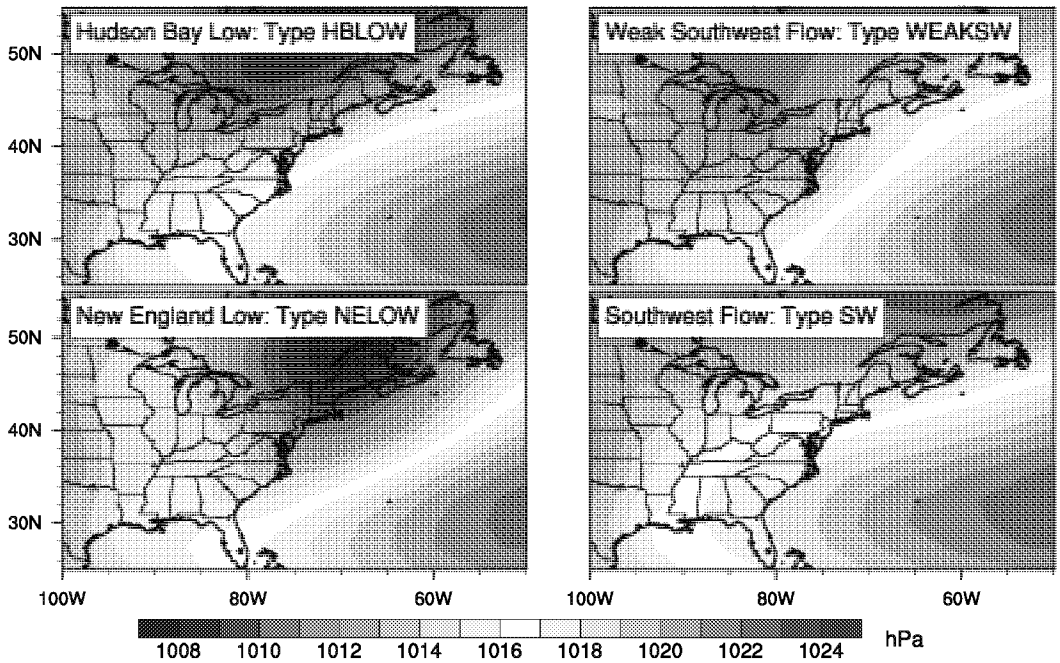


FIG. 4. Sea level pressure (hPa) composites from NCEP NCAR reanalysis data for the four synoptic types used to evaluate HO days.

types using SLP [Eq. (1)]. The day $t$ was assigned the type $j$ that had the highest correlation, as long as it was greater than a minimum threshold of 0.5. Furthermore, if the model day was classified as NELOW, SW, HBLOW, or WEAKSW, then it was a possible HO day.

However, classifying a climate model day as one of the four HO synoptic types is necessary but not sufficient

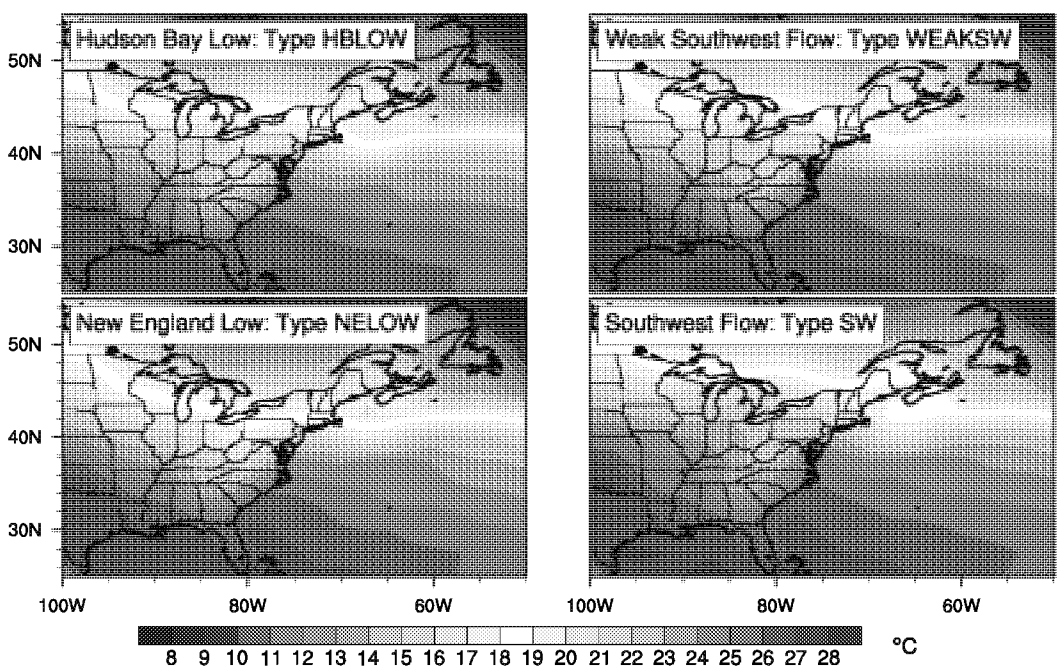


FIG. 5. Near surface temperature (°C) composites from NCEP NCAR reanalysis data for the four synoptic types used to evaluate HO days.

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for a HO day to occur. Based on our analysis of observed HO days in observations and reanalysis data, there are two additional conditions that must be met for a high-ozone day to occur.

First, high temperatures are required within those four HO synoptic types. We determined that 90% of the HO events that occurred during synoptic type SW (the warmest type) had a daily mean temperature of 25.5°C or higher. Although the other three HO synoptic types had lower temperature thresholds, we selected 25.5°C in order to capture the more "extreme" cases of the other three types and to minimize the probability of false HO days. Note that this threshold is for the mean daily temperature; the daily highest temperature on HO days consistently exceeded 32°C (90°F), but mean temperature is used since that variable is more readily available in the CMIP5 archive. Also, the choice of 25.5°C allowed us to better capture the observed distribution of HO days over the four synoptic types during the last decade (2006 15). Since ultimately we want to compare future climate to the present, it is more reasonable to calibrate our criteria based on the last decade of the historical period.

Second, only days when there was no measurable precipitation in the models (defined as less than 1 mm day $^{1}$) were considered to be favorable to high ozone. Precipitation prevents ozone formation because of both reduction of sunlight, which drives the photochemical reactions, and washout of the available precursor pollutants.

In summary, any model day that met all three criteria (HO synoptic type, mean daily temperature above 25.5°C, and precipitation below 1 mm day $^{1}$) was classified as an HO day.

## 4. Results

This section describes the results of the application of the three criteria described previously in section 3c to the five selected CMIP5 models, for the 30-yr historical record (1986 2015) and two future decades: 2025 34 and 2045 54. Before presenting the results, we would like to point out a few important properties of climate simulations that will help interpreting the findings of this study.

First, we do not expect an HO day in the model to exactly match an HO day in the real world. Weather evolves in a climate model the same way as it does in the real world, but not on a day-to-day or year-to-year basis. For example, if temperature was above 35°C on 1 September 2015, it is not expected to be above 35°C on the same day or year in the climate model. Rather, the climate model should have the same frequency of days above 35°C as the real world over the course of a decade. With respect to ozone, climate models are not expected to perfectly capture the number of HO days year by year, but rather the characteristics of the underlying variability and frequency over time scales of a decade or longer. In other words, the model results show how the number of HO days would have changed over the past 30 years if the regulatory and societal factors were held constant at 2015 levels (i.e., a standard of 70 ppb for 8-h average ozone, along with 2015 emission standards and industry pollution controls). This allows the climate models to provide estimates of how the number of HO days would fluctuate solely because of the climate, and not to societal and regulatory changes.

Second, since climate models do not account for changes in regulations or emissions that impact air pollution but do account for the positive correlation between ozone and temperature, the historical climate simulations will show increasing ozone days because of warming (as discussed shortly in section 4a), while observations previously indicated decreasing HO days because of air quality protection legislation and emission regulations (section 3a). Nonetheless, there is still value in analyzing trends in climate models over the historical period because 1) they explain how HO frequency is impacted by climate change alone and 2) they provide a baseline for comparison against future projections of HO days.

### *a. Trends in high-ozone days from the CMIP5 climate models*

The selected CMIP5 models were first evaluated for the 30-yr historical period from 1986 to 2015. This allows for assessment of the performance of the detection algorithm for a period of time for which ozone observation data were readily available. Recall that we calibrated our ozone day detection algorithm using the period 2006 15 (section 3c). Using this decade, we see that the average number of ozone days is about 16 yr $^{1}$ by 2015 (Fig. 6a), which slightly underestimates the observed number of days by three according to the trend line in Fig. 2. The most noticeable feature in Fig. 6a is that the number of HO days simulated by the CMIP5 models increases, which may appear to contradict the observations shown in Fig. 2. However, regulations introduced during the 30-yr period, accompanied by advances in emissions reducing technologies (e.g., improved automobile fuel economy), resulted in a decline in HO days. The effects of these changes are not included in climate models. Therefore, the models show increasing HO days because of the higher temperatures simulated in response to elevated greenhouse gases. Effectively, the models show an approximation of the number of HO days that would have been expected earlier in the time

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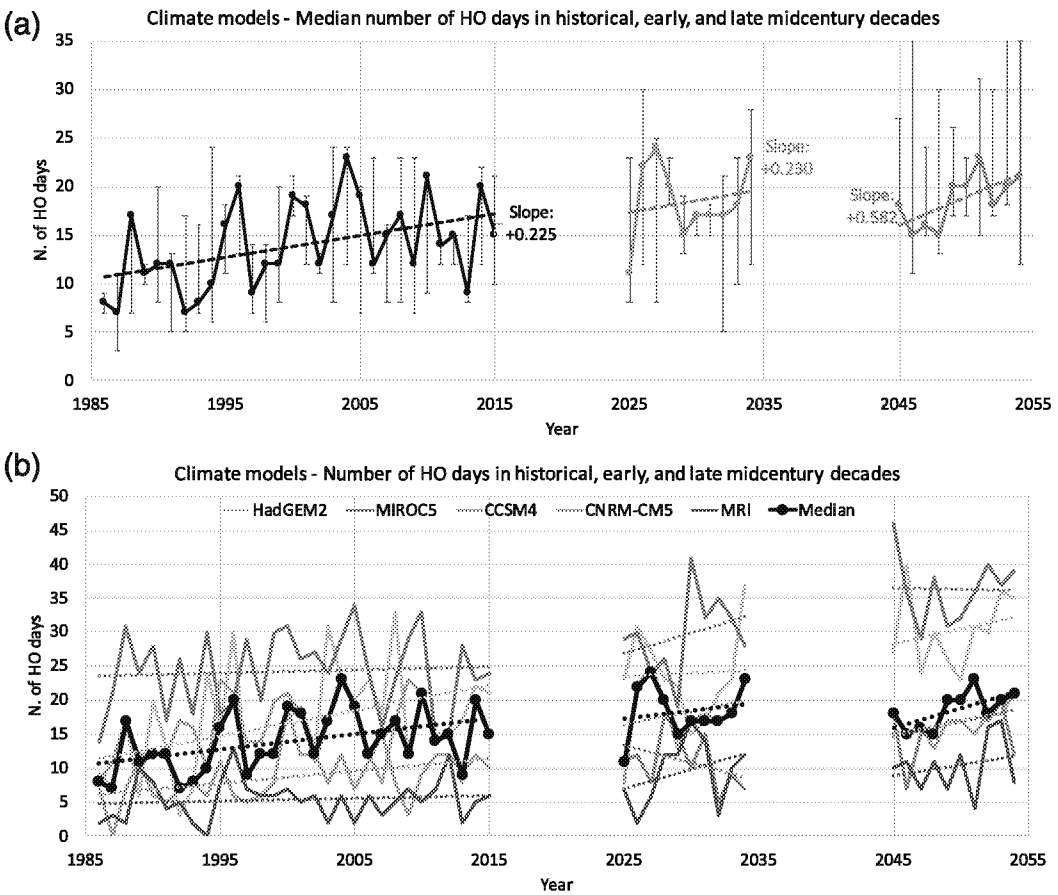


FIG. 6. Number of HO days predicted by the five CMIP5 climate models during the 30 yr historical period (1986 2015), the early midcentury (2025 34), and the late midcentury (2045 54). (a) The median of the five models is shown with error bars corresponding to the first and third quartiles; the trend lines are drawn with dashes and their slopes (HO days yr $^{1}$) are indicated. (b) The individual models are shown with thin colored lines, the median of the five models with a thick black line, and the trends with dotted lines.

period if emissions standards were consistent over the full 30-yr period. The models that simulate the highest number of HO days are the HadGEM2 and MIROC5 models, with between 20 and 23 HO days (Fig. 6b). All the models show a positive trend over 1986 2015, although the values vary from +0.04 to +0.37 HO days yr $^{1}$. The slope of the model median over the entire 30-yr period is +0.225 HO days yr $^{1}$, which means that it takes about 5 years to add another HO day per year. Since the criteria were tuned to the most recent decade (2006 15), the model results match the observations very well during those 10 years, but underestimate the number of HO days in the two earlier decades.

Next we look at two future decades (2025 34 and 2045 54) in Figs. 6. The slope of the median during the early midcentury is similar to the historical period (+0.230 HO days yr $^{1}$). Therefore, it takes about four years to increase the number of HO days by one. However, the trend accelerates during the late midcentury, increasing to +0.582 HO days yr $^{1}$, corresponding to an additional ozone day every 2 years. The variability does not change between the three periods, as the coefficient of variation is approximately the same (0.53, 0.52, 0.51, respectively, for 2006 15, 2025 34, and 2045 54).

All models show an increase in the number of HO days in the two midcentury periods compared to the historical period (Fig. 6b). There is a fairly wide spread in the number of HO days projected by the models with a range of 10 35 HO days by 2055. The Meteorological Research Institute (MRI) model projects the lowest number of HO days in all three periods, although notably the number of HO days increases in the later two periods. MIROC5 shows consistently high numbers of HO days in all three periods, with 25 HO days in the historical period and 40 HO days by the end of 2055. CCSM4 is similar to the model median for all periods. Some models show variability between the two midcentury periods, with more HO days during 2025 35

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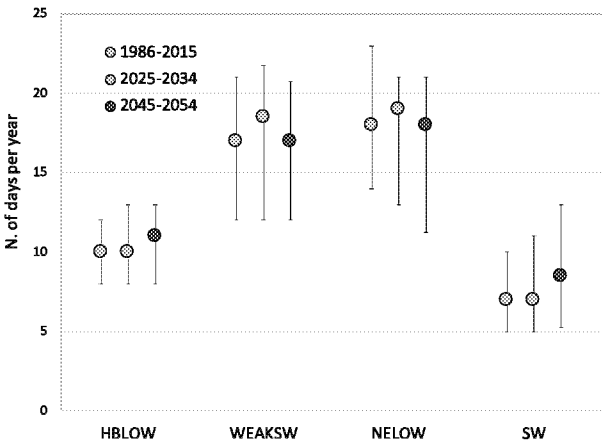


FIG. 7. Median frequency (days yr $^{-1}$) of the four HO synoptic types (HBLOW, WEAKSW, NELOW, and SW) from the five CMIP5 climate models during the historical (1986–2015; gray), early midcentury (2025–34; yellow), and late midcentury (2045–54; red) periods. The error bars represent the quartiles.

than during 2045–55. This is not unexpected because of the use of two fairly short periods in the midcentury, since the different representative concentration pathways do not diverge until the midcentury (IPCC 2013) and the radiative forcing remains below 5 W m $^{-2}$.

### b. *Climatic factors driving high-ozone-day changes*

The increases in HO days projected by the models may be the result of three factors: an increase in the frequency of synoptic types conducive to HO days (i.e., the four HO synoptic types SW, NELOW, HBLOW, and WEAKSW); an increase in daily mean temperature; and a decrease in the number of days with precipitation.

Starting with the synoptic types first, Fig. 7 shows the median predictions of number of days in each of the four HO synoptic types (without using the temperature or precipitation criteria). For two of the types (WEAKSW and NELOW), the frequency does not change substantially between the three periods, although it never decreases from the historical to the late midcentury period. However, there is a noticeable increase in the number of SW synoptic type days (by +1.5 days yr $^{-1}$, from 7 to 8.5 days yr $^{-1}$) in 2045–54 relative to the historical period. Also synoptic type HBLOW is projected to occur with higher frequency in 2045–54 than in the historical period (by +1 day yr $^{-1}$, from 10 to 11 days yr $^{-1}$), although less significantly that the SW type.

The increase in the number of SW and HBLOW synoptic type events (+1.5 and +1 days yr $^{-1}$, respectively, for a total of +2.5 days yr $^{-1}$) is smaller than the overall increase in HO days (+5 days yr $^{-1}$, Fig. 6). Because HO days in the model simulations must be one of these four synoptic types (i.e., changes in other synoptic types are not considered), increases in temperature or increases in the frequency of dry days (or decreases in the frequency of days with precipitation) must be contributing to the increase in HO days. To evaluate this, we examined what changes the models showed over the summer months in the average daily mean temperature and in the number of dry days predicted. Overall, the models did not show any statistically significant trends in the number of dry days (not shown). However, the models did predict an increase in the average daily mean temperature (Fig. 8); the overall model mean increased from 24°C in 1986 to nearly 27°C in 2054, a change in mean summer temperature of +0.38°C decade $^{-1}$. By the

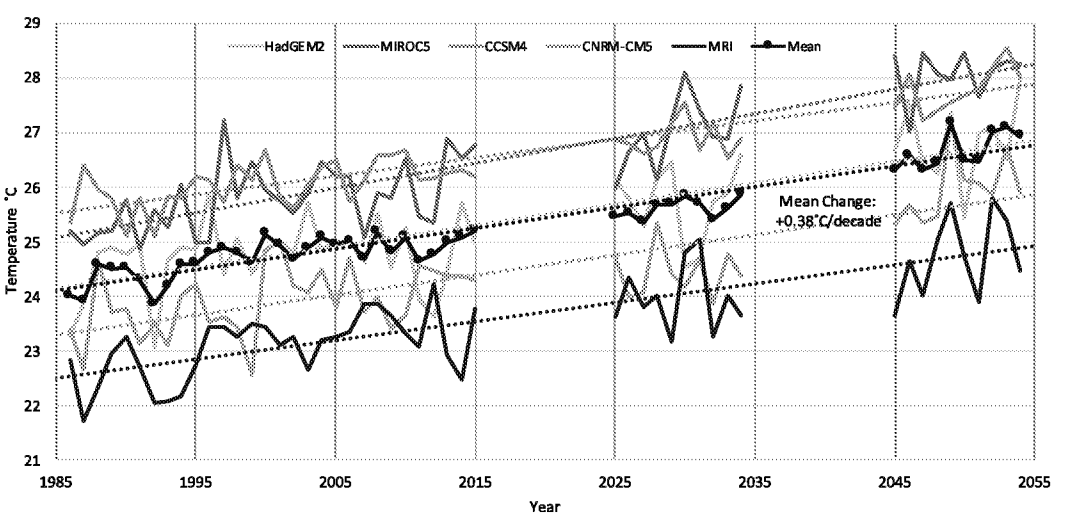


FIG. 8. Change in mean daily temperature over Delaware during the summer season for the five CMIP5 climate models, along with the model mean temperature.

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decade 2045 54, in fact, the five-model daily mean temperature exceeded the 25.5°C threshold that we adopted for HO days every year. Furthermore, it can be seen in Fig. 8 that the model with the lowest mean summer temperature, MRI, also predicted the fewest HO days (Fig. 6b), while one of the warmest climate models, MIROC5, also predicted the most HO days. This confirms qualitatively the importance of underlying temperature changes, not only synoptic type frequency changes, to the projected increases in the number of HO days by midcentury.

## 5. Discussion and conclusions

In this study, we examined climate model projections for the mid-twenty-first century to determine how the number of days with ozone levels high enough to be unhealthy for sensitive populations HO days may change over the mid-Atlantic. We used a two-step approach. First we identified the atmospheric circulation patterns ("synoptic types") that were most likely to occur during observed HO days in the past. Four synoptic patterns are associated with high-ozone days over the mid-Atlantic: New England low (NELOW), southwesterly flow (SW), weak southwesterly flow (WEAKSW), and Hudson Bay low (HBLOW). Second, we imposed two other criteria: no precipitation and high daily mean temperatures (exceeding 25.5°C).

Next we applied the three criteria above to five selected CMIP5 models (HadGEM2, MIROC5, CCSM4, CNRM-CM5, and MRI) to calculate the frequency of HO days in the future. Before looking at the RCP8.5 midcentury projections, however, we prepared model predictions for the historical period of 1986 2015, to establish a baseline for comparison. Midcentury projections from the five CMIP5 models show that HO days are expected to increase, from about one extra HO day every 5 years to 1 extra HO day every 2 years. This is due to an increase in the frequency of HO synoptic types (in particular, the dominant SW type associated with southwesterly flow) and to increases in temperature, without noticeable changes in the frequency of dry days.

Historically, the number of high-ozone days in Delaware decreased by 2 days every year because of stricter air quality regulations, despite the underlying increases in temperature due to increasing greenhouse gases. Our results indicate that this progress will be partially negated as temperatures continue to increase and southwesterly-flow synoptic types become more frequent. Therefore, maintaining current ozone levels will require even stricter regulations than currently exist. Our study focused on the frequency of HO days. However, the ozone concentration during HO days itself may also increase (i.e., more intense HO days).

Future work should focus on quantifying these potential changes and their direct health impacts. In addition, other synoptic types, not currently associated with HO days, may become HO types in the future; some synoptic types may disappear; and entirely new HO synoptic types may manifest themselves. Thus we may be underestimating the changes in future HO days. Future studies should also examine spring and fall, as these transition seasons are expected to become warmer in the future, and look for potential changes in the duration of HO events.

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# Attachment 2

Circulation

ORIGINAL RESEARCH ARTICLE

# Long-Term Association of Air Pollution and Hospital Admissions Among Medicare Participants Using a Doubly Robust Additive Model

**BACKGROUND:** Studies examining the nonfatal health outcomes of exposure to air pollution have been limited by the number of pollutants studied and focus on short-term exposures.

**METHODS:** We examined the relationship between long-term exposure to fine particulate matter with an aerodynamic diameter <2.5 micrometers ($PM_{2.5}$), $NO_2$, and tropospheric ozone and hospital admissions for 4 cardiovascular and respiratory outcomes (myocardial infarction, ischemic stroke, atrial fibrillation and flutter, and pneumonia) among the Medicare population of the United States. We used a doubly robust method for our statistical analysis, which relies on both inverse probability weighting and adjustment in the outcome model to account for confounding. The results from this regression are on an additive scale. We further looked at this relationship at lower pollutant concentrations, which are consistent with typical exposure levels in the United States, and among potentially susceptible subgroups.

**RESULTS:** Long-term exposure to fine $PM_{2.5}$ was associated with an increased risk of all outcomes with the highest effect seen for stroke with a 0.0091% (95% CI, 0.0086–0.0097) increase in the risk of stroke for each 1-μg/m$^3$ increase in annual levels. This translated to 2536 (95% CI, 2383–2691) cases of hospital admissions with ischemic stroke per year, which can be attributed to each 1-unit increase in fine particulate matter levels among the study population. $NO_2$ was associated with an increase in the risk of admission with stroke by 0.00059% (95% CI, 0.00039–0.00075) and atrial fibrillation by 0.00129% (95% CI, 0.00114–0.00148) per ppb and tropospheric ozone was associated with an increase in the risk of admission with pneumonia by 0.00413% (95% CI, 0.00376–0.00447) per parts per billion. At lower concentrations, all pollutants were consistently associated with an increased risk for all our studied outcomes.

**CONCLUSIONS:** Long-term exposure to air pollutants poses a significant risk to cardiovascular and respiratory health among the elderly population in the United States, with the greatest increase in the association per unit of exposure occurring at lower concentrations.

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**Key Words:** air pollution ▪ atrial fibrillation ▪ environment ▪ epidemiology ▪ ischemic stroke ▪ myocardial infarction ▪ pneumonia

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## Clinical Perspective

### What Is New?

- Long-term exposure to air pollution was associated with an increased risk of hospital admissions with cardiovascular and respiratory outcomes on an additive scale among the elderly population of the United States.
- Each unit increase in levels of particulate matter, nitrogen dioxide, and ozone were associated with thousands of additional admissions each year.

### What Are the Clinical Implications?

- Air pollution should be considered as a risk factor for cardiovascular and respiratory disease.
- The risk persists even at levels below current national and international guidelines.
- Patients should be conscious of the air quality in the region where they live to avoid harmful exposure over long periods of time.

Recent studies looking at the nonfatal health effects of air pollution have shifted their focus from short- to long-term exposure.[1–17] The effect estimates from studies on long-term exposure tend to be larger than studies on short-term exposure.[9,18] Furthermore, more studies are now exploring multiple air pollutants simultaneously in recognition of the fact that air pollution is a mixture of compounds with varying toxicities.[7,15,19] These changes suggest that current regulations may need to be amended. Some pollutants such as tropospheric ozone ($O_3$) do not have any national regulations on long-term exposure.

As research on the effect of long-term exposure to air pollution and health continues to proliferate, most of the current studies focus on mortality outcomes and estimate effects on a multiplicative scale, which are more difficult to interpret clinically because they depend on the distribution of other risk factors.[10,11,20,21] Cox proportional hazards models, for example, result in hazard ratios that are often interpreted interchangeably with relative risks, even though they are not the same.[22] Multiplicative models also make it more difficult to evaluate effect modification and identify vulnerable subpopulations. Cox proportional hazards models have multiplicative interactions built in to the model, which limits interpretability of further interactions in the model. Moreover, the Cox proportional hazards model provides an estimate of the effect of exposure that is conditional on the covariates and the baseline hazard. This makes use of those coefficients to estimate the attributable cases or risk problematic. In an additive model, the coefficients represent the risk difference as a result of exposure and the coefficients for interaction terms represent the additional risk difference in the subpopulation without reference to the baseline hazard or conditional on the distribution of the covariates. In addition, few studies use the propensity score–based doubly robust method that is often required to sway regulatory policy.[7,23–25] This limits knowledge on nonfatal outcomes and limits our ability to make convincing inferences to convince regulators. The studies that use causal methods often explore a single pollutant at a time and not the variety of compounds that comprise air pollution.

To address this gap, our study examines the relationship between average annual fine particulate matter (fine particulate matter with an aerodynamic diameter <2.5 micrometers [$PM_{2.5}$]), $NO_2$, and $O_3$, and 4 cardiovascular and respiratory hospitalization outcomes (myocardial infarction [MI]; ischemic stroke; atrial fibrillation and flutter; and pneumonia) using a doubly-robust additive model (DRAM) in fee-for-service Medicare beneficiaries across the contiguous United States from 2000 to 2016. In these models, we adjusted for multiple pollutants. We further evaluated effect measure modification (EMM) by demographic characteristics to identify particularly susceptible subpopulations.

## METHODS

The data and materials used in this study will not be made available publicly or to other researchers because of restrictions in the data use agreement with the Centers for Medicare and Medicaid Services (CMS). However, CMS data are publicly available to researchers on completion of separate data use agreements. In this study, we examined the relationship between long-term exposure to (1) $PM_{2.5}$, $NO_2$, and $O_3$ and (2) first hospital admissions with several cardiovascular and respiratory diseases on an additive scale.

### Study Population

Our full cohort consisted of all fee-for-service Medicare beneficiaries who were 65 years of age or older and who lived in the contiguous United States between 2000 and 2016. These data were derived from the Medicare denominator file and the Medicare Provider Analysis and Review file. We created a separate dataset for each outcome of interest. Patients entered the cohort on January 1 of the year after enrollment and were followed until they developed the outcome of interest, died, were censored, or reached the end of the follow-up time.

### Exposure Assessment

$PM_{2.5}$, $O_3$, and $NO_2$ levels were derived from high-resolution spatiotemporal ensemble models, each of which combined estimates from 3 different machine learning algorithms, including a neural network, a gradient boosting machine, and a random forest.[26–28]

The models used hundreds of predictors including land use terms, chemical transport model predictions, meteorologic variables, and satellite measurements to estimate daily levels of the pollutants on a scale of 1 km × 1 km. The advantage of using these machine learning techniques is that they make

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no assumptions about the functional form of the relationships between the predictors and the outcome. The quality of the estimates was assessed using 10-fold cross-validation against measured values at Environmental Protection Agency monitoring sites across the United States. The resulting $R^2$ values of 0.89, 0.84, and 0.86 for the annual averages of $PM_{2.5}$, $NO_2$, and $O_3$, respectively, show excellent model performance.[26–28] Grid-cell values were averaged across zip codes. Exposure was assigned on the basis of the residential zip code of the beneficiary. Long-term exposure in our study is defined as the calendar year average of daily estimates.

## Outcome Assessment

The dataset contains all hospital admissions for Medicare fee-for-service beneficiaries from 2000 through 2016. Medicare used *International Classification of Diseases, Ninth Revision* (*ICD-9*) codes through the end of the third quarter of 2015 and then switched to *International Classification of Diseases, Tenth Revision* (*ICD-10*). Primary discharge codes for myocardial infarction were defined as *ICD-9* codes 410.X0 and 410.X1 and *ICD-10* code I21 as the primary discharge code. Primary discharge codes for ischemic stroke were defined as *ICD-9* codes 433.X1, 434.X1, and 436, and *ICD-10* code I63 as the primary discharge code. Primary discharge codes for pneumonia were defined as *ICD-9* codes 003.22, 011.6, 055.1, 073.0, 115.05, 115.15, 115.95, 480, 481, 482, 483, 484, 485, 486, 487.0, 488.01, 488.11, 488.81, 516.3, 517.1, and 997.32, and *ICD-10* codes A01.03, A02.22, A20.2, A21.2,A22.1, A37.X1, A42.0, A43.0, A48.1, A54.84, A69.8, B01.2, B05.2, B06.81, B25.0, B37.1, B38.0,B39.0, B44.0, B44.1, B58.3, B59, B77.81, J15, J09.X1, J10.0, J11.0, J12, J13, J14, J17, J18, J84.2, J85.1, and J95.851 as primary discharge codes. Primary discharge codes for atrial fibrillation and flutter were defined as *ICD-9* code 427.3 and *ICD-10* code I48 as the primary discharge codes.

## Covariate Assessment

We obtained data on individual-level covariates sex, race, age group, and Medicaid eligibility from the Medicare denominator file. We used data from the US Census and the American Community Survey to find zip code–level socioeconomic data: proportion of the population >65 years of age living below the poverty line, population density, median value of owner occupied properties, proportion of the population listed as Black, median household income, proportion of housing units occupied by the owner, proportion of the population identified as Hispanic, and proportion of the population >65 years of age who had not graduated from high school. Measured data were available for 2000 and 2010 through 2016. Data for all other years and missing values were obtained using linear interpolation and extrapolation.

The lung cancer hospitalization rate in each zip code was used as a proxy for smoking and was derived from Medicare Provider Analysis and Review.[29–31]

We derived zip code–level data on mean body mass index and the smoking rate from the Behavioral Risk Factor Surveillance System. Behavioral Risk Factor Surveillance System data were collected at the county level and then linked to relevant zip codes and temporally interpolated using linear regression to fill in missing values.

We obtained zip code–level data on several access-to-care variables: proportion of Medicare beneficiaries with at least 1 hemoglobin A1c test in a year; proportion of elderly diabetic beneficiaries who had a lipid panel test in a year; proportion of beneficiaries who had an eye examination in a year; proportion of beneficiaries with at least 1 ambulatory doctor visit in a year; and proportion of female beneficiaries who had a mammogram during a 2-year period. These were obtained from the Dartmouth Atlas of Health Data. Data were collected at the hospital service area–level and linked to the relevant zip code. Missing values were filled in using linear interpolation. We also included region of residence to account for geographic differences and distance to hospital as a variable to measure access to health care. The distance to the nearest hospital was calculated from the centroid of the residential zip code of the patient. Hospital locations across the United States were derived from an ArcGIS dataset.[32]

Observations with missing exposure or covariate information were assumed to be missing at random and were excluded from further analysis. These represented less than 1% of the data.

## Statistical Analysis

We examined the relationship between long-term exposure to $PM_{2.5}$, $NO_2$, $O_3$, and admissions with cardiovascular and respiratory outcomes using a doubly robust additive model (DRAM). Specifically, confounding is accounted for through 2 mechanisms: first, in inverse probability weights of exposure; and second, by adjustment in the outcome regression model. If either of the models is correctly specified, the estimated coefficient is unbiased.[33] The equation for this model is as follows:

$$Pr(Admissions_{ij}) = \beta_0 + \beta x_{ij} + s(v_{ij}, \gamma)$$

$$= \beta_0 + \beta x\ (pollutant\ of\ interest)_{ij} + age + race + sex + year + region\ of\ residence + Medicaid\ eligibility + distance\ to\ nearest\ hospital + other\ pollutant\ 1 + other\ pollutant\ 2 + pct_eye_exam + pct_lipid_panel + pct_mammogram + pct_in_poverty + median\ house\ value + pct_below_high_school_education + median\ household\ income + pct_pop_black + pct_pop_hispanic + population\ density + lung\ cancer\ rate + pct\ owner\ occupied\ housing + pct_ambulatory_care_appt + pct_HgbA1c_exam + mean\ BMI + smoking\ rate$$

where $Pr\ (Admissions_{ij})$ represents the probability of the outcome for individual $i$ in year $j$, $x$ represents the exposure, $v$ represents the vector of covariates, and $\gamma$ represents the parameterization (eg, coefficients) of the covariates. In this case, the parametrization was assumed to be linear. This equation is weighted using stabilized inverse probability weighting for exposure from the following formula:

$$SW_{ij} = \frac{f(x)}{f(x|v)}$$

where $x$ represents the exposure and $v$ represents the covariates. In this case, we defined $f(x|v)$ as the probability density

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of the exposure on the basis of a linear regression with the exposure of interest as the outcome and the covariates and other pollutants as the predictors. For example, in the model for $PM_{2.5}$, we adjusted for individual and socioeconomic and behavioral covariates as well as $O_3$ and $NO_2$. The same covariates and other pollutants were adjusted for in the outcome regression model as well.

Assuming that (1) the underlying true outcome regression model follows the additive structure $Pr(Admissions_{ij}) = \beta_0 + \beta x_{ij} + s'(v_{ij}, \gamma)$, where $s'$ may or may not be the same as $s$; and (2) either the inverse probability weighting or the functional form of $s$ is correctly specified (ie, $s = s'$), the resulting risk difference estimate is consistent. To account for outliers, we trimmed the weights: values >99th percentile were given the value at the 99th percentile and values <1st percentile were given the value at the 1st percentile.

We ran 200 bootstraps of the weighted outcome regression for each analysis. The median value was used as the coefficient of interest and the 2.5 percentile and 97.5 percentile constituted the 95% CI.

We evaluated effect modification by sex, race, Medicaid eligibility, and age group using stratification. The coefficients from each stratum were compared with one another to identify vulnerable subpopulations. We also conducted a subgroup analysis on person-years with pollutant levels below international regulations. For $PM_{2.5}$, we restricted to individuals with levels <10 μg/m³ for all years; for $NO_2$, we restricted to individuals with levels <20 ppb for all years; and for $O_3$, we restricted to individuals with levels <40 ppb for all years with effect measure modification analyses for these subsets as well. As a sensitivity analysis, we calculated E-values for our main results. E-values measure the magnitude of the relationship a hypothetical unmeasured confounder would have to have with both the exposure and the outcome to fully account for the effect estimate that has been found.[34] A schematic of how the study was constructed and carried can be seen in Figure 1.

All data cleaning and statistical analyses were conducted in R Statistical Software (version 3.6.1) and the inverse probability weighting and outcome regression estimates were obtained using the "biglm" package.[35] Data cleaning and analysis was completed on the Research Computing Environment as part of Research Computer at Harvard University Faculty of Arts and Sciences.

This study was approved by the Harvard School of Public Health Institutional Review Board.

## RESULTS

The cohort consisted of 63 006 793 Medicare beneficiaries who used the fee-for-service program from 2000 to 2016 in the contiguous United States. Demographic characteristics for these individuals can be seen in Table 1. There are slightly more women than men, and most participants are White. Of the observations used in the analyses, 85% were not Medicaid-eligible, and about half were between 64 and 75 years of age. The majority of the observations came from the southern and midwestern regions of the United States.

Table 2 shows the distribution of air pollutants across the contiguous United States from 2000 to 2016. Annual average levels of $PM_{2.5}$ and $NO_2$ were generally low, below the Environmental Protection Agency annual standard of 12 μg/m³ and 53 ppb. $O_3$ does not have an annual standard level, but the levels are below the daily standard of 70 ppb.[36] This distribution also reveals that our lower exposure analysis, which was subset to only include individuals with lower values, was largely consistent with prevailing levels that a person might typically experience.

The distribution of weights across person-years in 1 of our datasets (MI) can be seen, after trimming, in Table 3. The distribution across years is largely consistent, and no observation received extreme weight values.

The results of our primary analysis can be seen in Figure 2A and Table 4. Long-term exposure to $PM_{2.5}$ was associated with a statistically significant increase in the risk of all outcomes. This translated to thousands of hospital admissions attributable to air pollution per year. For example, there were 2536 (95% CI, 2383–2691) additional admissions for each 1 μg/m³ increase in $PM_{2.5}$ for ischemic stroke, 637 (95% CI, 483–814) for myocardial infarction, 1575 (95% CI, 1426–1691) for atrial fibrillation, and 2489 (95% CI, 2245–2738) for pneumonia. Long-term exposure to

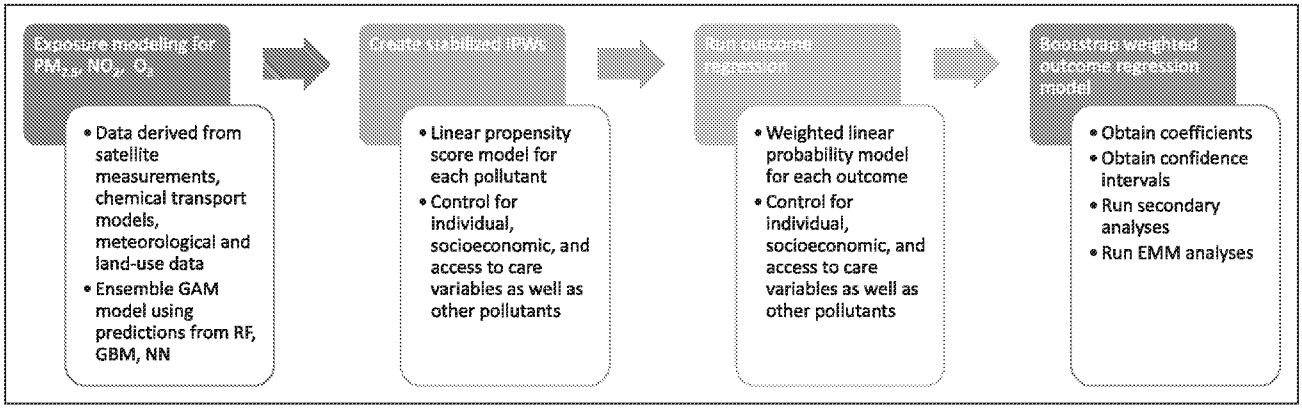


**Figure 1. Study design schematic.**
Flow chart of how study was conducted step-by-step.

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**Table 1. Demographic Characteristics of Medicare Fee-for-Service Patients**

| Variable | N (%) |
|---|---|
| Individual characteristics (N=63 006 793) | |
| Sex | |
| Female | 34 725 250 (55.11) |
| Male | 28 281 543 (44.89) |
| Race | |
| White | 53 207 613 (84.45) |
| Black | 5 511 770 (8.75) |
| Other | 4 287 410 (6.80) |
| Demographic characteristics, person-years (N=538 173 801) | |
| Medicaid eligibility | |
| Yes | 76 042 269 (14.13) |
| No | 462 131 532 (85.87) |
| Age group, y | |
| 65–74 | 277 788 354 (51.62) |
| 75–84 | 181 809 593 (33.78) |
| ≥85 | 78 575 854 (14.60) |
| US region | |
| Northeast | 105 812 685 (19.66) |
| Midwest | 132 107 154 (24.55) |
| South | 209 831 299 (38.99) |
| West | 90 422 663 (16.80) |

$NO_2$ was associated with an increased risk of stroke and atrial fibrillation and showed a negative effect for admissions of MI and pneumonia. Long-term exposure to $O_3$ led to mixed results; it increased the risk of pneumonia admissions, but the coefficient was negative for stroke and atrial fibrillation. The E-values suggested that the $PM_{2.5}$ model was the most robust to unmeasured confounding (the E-values are reported on the multiplicative scale). This meant that if an unmeasured confounder exits, it would need to have a stronger relationship with both the exposure and the outcome to fully explain away the harmful effects we observed. In general, the trend showed higher E-values for relationships where we found harmful effects versus those that had negative coefficients.

We further looked at hospital admissions for individuals who had low pollutant concentration throughout the follow-up period (Figure 2B). For all pollutants, the association of hospital admissions increased for cardiovascular and respiratory outcomes with larger effect size estimates. This shows that the greatest increase in the risk of admissions per unit change in exposure occurs at lower concentrations of air pollutants.

One of the advantages of our additive model is that effect measure modification can be measured on an additive scale. We assessed effect modification by Medicaid eligibility, sex, race, and age group for all of our pollutants and outcomes. Figure 3A shows the results for this analysis and MI. The results vary by pollutant. For $PM_{2.5}$, older beneficiaries were at a higher risk of admission as compared with younger beneficiaries, and White individuals had a higher risk of admission as compared with Black individuals. For $NO_2$, the stratified analysis was generally negative. However, Black individuals were at a higher risk than White individuals. For $O_3$, those who were Medicaid-eligible, male, and younger had a higher probability of hospital admission with an MI as compared with those who were not Medicaid-eligible, female, and older, respectively.

The results of the EMM analysis for ischemic stroke can be seen in Figure 3B. For $PM_{2.5}$, older participants had a significantly higher risk of admission than younger individuals. For $NO_2$, those who were not Medicaid-eligible were at a higher risk than those who were Medicaid-eligible and Black individuals were at a higher risk than White individuals. The results for the stratified ozone analysis showed negative coefficients.

Figure 3C shows the results of the EMM analysis for atrial fibrillation and flutter. For $PM_{2.5}$, those not Medicaid-eligible, White, and older were at increased risk of admission. Similarly, for $NO_2$, those who were not Medicaid-eligible and older had a higher probability of being admitted with atrial fibrillation than those who were Medicaid-eligible and younger. For ozone, the stratified analyses showed a generally protective effect.

The results for the EMM analysis of pneumonia are shown in Figure 3D. For $PM_{2.5}$, those who were Medicaid-eligible, Black, or in older age groups are at increased risk of admission with pneumonia as compared with those who are not. In contrast, the stratified analyses for $NO_2$ and pneumonia show a negative effect estimate for most subsets. Last, exposure to ozone was associated with a higher probability of admission with atrial fibrillation and flutter among those who are Medicaid-eligible, White, or in older age groups.

**Table 2. Exposure Distribution of Pollutants Across Person-Years**

| Variable | Minimum | 10th Percentile | 25th Percentile | Mean | Median | 75th Percentile | 90th Percentile | Maximum |
|---|---|---|---|---|---|---|---|---|
| $PM_{2.5}$ (μg/m³) | 0.01 | 6.36 | 8.11 | 10.21 | 10.05 | 12.29 | 14.32 | 30.92 |
| $NO_2$ (ppb) | 0.01 | 8.13 | 11.51 | 19.50 | 17.44 | 25.88 | 33.88 | 127.63 |
| $O_3$ (ppb) | 18.31 | 33.88 | 36.56 | 38.77 | 38.75 | 40.92 | 43.74 | 65.09 |

$O_3$ indicates tropospheric ozone; and $PM_{2.5}$, fine particulate matter with an aerodynamic diameter <2.5 micrometers.

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Table 3. Distribution of Inverse Probability Weights Across Years for Myocardial Infarction, After Trimming

| Pollutant and year | Minimum | 10th | 25th | Mean | Median | 75th | 90th | Maximum |
|---|---|---|---|---|---|---|---|---|
| $PM_{2.5}$ | | | | | | | | |
| 2000 | 0.159 | 0.342 | 0.614 | 1.301 | 1.024 | 1.386 | 2.319 | 8.414 |
| 2001 | 0.159 | 0.359 | 0.652 | 1.285 | 1.031 | 1.366 | 2.212 | 8.414 |
| 2002 | 0.159 | 0.457 | 0.746 | 1.320 | 1.059 | 1.360 | 2.199 | 8.414 |
| 2003 | 0.159 | 0.462 | 0.731 | 1.264 | 1.041 | 1.341 | 2.054 | 8.414 |
| 2004 | 0.159 | 0.543 | 0.806 | 1.306 | 1.072 | 1.359 | 2.089 | 8.414 |
| 2005 | 0.159 | 0.425 | 0.696 | 1.258 | 1.030 | 1.339 | 2.112 | 8.414 |
| 2006 | 0.159 | 0.645 | 0.873 | 1.292 | 1.076 | 1.337 | 1.980 | 8.414 |
| 2007 | 0.159 | 0.563 | 0.812 | 1.275 | 1.060 | 1.325 | 1.996 | 8.414 |
| 2008 | 0.159 | 0.737 | 0.973 | 1.325 | 1.104 | 1.370 | 1.992 | 8.414 |
| 2009 | 0.159 | 0.688 | 0.969 | 1.354 | 1.116 | 1.409 | 2.095 | 8.414 |
| 2010 | 0.159 | 0.631 | 0.929 | 1.299 | 1.102 | 1.369 | 1.987 | 8.414 |
| 2011 | 0.159 | 0.722 | 0.999 | 1.342 | 1.119 | 1.396 | 2.023 | 8.414 |
| 2012 | 0.159 | 0.619 | 0.942 | 1.396 | 1.116 | 1.459 | 2.243 | 8.414 |
| 2013 | 0.159 | 0.611 | 0.929 | 1.469 | 1.112 | 1.530 | 2.537 | 8.414 |
| 2014 | 0.159 | 0.537 | 0.893 | 1.387 | 1.098 | 1.453 | 2.329 | 8.414 |
| 2015 | 0.159 | 0.523 | 0.855 | 1.442 | 1.088 | 1.522 | 2.598 | 8.414 |
| 2016 | 0.159 | 0.421 | 0.750 | 1.536 | 1.032 | 1.640 | 3.122 | 8.414 |
| All | 0.159 | 0.512 | 0.836 | 1.346 | 1.084 | 1.402 | 2.217 | 8.414 |
| $NO_2$ | | | | | | | | |
| 2000 | 0.094 | 0.382 | 0.800 | 1.405 | 1.040 | 1.398 | 2.434 | 10.817 |
| 2001 | 0.094 | 0.359 | 0.790 | 1.393 | 1.034 | 1.369 | 2.371 | 10.817 |
| 2002 | 0.094 | 0.409 | 0.771 | 1.338 | 1.021 | 1.326 | 2.256 | 10.817 |
| 2003 | 0.094 | 0.395 | 0.754 | 1.321 | 1.018 | 1.310 | 2.212 | 10.817 |
| 2004 | 0.094 | 0.517 | 0.801 | 1.322 | 1.020 | 1.301 | 2.136 | 10.817 |
| 2005 | 0.094 | 0.485 | 0.778 | 1.318 | 1.017 | 1.309 | 2.160 | 10.817 |
| 2006 | 0.094 | 0.527 | 0.778 | 1.292 | 1.015 | 1.283 | 2.031 | 10.817 |
| 2007 | 0.094 | 0.502 | 0.725 | 1.292 | 0.993 | 1.283 | 2.076 | 10.817 |
| 2008 | 0.094 | 0.546 | 0.769 | 1.275 | 1.000 | 1.259 | 1.988 | 10.817 |
| 2009 | 0.094 | 0.542 | 0.759 | 1.266 | 0.994 | 1.250 | 1.996 | 10.817 |
| 2010 | 0.094 | 0.574 | 0.776 | 1.283 | 0.997 | 1.252 | 1.995 | 10.817 |
| 2011 | 0.094 | 0.599 | 0.794 | 1.290 | 1.003 | 1.260 | 2.018 | 10.817 |
| 2012 | 0.094 | 0.670 | 0.837 | 1.316 | 1.014 | 1.269 | 1.966 | 10.817 |
| 2013 | 0.094 | 0.611 | 0.791 | 1.316 | 1.006 | 1.264 | 1.997 | 10.817 |
| 2014 | 0.094 | 0.598 | 0.796 | 1.331 | 1.009 | 1.255 | 2.062 | 10.817 |
| 2015 | 0.094 | 0.625 | 0.804 | 1.337 | 1.011 | 1.259 | 2.048 | 10.817 |
| 2016 | 0.166 | 0.628 | 0.808 | 1.447 | 1.021 | 1.329 | 2.297 | 10.817 |
| All | 0.094 | 0.548 | 0.786 | 1.327 | 1.014 | 1.292 | 2.115 | 10.817 |
| $O_3$ | | | | | | | | |
| 2000 | 0.177 | 0.490 | 0.722 | 1.034 | 0.910 | 1.066 | 1.486 | 6.173 |
| 2001 | 0.177 | 0.584 | 0.807 | 1.072 | 0.952 | 1.084 | 1.486 | 6.173 |
| 2002 | 0.177 | 0.615 | 0.834 | 1.073 | 0.956 | 1.089 | 1.454 | 6.173 |
| 2003 | 0.177 | 0.573 | 0.830 | 1.042 | 0.955 | 1.075 | 1.391 | 6.173 |
| 2004 | 0.177 | 0.512 | 0.775 | 1.035 | 0.943 | 1.066 | 1.401 | 6.173 |
| 2005 | 0.177 | 0.607 | 0.808 | 1.062 | 0.948 | 1.067 | 1.432 | 6.173 |

(Continued)

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Table 3. Continued

| Pollutant and year | Minimum | 10th | 25th | Mean | Median | 75th | 90th | Maximum |
|---|---|---|---|---|---|---|---|---|
| 2006 | 0.177 | 0.537 | 0.750 | 1.010 | 0.921 | 1.038 | 1.393 | 6.173 |
| 2007 | 0.177 | 0.563 | 0.798 | 1.075 | 0.951 | 1.092 | 1.505 | 6.173 |
| 2008 | 0.177 | 0.575 | 0.808 | 1.060 | 0.945 | 1.051 | 1.391 | 6.173 |
| 2009 | 0.177 | 0.413 | 0.774 | 1.061 | 0.954 | 1.120 | 1.506 | 6.173 |
| 2010 | 0.177 | 0.692 | 0.844 | 1.168 | 0.960 | 1.127 | 1.651 | 6.173 |
| 2011 | 0.177 | 0.648 | 0.832 | 1.113 | 0.953 | 1.077 | 1.514 | 6.173 |
| 2012 | 0.177 | 0.675 | 0.865 | 1.115 | 0.963 | 1.113 | 1.536 | 6.173 |
| 2013 | 0.177 | 0.707 | 0.905 | 1.199 | 0.990 | 1.202 | 1.682 | 6.173 |
| 2014 | 0.177 | 0.705 | 0.895 | 1.128 | 0.974 | 1.131 | 1.514 | 6.173 |
| 2015 | 0.177 | 0.709 | 0.905 | 1.132 | 0.981 | 1.148 | 1.539 | 6.173 |
| 2016 | 0.177 | 0.699 | 0.896 | 1.104 | 0.970 | 1.106 | 1.472 | 6.173 |
| All | 0.177 | 0.595 | 0.829 | 1.088 | 0.956 | 1.098 | 1.491 | 6.173 |

$O_3$ indicates tropospheric ozone; and $PM_{2.5}$, fine particulate matter with an aerodynamic diameter <2.5 micrometers.

When looking at the EMM analysis for those exposed to lower concentrations, the harmful effects seen previously persisted across strata for all pollutants and across outcomes (Figure 4). For MI, $PM_{2.5}$ and $NO_2$ were associated with an increased risk of the admissions for men, elderly adults, and those who were Medicaid-eligible as compared with those who were not. $O_3$ increased the risk of hospital admission with MI for men and Black individuals (Figure 4A).

For ischemic stroke (Figure 4B), $PM_{2.5}$ increased the risk of admission for those who were Medicaid-eligible, women, or elderly. For $NO_2$, the more vulnerable subpopulations were those who were Medicaid-eligible, Black, or elderly. For $O_3$, those who were Medicaid-eligible, women, or White were at increased risk of stroke.

$PM_{2.5}$ and $NO_2$ increased the risk of atrial fibrillation and flutter among those who were White and very elderly adults, as compared with those who were not. $O_3$ was found to particularly increase the risk of admission among those who were not Medicaid-eligible and who were White.

For pneumonia, all pollutants increased the risk of hospital admissions among those who were Medicaid-eligible and elderly as compared with those who were not. On the other hand, $PM_{2.5}$ was associated with an increased risk of atrial fibrillation among those who were White while $O_3$ was associated with an increased risk among those who were Black.

## DISCUSSION

The results of our study showed several important trends. First, $PM_{2.5}$ was associated with an increased risk of hospital admissions with all of our studied outcomes. This was particularly true for elderly individuals who were at increased risk. Second, $NO_2$ was associated with an increased the risk of stroke and atrial fibrillation and flutter. This trend was largely consistent across strata. However, $O_3$ was negative in the cardiovascular outcomes but was associated with an increased probability of pneumonia. This is consistent with other literature linking ozone to respiratory outcomes.[37–39] This seemed to suggest that $NO_2$ and $O_3$ confound each other's effects or may be confounded by an unknown or unmeasured variable. Support for this comes from the pattern of $NO_2$, showing positive associations for outcomes where $O_3$ shows negative associations and vice versa. The partial correlation coefficient between the 2 in our data was −0.186, which shows a moderate negative correlation after adjusting for all other variables. Moreover, the E-values tended to be smaller for the negative coefficients, which implies that those relationships are more susceptible to unmeasured confounding as compared with the harmful effects that were less susceptible to unmeasured unconfounding. It is also likely that there is greater exposure measurement error at higher concentrations because the models were primarily trained on monitoring data at lower concentrations. This could account for the inconsistent results in the full range of exposure analyses.

At lower concentrations, all pollutants increased the probability of hospital admissions with larger effect estimates than the primary results. That the negative effects of $NO_2$ and $O_3$ disappear when restricted to pollution concentrations in the more normal range suggests that those effects in the full analysis may be attributable to outlier exposures, more exposure error, and stronger negative correlations between high $NO_2$ and low $O_3$ than for more common concentrations. The higher effect sizes for risk of cardiovascular and respiratory outcomes at the lower end of air pollution exposure is consistent with several other studies in this population looking at health effects at lower concentrations.[7,21,40,41] In the subgroup analyses, $PM_{2.5}$ and $NO_2$ were associated with an increased risk of

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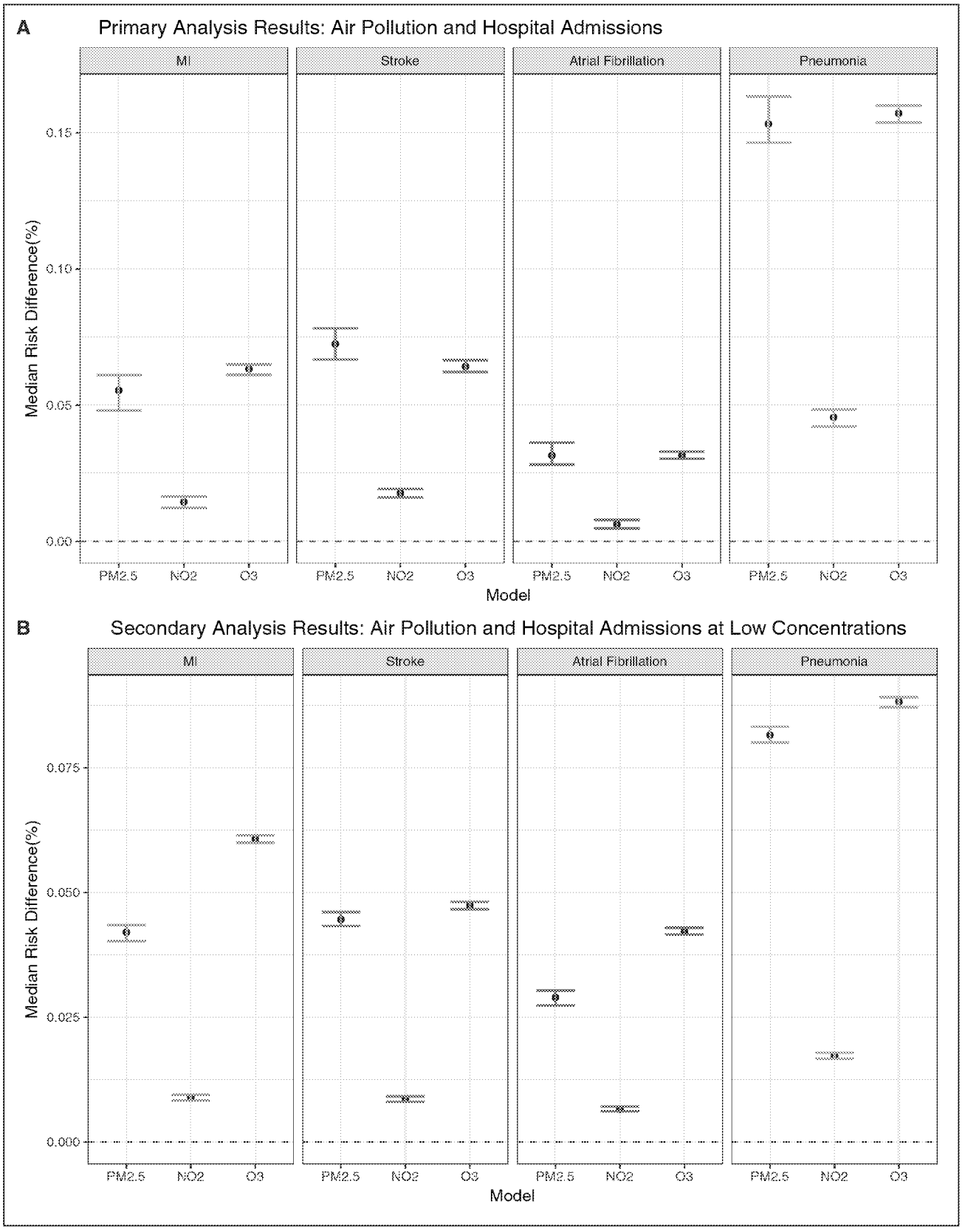


**Figure 2. Primary and secondary analyses results.**
**A**, Primary analyses results: median risk difference (95% CI) for each unit increase in air pollutants and hospital admission with cardiovascular and respiratory outcomes across the full range of exposure. **B**, Secondary analyses results: median risk difference (95% CI) for each unit increase in air pollutants and hospital admission with cardiovascular and respiratory outcomes at lower concentrations of exposure.

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**Table 4. Main Analyses Results and Sensitivity Analyses (E-Values)**

| Outcome | Pollutant | Median risk difference (%) | Lower 95% CI (%) | Upper 95% CI (%) | Attributable increase in the number of cases* (95% CI) | E-value (multiplicative scale) |
|---|---|---|---|---|---|---|
| Myocardial infarction | $PM_{2.5}$ (μg/m³) | 0.00231 | 0.00175 | 0.00295 | 637 (483–814) | 1.0160 |
| | $NO_2$ (ppb) | −0.00084 | −0.00103 | −0.00067 | N/A† | 1.0096 |
| | $O_3$ (ppb) | −0.00024 | −0.00052 | 0.00002 | N/A† | 1.0050 |
| Stroke | $PM_{2.5}$ (μg/m³) | 0.00914 | 0.00859 | 0.00970 | 2536 (2383–2691) | 1.0323 |
| | $NO_2$ (ppb) | 0.00059 | 0.00039 | 0.00075 | 163 (108–208) | 1.0080 |
| | $O_3$ (ppb) | −0.00278 | −0.00300 | −0.00246 | N/A† | 1.0175 |
| Atrial fibrillation and flutter | $PM_{2.5}$ (μg/m³) | 0.00569 | 0.00515 | 0.00611 | 1575 (1426–1691) | 1.0253 |
| | $NO_2$ (ppb) | 0.00129 | 0.00114 | 0.00148 | 357 (316–410) | 1.0119 |
| | $O_3$ (ppb) | −0.00072 | −0.00091 | −0.00047 | N/A† | 1.0088 |
| Pneumonia | $PM_{2.5}$ (μg/m³) | 0.00909 | 0.00820 | 0.01004 | 2489 (2245–2738) | 1.0322 |
| | $NO_2$ (ppb) | −0.00134 | −0.00158 | −0.00110 | N/A† | 1.0121 |
| | $O_3$ (ppb) | 0.00413 | 0.00376 | 0.00447 | 1131 (1030–1224) | 1.0215 |

*Per one-unit increase per year in pollutants.
†Negative values on a probability scale are not logical. As such, the attributable number of cases were not calculated.
$O_3$ indicates tropospheric ozone; and $PM_{2.5}$, fine particulate matter with an aerodynamic diameter <2.5 micrometers.

hospitalization for cardiovascular outcomes among very elderly adults in both the full exposure range and the lower concentration range. Those who were Medicaid eligible were at increased risk of pneumonia attributable to $PM_{2.5}$ and $O_3$ in both the full and low concentration groups. Individuals who identified as White were at greater risk of atrial fibrillation attributable to $NO_2$ than those who identified as Black. In contrast, those who identified as Black were at greater risk of stroke attributable to $NO_2$ than those who identified as White.

The existing literature on the nonfatal health effects of long-term exposure to air pollution shows mixed results depending on the pollutants and the population studied and the method used. A previous study in the same population that focused on the southeastern region of the United States found both $PM_{2.5}$ and $O_3$ to be risk factors for MI, stroke, and pneumonia on the multiplicative scale, while we found ozone to be negative for ischemic stroke on an additive scale here in the full exposure model,[7] but a risk factor at more modest concentrations. Researchers working with the ESCAPE (European Study of Cohorts for Air Pollution Effects) data looked at several air pollutants and the incidence of acute coronary disease between 1997 and 2007 in Finland, Sweden, Denmark, Germany, and Italy. Both $PM_{2.5}$ and $NO_2$ were nonsignificantly associated with an increased hazard of acute coronary events in an adjusted model.[10] They further found that neither $PM_{2.5}$ nor $NO_2$ were significantly associated with stroke incidence in the ESCAPE cohort.[11] This contrasts with our results that found $PM_{2.5}$ to be harmful and $NO_2$ to be negative for MI, and both pollutants to be harmful for stroke (including all observations, though both were harmful for all outcomes at lower concentrations). Among a cohort of women enrolled in the Women's Health Initiative , long-term exposure to $PM_{2.5}$ was associated with a higher hazard of stroke, though no relationship was found with MI.[42] A case-control study nested in the Worcester Heart Attack cohort found positive but nonsignificant association between long-term exposure to $PM_{2.5}$ and acute MI overall.[12] A study in the Danish, Diet, Cancer and Health cohort between 1993 and 2006 looked at ischemic stroke and found a nonsignificant increase in the hazard of the incidence of disease with long-term exposure to $NO_2$.[43] In a study among the EPIC (European Prospective Investigation into Cancer and Nutrition) cohort in Greece, $NO_2$ was not associated with an increase in the hazard of stroke and ischemic heart disease.[13] A study done in South Korea examining the effect of long-term exposure to air pollutants, including $PM_{2.5}$ and $NO_2$, found similar results to ours. $PM_{2.5}$ increased the hazard of MI and ischemic stroke, in both single and multipollutant models, and ozone showed a decreased hazard of both conditions. However, unlike our study, they found $NO_2$ to increase the risk of MI.[15] A study of British patients between 2003 and 2007 looked at air pollutants including $NO_2$ and $O_3$ and incident cases of cardiovascular disease, and researchers found largely nonsignificant results for MI, stroke, and arrythmia in their single pollutant model.[16] Last, a meta-analysis of long-term exposure to $PM_{2.5}$ as a risk factor for stroke found a 6.4% (95% CI, 2.1–10.9%) increase in the hazard of admission for each 5-μg/m³ increase in $PM_{2.5}$ levels which is consistent with our results of an increased probability of stroke.[17]

The harm caused by air pollution to the cardiovascular and respiratory systems is generally attributed to its ability to increase inflammation and oxidative stress and disrupt the coagulation cascade.[44-47] In SEBAS (Social

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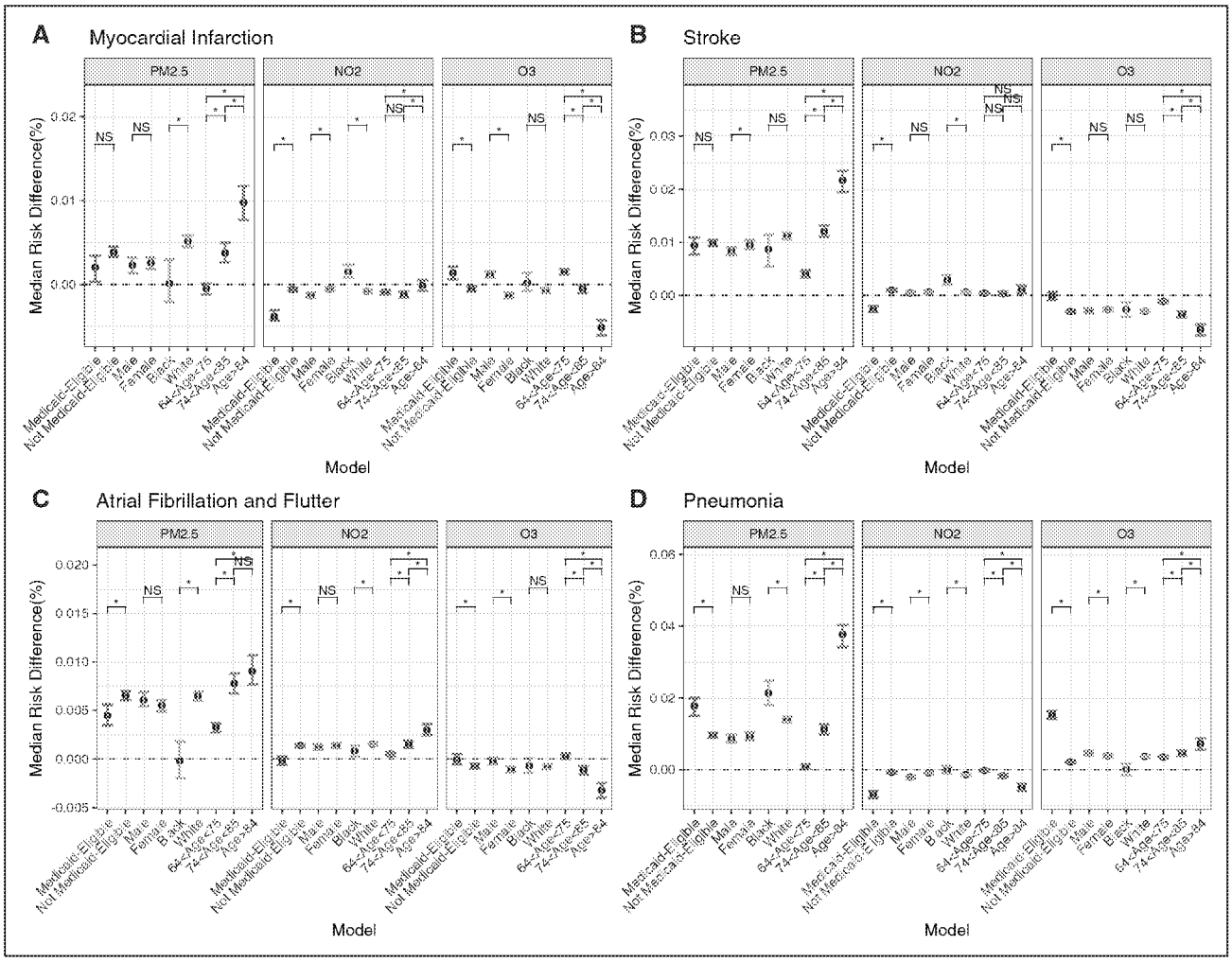


**Figure 3. Effect measure modification analyses: full range of exposure concentration.**
Effect measure modification analyses: median risk difference (95% CI) for each unit increase in air pollutants and hospital admission with myocardial infarction (**A**), stroke(**B**), atrial fibrillation (**C**), and pneumonia (**D**) across the full range of exposure, within strata. Pairwise comparisons of coefficients were conducted. *Statistically significant differences ($P$<0 05). $NO_2$, nitrogen dioxide; NS, nonsignificant difference; $O_3$, tropospheric ozone; and $PM_{2.5}$, fine particulate matter with an aerodynamic diameter <2.5 micrometers.

Environment and Biomarkers of Aging Study) in Taiwan, changes in annual $PM_{2.5}$ and $O_3$ levels were associated with higher levels of systolic and diastolic blood pressure, total cholesterol, fasting glucose, hemoglobin A1c, and neutrophils. $NO_2$ was associated with all, as well as elevated levels of interleukin-6 . Lipids, glucose levels, and inflammatory biomarkers are all risk factors for cardiovascular disease.[48] Moreover, in the ESCAPE study, participants showed decreased lung function, as measured by forced expiratory volume in 1 second and forced vital capacity, in response to $NO_2$, which can be a marker of respiratory disease.[49]

Our study has numerous strengths that make the results particularly compelling. First, the coefficients obtained are risk differences and do not require transformation to be interpretable. Furthermore, the coefficients are on the additive scale. This is particularly helpful for the stratified analyses in which the additional number of cases attributable to the variable can be identified directly and are of greater public health importance.[50] Second, this study uses a causal modeling approach. Randomized trials produce causal estimates because randomization renders intention-to-treat independent of other predictors of outcome. Propensity score methods try to achieve the same result. The inverse probability weights create a pseudo population in which exposure is independent from the measured confounders.[51] If all confounders are measured and the model for the dependence of exposure on confounders (used to create the weights) is correct, this approach will similarly produce a causal estimate. Given that we also control for the covariates, our approach is also doubly robust, meaning that if either the inverse probability weighting model or the outcome model are correctly specified, our estimates are unbiased and causal. Furthermore, we derived our estimates and CIs empirically using bootstrapping. In our model, we account for multiple air pollutants, which were estimated from prediction models on a fine scale,

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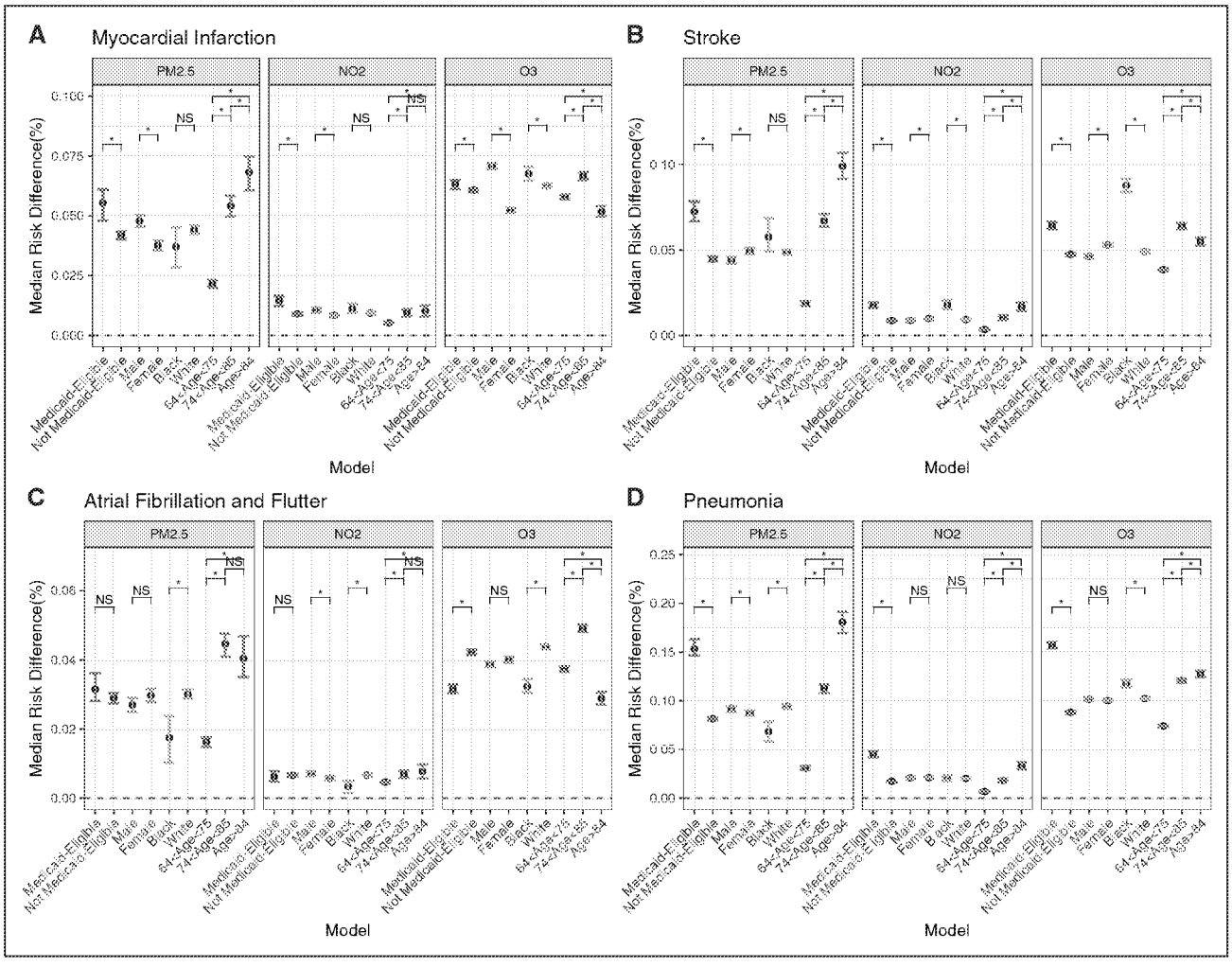


**Figure 4. Effect measure modification analyses: lower range of exposure concentration.**
Median risk difference (95% CI) for each unit increase in air pollutants and hospital admission with myocardial infarction (**A**), stroke(**B**), atrial fibrillation(**C**), and pneumonia (**D**) at lower exposure concentrations, within strata. Pairwise comparisons of coefficients were conducted. *Statistically significant differences ($P$<0.05). $NO_2$, nitrogen dioxide; NS, nonsignificant difference; $O_3$, tropospheric ozone; and $PM_{2.5}$, fine particulate matter with an aerodynamic diameter <2.5 micrometers.

allowing us to identify the more toxic components of the air pollution mixture while adjusting for others. Last, our study focuses on long-term effects, which have not been as thoroughly examined, but may be of greater importance in terms of the health effect of air pollution. This is particularly important to reaffirm, or in some cases establish, the need for long-term guidelines, such as for $O_3$ which does not even have national annual guidelines. Our study suggests that long-term $O_3$ guidelines may be particularly necessary given the effect of long-term ozone on respiratory outcomes.

Our approach also had several limitations. The causal methodology we use relied on the strong assumption of no unmeasured confounding which is not testable. Hence, causality is not proven, and can only be an interpretation, which should include support from toxicology. We did, however, calculate E-values to see the strength of the relationship a hypothetical unmeasured confounder would have to have with both the exposure and the outcome to fully account for the results we found. Moreover, we chose a more conservative approach and controlled for lung cancer rate as a proxy for smoking. However, air pollution is itself a risk factor for lung cancer. As such, we may be overcontrolling for smoking and underestimating the true effect size. We also assumed that loss to follow-up among our population was unrelated to air pollution. In addition, Medicare is an administrative database and billing codes could leave the door open to potential outcome misclassification. We expect that this will not be related to exposure to air pollution and nondifferential misclassification should bias the results to the null.

## Conclusion

This study demonstrates that, on an additive scale, air pollution components pose a risk to human health, particularly among the very elderly population in the United States. The increase in the probability of hospital admissions with cardiovascular and respiratory

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outcomes seems to be most pronounced at lower exposure concentrations for all pollutants. Given that more than half of the US population is exposed to such levels, this issue should be of great concern to clinicians and policymakers alike.

## ARTICLE INFORMATION

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### Disclosures

Dr Schwartz has appeared as an expert witness on behalf of the US Department of Justice in cases involving violations of the Clean Air Act. The other authors report no conflicts.

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# Attachment 3

Article

# Premature mortality related to United States cross-state air pollution

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Outdoor air pollution adversely affects human health and is estimated to be responsible for five to ten per cent of the total annual premature mortality in the contiguous United States[1–3]. Combustion emissions from a variety of sources, such as power generation or road traffic, make a large contribution to harmful air pollutants such as ozone and fine particulate matter ($PM_{2.5}$)[4]. Efforts to mitigate air pollution have focused mainly on the relationship between local emission sources and local air quality[2]. Air quality can also be affected by distant emission sources, however, including emissions from neighbouring federal states[5,6]. This cross-state exchange of pollution poses additional regulatory challenges. Here we quantify the exchange of air pollution among the contiguous United States, and assess its impact on premature mortality that is linked to increased human exposure to $PM_{2.5}$ and ozone from seven emission sectors for 2005 to 2018. On average, we find that 41 to 53 per cent of air-quality-related premature mortality resulting from a state's emissions occurs outside that state. We also find variations in the cross-state contributions of different emission sectors and chemical species to premature mortality, and changes in these variations over time. Emissions from electric power generation have the greatest cross-state impacts as a fraction of their total impacts, whereas commercial/residential emissions have the smallest. However, reductions in emissions from electric power generation since 2005 have meant that, by 2018, cross-state premature mortality associated with the commercial/residential sector was twice that associated with power generation. In terms of the chemical species emitted, nitrogen oxides and sulfur dioxide emissions caused the most cross-state premature deaths in 2005, but by 2018 primary $PM_{2.5}$ emissions led to cross-state premature deaths equal to three times those associated with sulfur dioxide emissions. These reported shifts in emission sectors and emission species that contribute to premature mortality may help to guide improvements to air quality in the contiguous United States.

Long-term exposure to fine particulate matter ($PM_{2.5}$) and ozone leads to an increased risk of premature death[7–12]. Indeed, $PM_{2.5}$ and ozone are the most prominent known causes of early deaths associated with outdoor air pollution, resulting in more than 90% of total air-pollution-related mortalities[8,11]. For this reason, $PM_{2.5}$ and ozone have become the predominant pollutants for quantifying air quality[2]. These pollutants form mainly through atmospheric chemical reactions following the release of precursor emissions. $PM_{2.5}$, which consists of particles and liquid droplets, forms from gaseous precursor emissions of nitrogen oxides ($NO_x$), sulfur oxides ($SO_x$), ammonia ($NH_3$), and others. $PM_{2.5}$ can also be emitted directly, as in the case of black carbon. Ozone forms from gaseous precursor emissions of $NO_x$ and volatile organic compounds (VOCs). The adverse health impacts due to exposure to $PM_{2.5}$ and ozone can therefore be attributed to the precursor emissions that lead to their formation. Such attribution is useful, as it is these emissions that can be directly controlled, rather than the exposure that results from them.

Combustion emissions constitute the largest source of anthropogenic emissions in the USA, and therefore contribute to the formation of $PM_{2.5}$ and ozone[2]. The health impacts attributable to these emissions have been estimated in various studies[6,13,14], with estimates varying between 90,000 and 360,000 early deaths per year. In the context of the Environmental Protection Agency (EPA) Cross-State Air Pollution Rule (CSAPR) and individual state regulation, measures to further reduce the health impacts of pollution would benefit from a greater understanding of which sectors and which states are responsible for the health impacts in every other state.

Prior studies have investigated parts of this problem. One study[6] estimated the sources of US $PM_{2.5}$ pollution impacts on a fine scale, with other work focusing on the roles of individual emission sectors[15]

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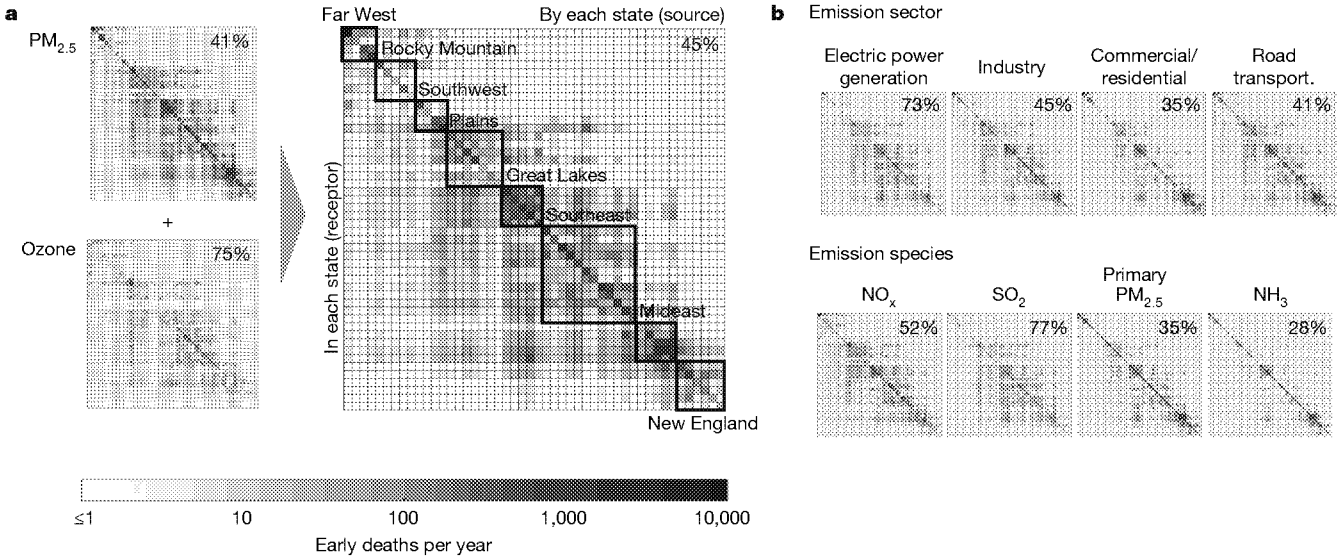


**Fig. 1 | Early-death source–receptor matrices for 2011. a**, Source–receptor matrix showing total early deaths per year for 48 × 48 states (right), and its breakdown into $PM_{2.5}$- and ozone-attributable impacts (left). **b**, Source–receptor early-death attribution to emission sectors (top) and emission species (bottom) that lead to the formation of $PM_{2.5}$ and/or ozone. States are grouped into US Bureau of Economic Analysis regions[24] and ordered west (left) to east (right) (ordering presented in Extended Data Fig. 1). Boxed percentages represent the fraction of impacts that occur out of the state that caused the corresponding emissions. Obtaining the summarized matrices shown using conventional approaches ('forward difference') would require 433-year-long simulations. Extended Data Fig. 2 presents corresponding matrices for 2005 and 2018.

or species[16,17] for either pollutant. Numerous other studies have focused on examining the roles of different emission sectors[13,18] or species[19,20], without quantifying the aspect of pollution exchange. Variations in time have also been discussed[21]. In all cases these studies have focused on only one or two of the dimensions of the problem (emission sector, emission species, pollutant and exchange), and no previous work has integrated these aspects together into a single study. As such, to date there has been no assessment of cross-state pollution exchange that quantifies the influence, by sector and chemical species, of each state on every other state's health risk, using detailed chemistry-transport modelling and including both $PM_{2.5}$ and ozone.

In this work, we estimate the pollution exchange between the 48 contiguous US states, and form source–receptor relationships between them for combustion emissions from seven sectors: electric power generation; industry; commercial/residential; road transportation; marine; rail; and aviation. The commercial/residential sector includes residential combustion (for example, of biomass), nonindustrial commercial and institutional processes, and waste treatment, among other sources. This analysis yields estimates for the number of early deaths due to $PM_{2.5}$ (primary and secondary, excluding secondary organic aerosols) and ozone exposure in every state, with attribution of impacts to each sector and each emitted chemical species from every state. We estimate combustion emissions for the seven sectors for 2005 (based on the 2005 National Emissions Inventory (NEI)), 2011 (based on NEI2011) and 2018 (based on the NEI2011 forecast), and present these findings in Extended Data Table 1. Lists of the specific sources that are grouped in each sector are included in the associated data repository (see Methods). The impacts of these emissions on each state's air quality are then quantified using receptor-oriented atmospheric sensitivities from the adjoint of the GEOS-Chem chemistry-transport model[22] (see Methods).

We calculate the pollution exchange between every state pair for the contiguous US for every combination of emission sector, $PM_{2.5}$ or ozone precursor emission species, and year. The 2011 source–receptor relations for the two pollutants and the total impacts are summarized in Fig. 1a. Matrices for different sectors and emission species are presented in Fig. 1b. Source–receptor matrices for all three years are presented in Extended Data Fig. 2.

The relative percentage of total impacts that occurred outside of the emitting state decreased with time, from 53% in 2005, to 45% in 2011 and 41% in 2018, meaning that there has been a declining relative magnitude of cross-state impacts. This fraction varies substantially between sectors. Electric power generation is the only sector that is regulated by the CSAPR, and has the highest out-of-state impacts as a fraction relative to in-state impacts: on average, approximately 70% of early deaths from this sector occur outside of the state that caused the emissions. However, with reductions in emissions from electric power generation, by 2018 there were 70% fewer out-of-state early deaths (approximately 13,000 fewer early deaths) by comparison with 2005. Road transportation, industry and commercial/residential emissions resulted in higher cross-state early deaths in 2018 than electric power generation (by 28%, 42% and 74% respectively), but are not regulated by the CSAPR at present. Although $PM_{2.5}$ and ozone impacts can vary by +125% to −65% depending on the specific choice of concentration-response function (see Methods), this disagreement does not affect the net pollution exchange between states and the impacts attributable to each sector.

The results presented in Fig. 1a, b reflect both $PM_{2.5}$- and ozone-attributable early deaths. Although the number of early deaths per additional unit of emission is approximately eight times higher for $PM_{2.5}$ than for ozone (not accounting for nonlinear interactions; see Methods), ozone impacts are typically transported farther. The fraction of $PM_{2.5}$ impacts that happen out of the state that caused them was approximately 41% for 2011, compared with approximately 75% for ozone for the same year. The full source–receptor matrices for each sector–year and species–year combination are included in the data repository (see Methods).

The fact that the source–receptor matrices, presented in Fig. 1, are not symmetric about the diagonal implies that there is a net imbalance in the exchange of early deaths between the US states. Figure 2 presents this exchange in terms of the air-quality-related early deaths per capita because of emissions from each state (Fig. 2a) and occurring within each state (Fig. 2b), as well as the net exchange between states (Fig. 2c). A positive value in Fig. 2c indicates that a given state is a net 'exporter' of early deaths—that is, that emissions in that state cause

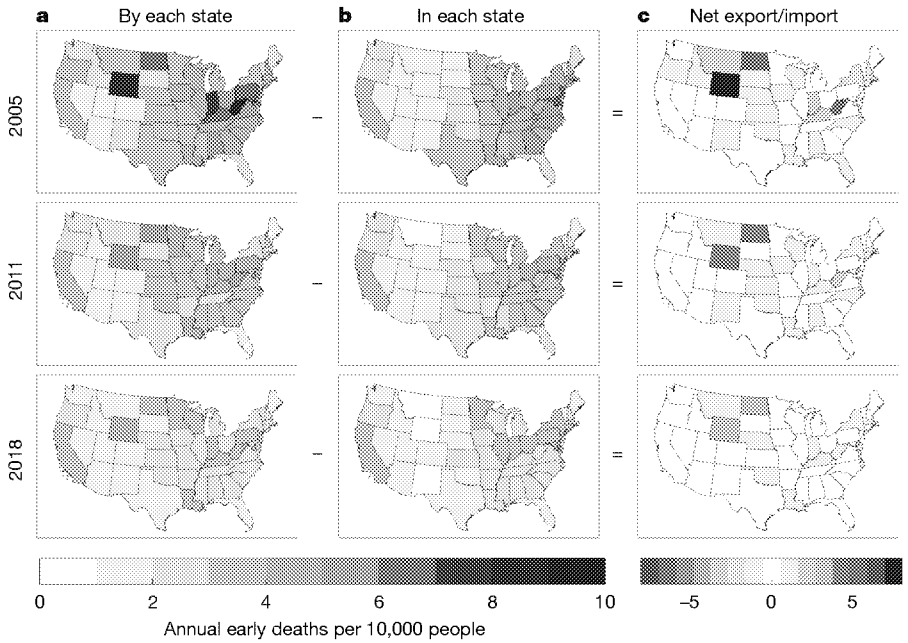


**Fig. 2 | Total annual early deaths caused per 10,000 people for 2005, 2011 and 2018.** The left plots (**a**) show the total aggregate early deaths caused by emissions in each state, divided by the population of the emitting state. The middle plots (**b**) show the total early deaths caused in each state, divided by the population of the state. The right plots (**c**) show the total early deaths exported by each state, divided by the population of the state (that is, the difference between plots **a** and **b**). These impacts are based on summed contributions from each emitted species (see Fig. 3).

more early deaths outside of the state, than are caused within that state by emissions from elsewhere. A negative value indicates the opposite: that the state is a net importer of early deaths.

Three broad patterns are visible. First, the largest exporters are in the northern midwest, owing to low local populations, high emissions, and large downwind populations. Wyoming was the highest exporter on a per capita basis in 2005, with North Dakota and West Virginia following. While these states remained some of the largest per-capita exporters in 2018, their exported impacts fell by roughly 50% over this period (see the examples in Extended Data Table 2). Second, a cluster of states in the northeast are consistent net importers of impacts. New York was the highest net importer of early deaths in all three years, on both a per-capita and an absolute basis. For 2011, the approximately 2,800 deaths incurred in New York because of New York emissions represent 60% of the total deaths caused by New York emissions, and approximately 40% of the total air-quality-attributable deaths in the state. This implies that around 60% of deaths in New York are imported from other states. Finally, states on the west coast have a net exchange of around 0, owing to a combination of no upwind emissions (attributable to any state), relatively sparse population downwind, and large local populations. We present examples of state-level sectoral contributions in Extended Data Figs. 3–5.

Figures 3a, b present the US-wide early-death impacts for each sector and each chemical species, respectively. Impacts from all sectors decrease over the studied period, with the exception of commercial/residential and aviation (landing and take-off only). Impacts due to commercial/residential emissions increase by 31% between 2005 and 2011, but remain steady (within approximately 5%) from 2011 to 2018. Aviation landing and take-off impacts increase by approximately 60% between 2005 and 2018, but contribute around 0.3% to the summed 2018 impacts. Impacts from electric power generation reduce from 22% of total summed impacts in 2005 to 11% in 2018. We estimate that reductions in emissions from electric power generation have led to around 15,900 avoided early deaths in 2018 and, interpolating linearly, to approximately 137,000 avoided early deaths integrated over the 14 years analysed here. Because of these changes, electric power generation changes from being the second most important emission sector to the fourth, while commercial/residential emissions go from fourth to first, responsible for 37% of the summed early deaths attributable to combustion emissions in 2018.

In terms of speciated impacts—that is, emissions species that contribute to the formation of, and exposure to, $PM_{2.5}$ and/or ozone—primary $PM_{2.5}$ emissions had the greatest impact in all three model years. They also stayed relatively consistent, with a 13% reduction in health impacts from 2005 to 2018. $SO_2$—which was the third-greatest contributor to impacts in 2005, making up 19% of the summed impacts—was contributing less than 6% by 2018. This was due to an approximately 80% reduction in $SO_2$ emissions.

Ammonia-attributable impacts increased by around 21% between 2005 and 2018. This difference was driven by an increase in the sensitivity of $PM_{2.5}$ exposure with respect to a unit of ammonia emissions between 2005 and 2011. Owing to the decline in the importance of $SO_2$, ammonia impacts went from being the fourth-greatest to the third-greatest contributor to total impacts over this period, increasingly close to the contribution of $NO_x$ species. $NO_x$ remained the second-greatest contributor to impacts from 2005 to 2018. Despite the roughly 50% reduction in total $NO_x$ emissions between 2005 and 2018, impacts attributable to $NO_x$ reduced by only around 35% between the two years. This is largely due to the increased sensitivity of $PM_{2.5}$ formation to $NO_x$ emissions between 2005 and 2011, as noted previously[23].

On the basis of a linear combination of impacts by sector, we estimate US combustion emissions in 2005, 2011 and 2018 to have resulted in 111,200 (95% confidence interval 78,100–144,800), 93,700 (65,600–121,800) and 76,500 (53,300–99,600) early deaths, respectively. However, the total impact of all US anthropogenic emissions is different to the combined effect of each individual sector or species, owing to nonlinear interactions between the emitted chemicals (Fig. 3c). These interactions reduce the total impacts attributable to $PM_{2.5}$ by 30–34%. Impacts attributable to ozone instead increase by a factor of 2.4 to 2.8 (with the nonlinearity underlying this shown in Extended Data Fig. 6), raising the fraction of total early deaths attributable to ozone exposure from roughly 10% to around 30%.

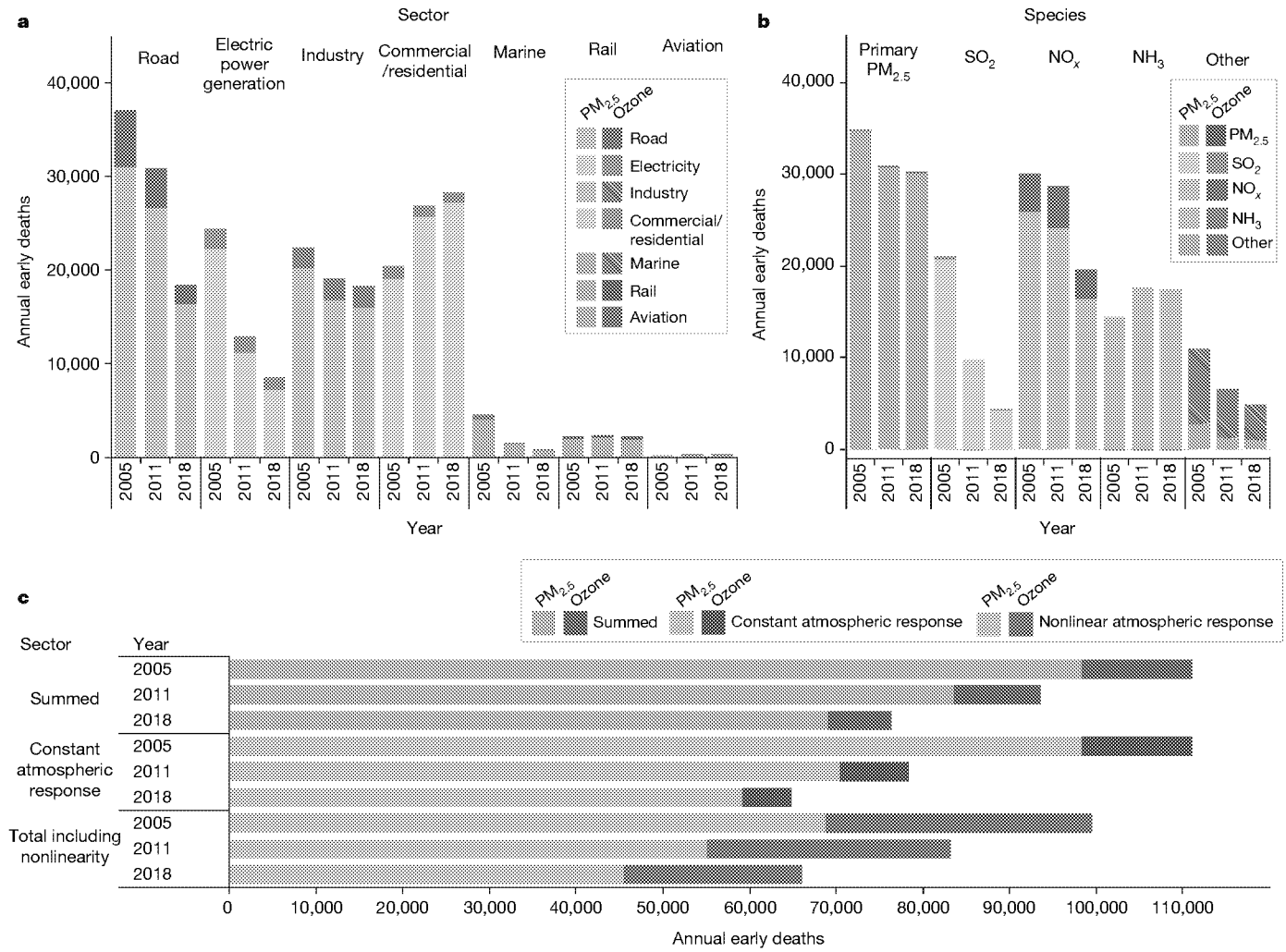


**Fig. 3 | Total annual early deaths attributable to emission sector, emission species and in total. a**, Total annual early deaths attributable to each emission sector. **b**, Total annual early deaths attributable to each emission species that leads to the formation of $PM_{2.5}$ and/or ozone. **c**, Total annual early deaths. Data are shown for 2005, 2011 and 2018, and for $PM_{2.5}$ and ozone. In **c**, three totals are presented: the sum of all sectors/species ('Summed'), which does not account for nonlinear interactions between species; the sum of all sectors/species with varying emissions, but constant (2005) atmosphere ('Constant atmospheric response'); and the total impacts after accounting for nonlinear interactions between species. Tabulated results are presented in Extended Data Table 3.

Taking these nonlinearity effects into account results in total US combustion emissions impacts of 96,600 (95% confidence interval 74,200–125,000), 83,300 (62,400–104,200) and 66,100 (49,300–82,900) early deaths for 2005, 2011 and 2018, respectively. This effect highlights the difference in expected changes in population exposure that result from marginal changes by comparison with larger-scale emissions increases or reductions. An explanation of this effect and its quantification is given in the Methods. The atmospheric nonlinearity is also reflected in our computed sensitivity differences between 2005 and 2011. Thus, a 1% reduction in 2011 emissions would lead to roughly 940 avoided early deaths. Had the atmospheric response to a unit of emissions remained constant between 2005 and 2011 (in terms of meteorology and background concentrations), the same emissions reduction would have led to around 780 avoided early deaths. The changing atmospheric composition thus increases the early deaths attributable to a unit of emission. These three effects are displayed in Fig. 3c.

Overall, we have found that more than 40% of the combustion-emissions-related early deaths cross state lines. This highlights the need for a cooperative approach between states for reaching air-quality targets or targeting problematic areas, as underlined by the introduction of EPA's CSAPR[5]. We find that the electric power generation sector is of declining importance to air quality, by comparison with the increasing importance of commercial/residential emissions. A 10% decrease in emissions from the commercial/residential sector would have 3.3 times greater benefit than a further 10% decrease in emissions from electric power generation. This is reflected in the declining relative importance of $SO_2$, and the increasing relative importance of primary $PM_{2.5}$ and ammonia. A 10% decrease in primary $PM_{2.5}$, $NO_x$ and ammonia emissions would now have 7, 4.5 and 4 times the benefit, respectively, compared with a further 10% decrease in $SO_2$ emissions. These changing relative sectoral and speciated influences provide room to advance air-quality mitigation efforts in the US.

## Online content

Any methods, additional references, Nature Research reporting summaries, source data, extended data, supplementary information, acknowledgements, peer review information; details of author contributions and competing interests; and statements of data and code availability are available at https://doi.org/10.1038/s41586-020-1983-8.

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## Methods

We present here the data and models used in calculating the cross-state early-deaths caused by combustion emissions. We first estimate the speciated emissions for each combustion sector. We then use the adjoint of a chemistry-transport model to estimate the impact of changes in emissions on population exposure. Finally, we relate increases in population exposure to public health impacts (early deaths) using epidemiologically derived concentration-response functions. These steps, intercomparison of our results against existing literature, and the limitations of our approach are outlined below.

### Combustion emissions

Emissions are attributed to each of the six nonaviation sectors in the US using SMOKE and the EPA National Emissions Inventory (NEI) for the year of 2005 (previously used in ref. [13]), 2011 (NEI2011v6 version 1) and the 2011-based forecast for 2018 (refs. [25–27]). These are generated on a 12 km × 12 km or 36 km × 36 km grid, and regridded to the 0.5° × 0.666° (latitude × longitude) grid of the nested GEOS-Chem adjoint model. The full list of individual sources (and corresponding EPA source classification code (SCC) identifiers) that comprise each sector are provided in the data repository noted in the Methods section 'Data and code availability'. For road transportation for 2011 and 2018, we use the EPA MOtor Vehicle Emissions Simulator (MOVES)-processed emissions[28]. For aviation emissions we use the Aviation Environmental Design Tool (AEDT) inventories for 2006, 2010, 2012 and 2015 (ref. [29]). When referring to each of 2005, 2011 and 2018 aviation impacts, we imply impacts from 2006, the average of 2010 and 2012, and 2015 emissions respectively, owing to the absence of more recent datasets. Only aviation emissions that occur within 1 km of the surface (landing and take-off emissions) are taken into account. These have been shown to capture roughly one-third of total aviation-emissions-attributable early deaths in the US[30,31]. We account for the underrepresentation of EPA's point-source oil and gas sector (pt_oilgas) in NEI2011v6 version 1, by distributing the underrepresented $NO_x$ (the difference in pt_oilgas $NO_x$ between version 3 and version 1) to the industry sector $NO_x$ emissions on a state level, assuming the existing spatial distribution[27]. When calculating state source–receptor matrices for the marine sector, we only consider marine emissions within state boundaries and within, on average, around 25 km off the coast over the sea (where applicable). Besides the marine sector, which does not necessarily fall within state boundaries, we do not account for the impacts of emissions that occur outside of this domain and might contribute to US early deaths. Further details on emissions modelling are provided in the data repository.

### Air-quality modelling

We use the adjoint of the GEOS-Chem chemistry-transport model[22] to calculate the sensitivities of the aggregate population exposure in each of the 48 contiguous US states with respect to the various emission species in the North American domain. The resolution of the horizontal grid is 0.5° × 0.666° (roughly 55 km × 55 km) (latitude × longitude), with 47 vertical layers up to 80 km. This horizontal resolution is adequate for capturing state-wide impacts[32–34]. Boundary conditions for the nested domain are obtained from the global GEOS-Chem model run at 4° × 5° resolution, driven by corresponding global meteorological data. Each of the 48 sensitivities quantifies the effect that any emission species in any location in the contiguous US and at any time will have on the population exposure to $PM_{2.5}$ or ozone in each corresponding state. We define $PM_{2.5}$ as the mass sum of nitrates, sulfates, ammonium, black carbon and organic carbon, capturing both primary and secondary $PM_{2.5}$ concentrations. Secondary organic aerosols are not captured. We perform an annual simulation for each of $PM_{2.5}$ and ozone state-level exposure, in each contiguous US state, for 2006 and 2011, resulting in 192 annual adjoint simulations in total (48 × 2 × 2). We use GEOS assimilated meteorological data from the Global Modelling and Assimilation Office (GMAO) at the NASA Goddard Space Flight Center. The year 2006 was climatologically warm in the US, with the annual average temperature being 0.55 °C higher than the 1995–2015 mean, whereas 2011 was climatologically average with an average temperature 0.04 °C lower than the 1995–2015 mean[35]. For 2018 we use the 2011 atmospheric response. Given the change between 2005 and 2011 (comparing the 'Summed' and 'Constant atmospheric response' in Fig. 3), we expect that this approximation will result in a maximum error of around 15% (as there were larger emissions changes between 2005 and 2011 than between 2011 and 2018). Total impacts across all sectors are calculated using additional 'forward' runs, described at the end of this section.

The GEOS-Chem baseline emissions are from EPA's NEI for 2005 and 2011 accordingly[26,27]. Previous studies have found that the NEI 2011 road transportation $NO_x$ emissions are overestimated by around 50% in the southeast and nationally[36,37]. The effects of this are not included here as they are, as of the time of writing, not incorporated in EPA's NEI. An overestimation of 50% in the road transportation $NO_x$ emissions in 2011 implies that results presented here overestimate road transportation early deaths by around 7,500 (95% confidence interval 5,200–9,700) early deaths per year. Other emissions sources, both natural and anthropogenic, are simulated using the standard GEOS-Chem nested North American domain datasets. The Electronic Data Gathering, Analysis and Retrieval (EDGAR) global anthropogenic emissions inventory drives the global model (from which the boundary conditions for the nested simulations are generated)[38]. This is replaced by regional emissions inventories where available (for example, NEI). Biogenic emissions are from the Model of Emissions of Gases and Aerosols from Nature (MEGAN) inventory[39], and lighting $NO_x$ emissions are calculated on the basis of ref. [40].

We estimate the impacts of each sector by performing an inner (Hadamard) product of the sensitivities with the gridded emissions for each of the seven sectors, and calculate the corresponding population exposure impacts. This linear approach was used and validated in refs. [19,20,41–43] against the forward model difference method.

When calculating the total impacts from all sectors combined, we use a different approach to take into account nonlinear interactions between the sectors. Total impacts are calculated by comparing the surface concentrations in forward GEOS-Chem simulations with and without all US anthropogenic emissions. These forward model simulations allow us to quantify nonlinearity in the response of US air quality. Sets of seven forward simulations are conducted for both 2005 and 2011 to quantify this nonlinearity. Extended Data Fig. 6 shows how the simulated, population-weighted concentrations of ozone and $PM_{2.5}$ respond to large changes in emissions ('Average sensitivity'). Compared with the sensitivities used for single-sector and speciated impact calculations ('Marginal sensitivity'), the full, nonlinear $PM_{2.5}$ response to removal of all emissions is found to be 30–34% smaller, while the ozone response is found to be 2.4–2.8 times greater, implying greater nonlinearity effects for ozone by comparison with $PM_{2.5}$. This is because ozone sensitivities are larger when ozone concentrations are low, owing to the greater ozone-production efficiencies in a clean background atmosphere[44]. For $PM_{2.5}$, the response nonlinearity is driven by competition between $SO_4$ (from emitted $SO_2$) and $NO_3$ (from emitted $NO_x$) for ammonia[23,45].

Total impacts for 2018 are estimated by scaling the 2011 response. The scaling factor is calculated as the total growth in US population, multiplied by the ratio of the linearized response to 2018 and 2011 emissions.

### Health impacts

We quantify air-quality impacts in terms of early deaths (premature mortalities). The toxicity of different $PM_{2.5}$ species is assumed to be equal, consistent with EPA practice. As with any study of air pollution impacts, our results are sensitive to the specific choice of concentration–response function (CRF). To calculate the effects of $PM_{2.5}$ exposure, we apply the American Cancer Society (ACS) cohort study

log-linear response estimate of 6% (range 4–8%) increased risk of all-cause mortality per 10 μg m$^{-3}$ increase in annually averaged $PM_{2.5}$ exposure, derived for 1999–2000 exposures using the random-effects Cox model, and adjusted for 44 individual-level and 7 ecological covariates[7]. This estimate is linearized and applied here for adults over the age of 30 years old. This CRF has been applied in a number of estimates of US pollution impacts[46–48]; it is consistent with the results of a global meta-analysis of epidemiological literature, which also found a 6% (range 4–8%) increase in risk per 10 μg m$^{-3}$ (ref. [9]).

Using a different risk estimate would result in a change in the total estimated impact. An expert elicitation performed by the EPA indicated a 1% (range 0.4–1.8%) increase in all-cause mortalities per 1 μg m$^{-3}$ of exposure[2]. This would imply a roughly 70% increase in calculated early deaths, although all relative comparisons would remain the same. Another alternative based on the US medicare cohort would imply a roughly 18% increase in the calculated early deaths for $PM_{2.5}$, when applied to the same 30-plus population (again with all relative comparisons staying the same, but with the caveat that this was derived in a 65-plus cohort)[49]. Extended Data Table 4 shows how the estimate of total impacts, accounting for nonlinearity of the atmospheric response, is affected by the estimated relative risk, including the previously cited studies[2,7,12], refs. [49–51] and the results of a meta-analysis of epidemiological literature[9]. Although we cannot directly apply a nonlinear CRF, using the mean 2011 US concentration of $PM_{2.5}$ in the global exposure mortality model (GEMM)[12], we estimate a 35% increase in calculated early deaths.

For ozone, we apply the respiratory disease mortality CRF of ref. [52]; this is based on US exposure data from the same ACS study as above[7]. Impacts are calculated using the 8-hour maximum daily average ozone over the entire year, and applied to the same population. However, as with $PM_{2.5}$, there is disagreement regarding the correct exposure response curve to use. Extended Data Table 4 also includes estimates of ozone impacts, accounting for nonlinearity of the atmospheric response, using different ozone exposure response curves from the literature[50,52,53]. Using the all-cause mortality CRF of ref. [52] would result in a 110% increase in total mortality due to ozone exposure. Applying the all-cause mortality CRF of ref. [50] to quantify ozone health impacts would instead result in a roughly 17% increase in the reported early deaths due to ozone exposure. We note that the CRF of ref. [50] is based on mean summertime ozone exposure, whereas we measure annual-average exposure to 8-hour maximum ozone. However, ref. [52] showed that the response of respiratory mortality to chronic ozone exposure is similar when using either annual average (12% increase per 10 ppbv) or warm season (10% per 10 ppbv) exposure.

Population data are obtained from the global rural urban mapping project (GRUMP)[54] and LandScan[55] databases. For 2018, we scale the 2011 population to match the 2017 US Census totals[56]. State population fractions over the age of 30 years old are obtained from the US Census Bureau for 2011 (ref. [57]). The US baseline all-cause and respiratory disease incidence rates are obtained from the WHO for 2012 (ref. [58]). For both $PM_{2.5}$ and ozone, the early-deaths confidence intervals reflect the reported uncertainty range for the CRF. Uncertainty in the summed $PM_{2.5}$ and ozone impacts is calculated by performing a Monte Carlo simulation with $10^6$ independent draws of each CRF, applying a triangular distribution to both.

### Intercomparison with other studies

Pollution exchange on an intercontinental scale has previously been estimated for ozone[59–61], $PM_{2.5}$ (refs. [62–65]), and both[66], highlighting the influence of emissions from cross-continental sources. Regional studies have focused on individual species or species and pollutants—for example, the $NO_x$ to ozone effect between EU countries[67] and between US states[17], sources of black-carbon impacts in parts of the US[16], and fine-scale monetized US $PM_{2.5}$ impacts of different sectors[6], in addition to other studies not using detailed chemistry-transport model (CTM) approaches.

The main contribution of our work is the breakdown of both air-pollution causes and impacts in the US, and there are no studies to which direct comparisons at the level of disaggregation in our work can be made. However, the aggregate results of this study compare well with those in the existing literature. Ref. [68] reports a roughly 25% decrease in $PM_{2.5}$-attributable early deaths in the US between 2005 and 2014, which is similar to the roughly 22% found here (interpolating for these two years). Our estimated total early deaths fall within the uncertainty ranges of recent studies, for example, the 79,300 (95% confidence interval 39,700–113,000) non-agriculture-related 2015 US early deaths reported in ref. [69]; the 88,400 (66,800–115,000) 2015 US $PM_{2.5}$-attributable early deaths reported in ref. [70]; and the central estimate of 107,000 total 2011 US $PM_{2.5}$-attributable deaths (of which around 85,600 correspond to non-agriculture- and non-fire-related deaths) reported in ref. [6]. As in these studies, our 2011 estimates are higher than the 2010 estimates of ref. [4] (around 37,400 US early deaths for non-natural and non-agriculture-related deaths). In addition, refs. [4,69] report different sectoral attributions, probably owing to the different emissions inventory used (EDGAR versus NEI). Our sectoral and speciated relative attribution is similar (for 2005) to that of ref. [19] (with the absolute values being different because of the different health-impacts function applied).

We also compare our estimated changes in population exposure to data obtained from monitor sites. We find that, between 2005 and 2011, the simulated population exposure to $PM_{2.5}$ and ozone (taking into account nonlinearities) fell by roughly 20% and 8.6% respectively. For the same two years, EPA's annual trends from nationwide monitor sites show a decrease of 24% and 8% for $PM_{2.5}$ and ozone concentrations respectively[71].

### Limitations

In terms of air-quality modelling, even though the 0.5° × 0.666° (roughly 55 km × 55 km) (latitude × longitude) resolution is sufficient for capturing state-level regional impacts, it may underestimate primary $PM_{2.5}$ impacts and misrepresent ozone impacts in densely populated urban areas. This is in part due to the instantaneous dilution of the emissions, and, for ozone, to the highly nonlinear relationship between ozone formation and background VOC and $NO_x$ concentrations. The EPA NEIs that are used here, and in policy assessments, are also only an approximation, with some known issues that we do not explicitly account for[36,37]. This could affect both the baseline calculation of the sensitivity and the absolute impacts attribution. In addition, the emissions presented for 2018 are forecasted from the NEI2011 inventory. Such forecasts are inherently uncertain[72–74]. Finally, previous studies have shown a tendency for GEOS-Chem simulations to overestimate nitrates[75,76]. This may result in artificially increased $PM_{2.5}$ formation in response to combustion emissions.

In estimating health impacts, the choice of CRF is critical for early-death calculations. Here we apply the all-cause CRF for $PM_{2.5}$ from the ACS cohort study[7] because of the large and nationally representative cohort it is based on, and because of its wide application in $PM_{2.5}$-attributable health-impact estimates in the literature. This CRF was derived for pre-2000 concentrations, and we thus assume no heterogeneity in effect estimates over time (as concentrations change). An analysis of the level of disagreement between different CRFs, and the effect on our estimated impacts, is presented in the 'Health impacts' section above.

We assume equal toxicity between different $PM_{2.5}$ species, consistent with EPA's practice. However, epidemiological work on differential toxicity has provided estimates for mortality predictors based on exposure to individual $PM_{2.5}$ constituents[77]. Sulfates and black carbon have specifically been highlighted because of their suspected higher toxicity amongst $PM_{2.5}$ constituents[9,78].

Here we choose to quantify all-cause and respiratory-disease mortality for long-term exposure to $PM_{2.5}$ and ozone respectively, but note that human exposure to $PM_{2.5}$ and ozone has been correlated with a variety of specific health endpoints, such as neurological diseases[79], various forms of cancer[80], low birth weight[81], and others. Short-term exposure to $PM_{2.5}$ and ozone has also been found to correlate causally with an increased likelihood of early death[82,83], and is not included here. Nonfatal (morbidity) effects attributable to $PM_{2.5}$ and ozone exposure—including acute respiratory symptoms, exacerbated asthma, days of work and school lost, upper and lower respiratory symptoms, nonfatal heart attacks, acute bronchitis, and hospital and emergency-department visits—are also not captured. In addition, given the aggregate nature of the adjoint objective function, we present results for the aggregate state-level population. Air-pollution-related health impacts, however, have been known to disproportionally affect different races, ages and socioeconomic backgrounds[84,85]. These are not broken down here.

We also note that this work quantifies the pollution exchange between the contiguous US states, and does not take into account sources outside of this domain (for example, Mexico, Canada and intercontinentally[65,86]). In addition, while changes in emissions are probably the largest driver of changes in the cross-state, sectoral and speciated patterns between the years, effects of meteorological changes can also contribute, and are not specifically decoupled here. Finally, for simultaneous, large changes in multiple pollutant emissions, there may be nonlinear interactions. These interactions could change the total impact relative to that calculated for individual sectors here, where independent changes are assumed. For this reason, and as discussed above, we calculate and present total impacts (aggregated across all sectors) using forward simulations in which all emissions are reduced simultaneously.

## Data availability

The cross-state source–receptor matrices generated and analysed here, together with sector definitions, are available in the 4TU.ResearchData repository at https://doi.org/10.4121/uuid:edfc5304-39ed-4556-a95a-f8b3313f7cfc.

## Code availability

The atmospheric modelling code used is publicly available; instructions for download are given at http://wiki.seas.harvard.edu/geos-chem/index.php/GEOS-Chem_Adjoint.


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**Additional information**


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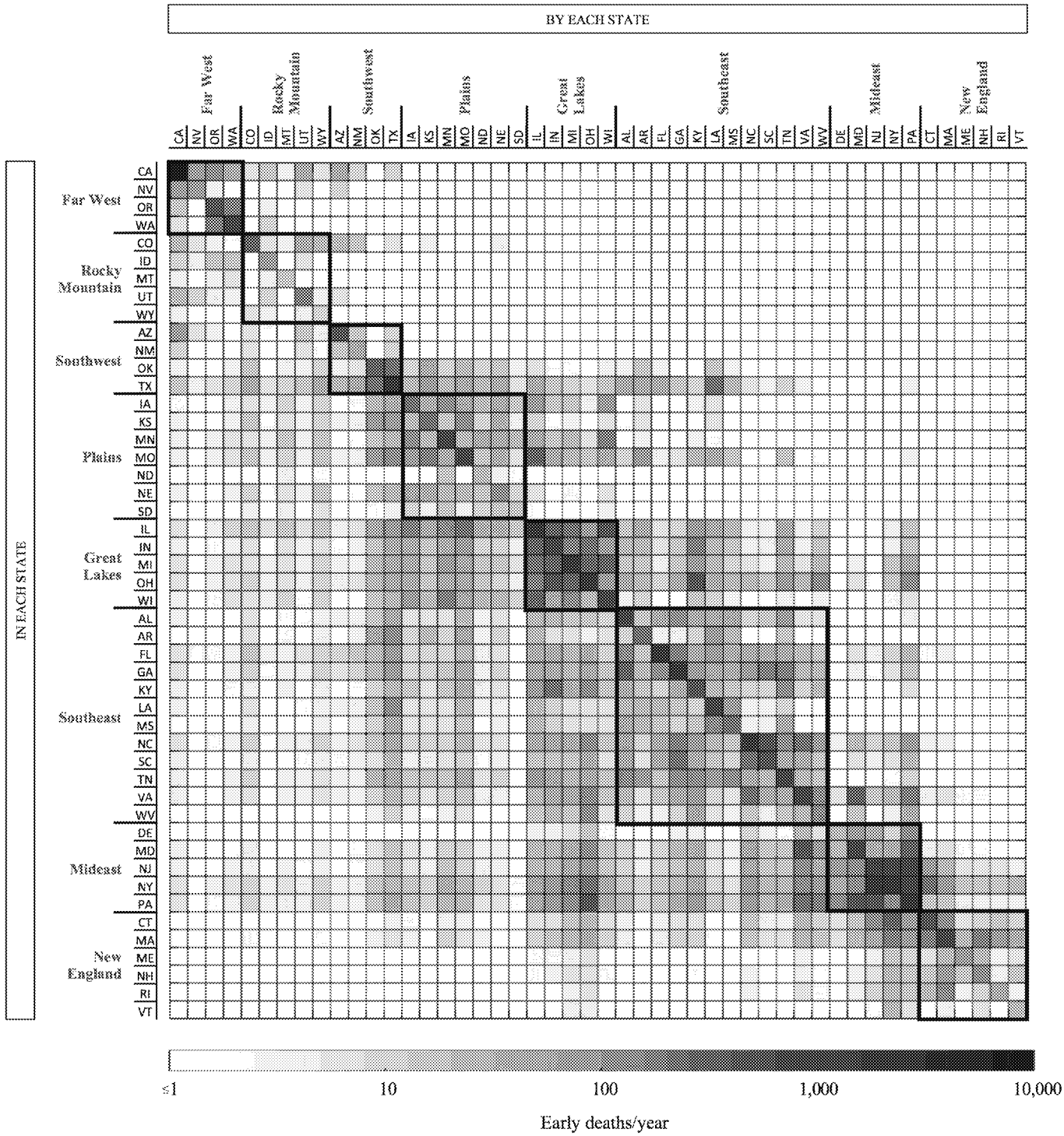
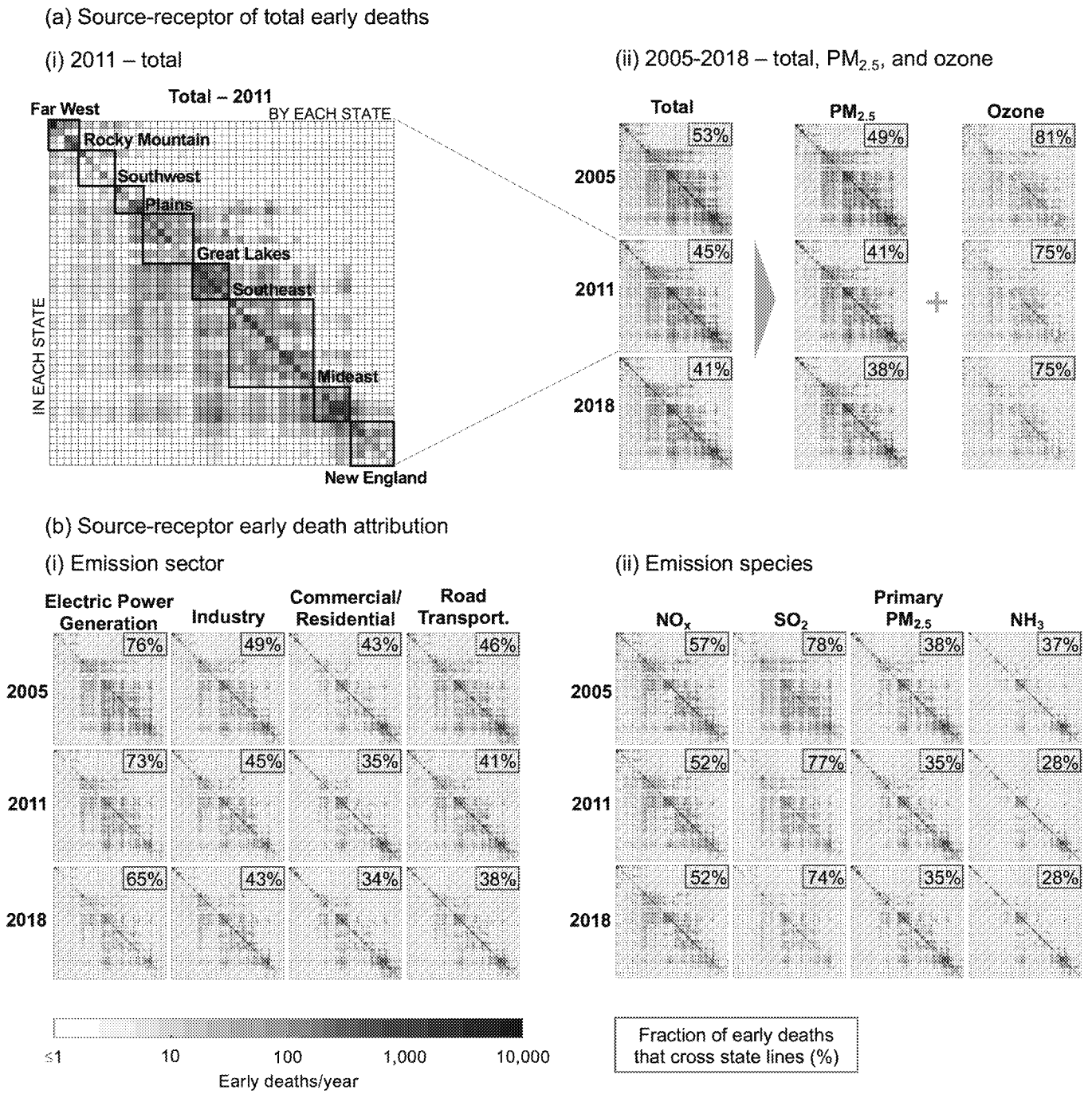
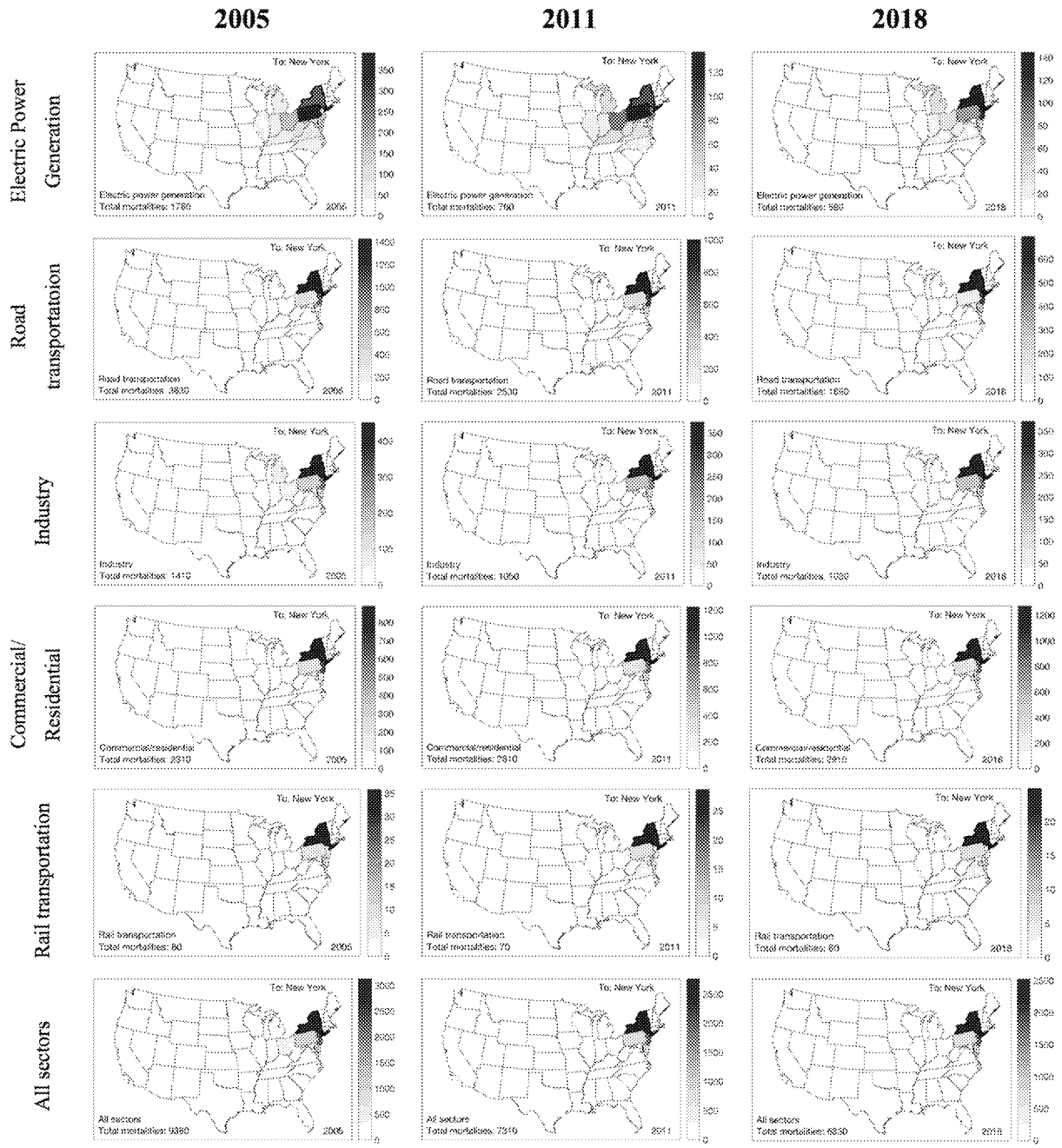


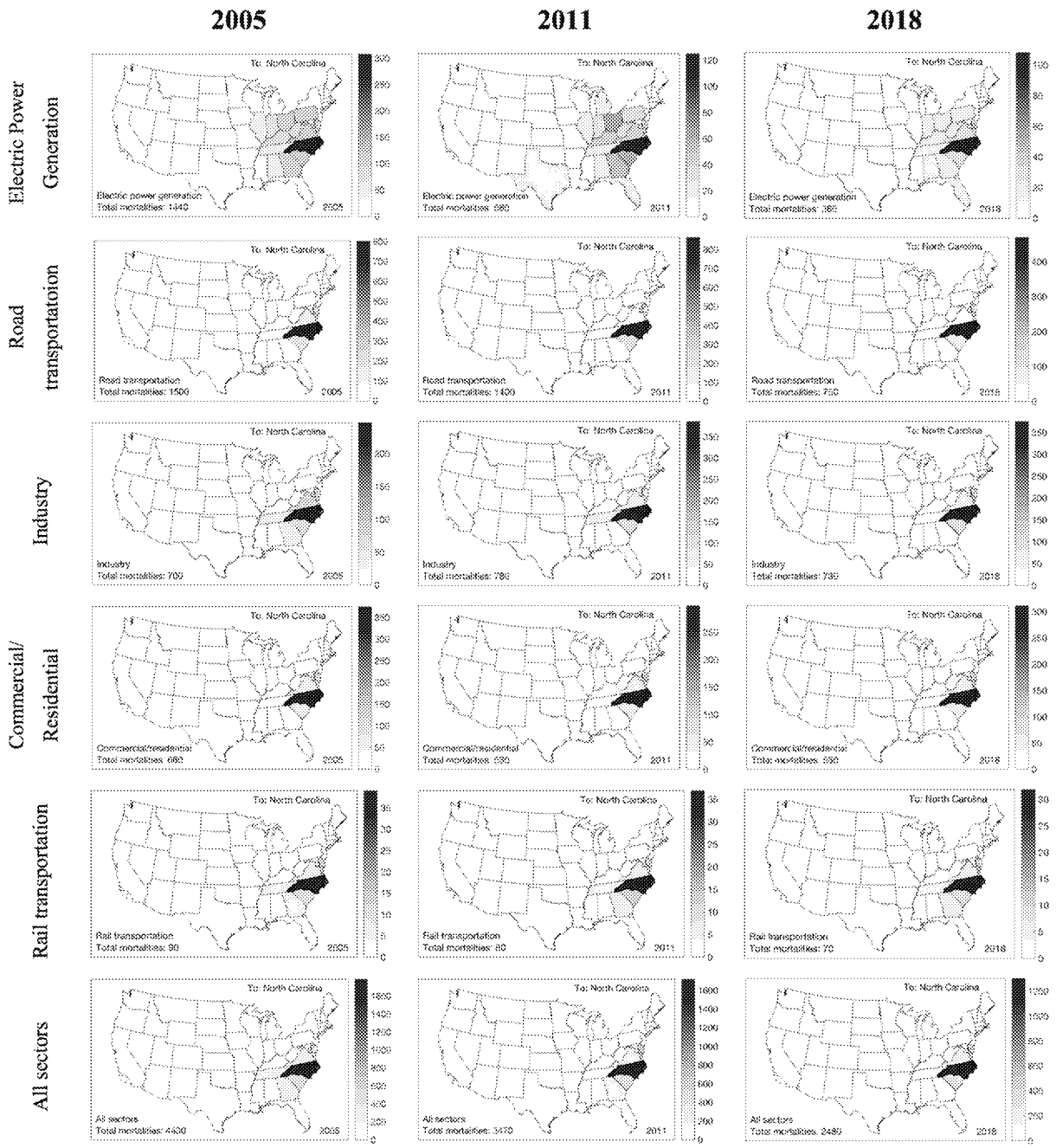

**Extended Data Fig. 1 | Source–receptor matrix showing total impacts in 2011 for the contiguous US.** 'By each state' indicates sources; 'in each state' indicates receptors. The matrix is annotated with state abbreviations and their regional grouping.



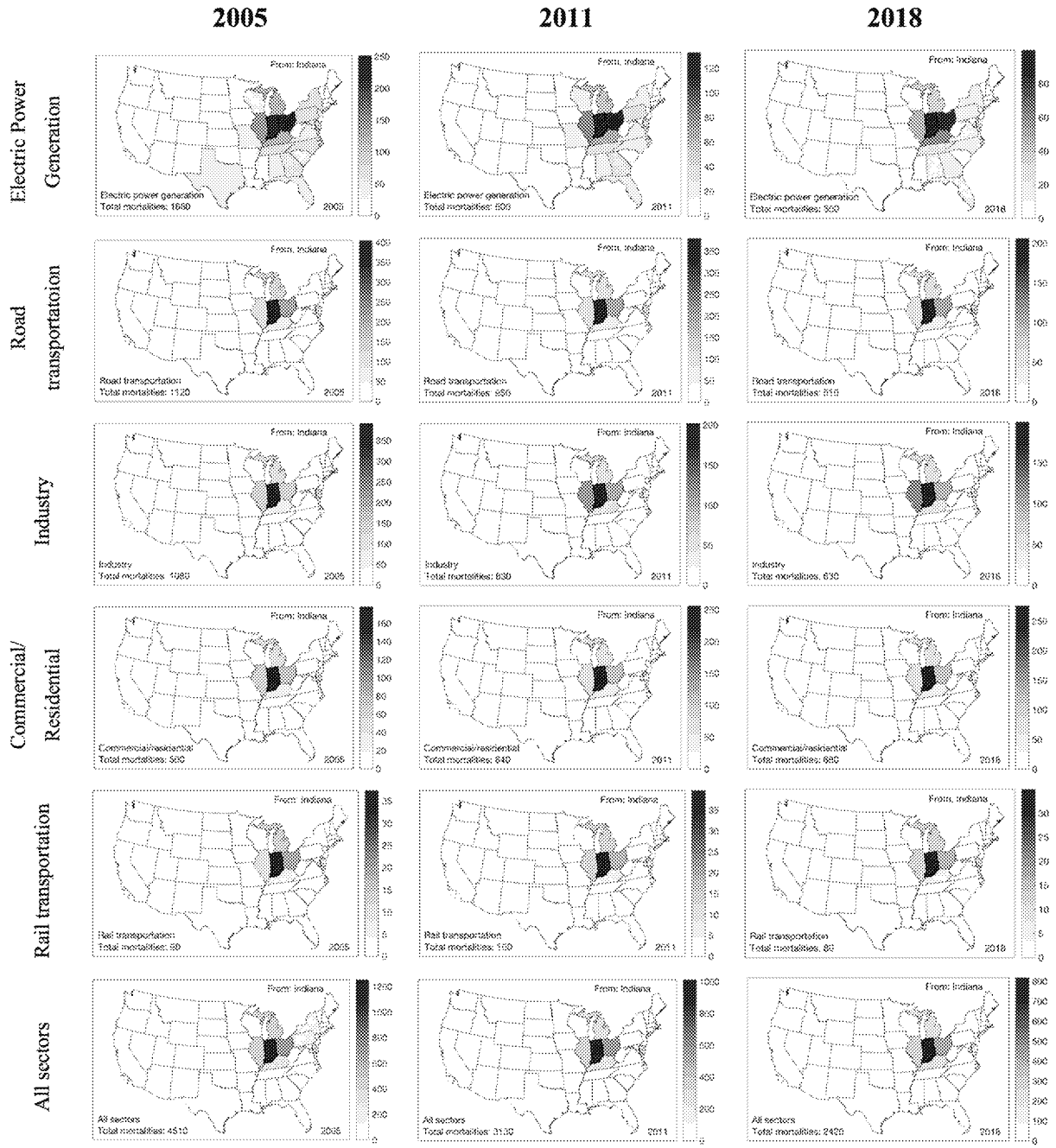

**Extended Data Fig. 2 | Annual early-death source–receptor matrices for 2005, 2011 and 2018 for the contiguous US.** Each matrix comprises 48 × 48 states. **a** (**i**), The total source–receptor matrix for 2011. **a** (**ii**), Its breakdown to $PM_{2.5}$-attributable and ozone-attributable impacts for all three years. **b**, Source–receptor early-death attribution to emission sectors (**i**) and emission species that lead to the formation of $PM_{2.5}$ and/or ozone (**ii**). States are grouped in regions defined by the Bureau of Economic Analysis[20] (labelled in **a**) and ordered from west (left) to east (right). The ordering of individual states is presented in Extended Data Fig. 1. Boxed percentages represent the fraction of impacts that occur out of the state that caused the corresponding emissions. We note that to obtain these summarized source–receptor matrices using conventional modelling approaches ('forward difference simulations') would have required around 1,300 simulations.



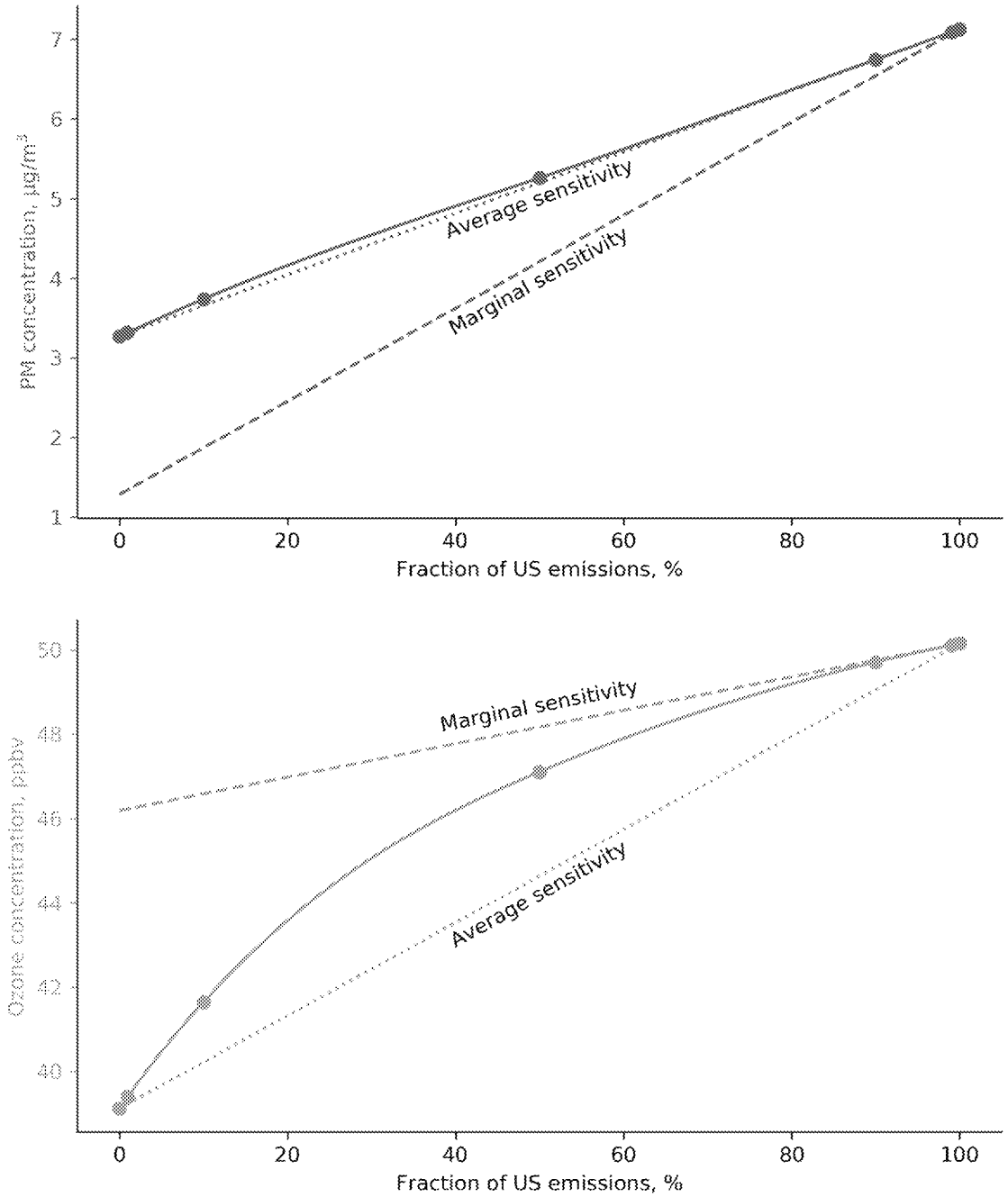

**Extended Data Fig. 3 | Origins of New York annual early deaths, for 2005, 2011 and 2018, for five sectors and in total.** Each state is coloured according to the annual early deaths that emissions from that state cause in the state of New York, for each sector–year combination. The total early deaths occurring in New York (that is, the sum of all states' values) for each sector–year combination is displayed at the bottom left of each panel.




**Extended Data Fig. 4 | Origins of North Carolina annual early deaths, for 2005, 2011 and 2018, for five sectors and in total.** Each state is coloured according to the annual early deaths that emissions from that state cause in the state of North Carolina, for each sector–year combination. The total early deaths occurring in North Carolina (the sum of all states' values) for each sector–year combination is displayed at the bottom left of each panel.




**Extended Data Fig. 5 | Receptors of annual early deaths due to emissions in Indiana for 2005, 2011 and 2018, for five sectors and in total.** Each state is coloured according to the annual early deaths that occur in that state because of emissions in Indiana, for each sector–year combination. The total early deaths caused by Indiana emissions (that is, the sum of all states' values) for each sector–year combination is displayed at the bottom left of each panel.




**Extended Data Fig. 6 | Changes in the response of surface-population-weighted $PM_{2.5}$ and ozone concentrations to US emissions.** Data points show the results of a series of forward simulations, in which the input conditions of the simulation (the total US anthropogenic emissions of all species) are reduced, joined by a cubic spline fit. The 'average sensitivity' lines indicate the gradient implied when impacts due to all sectors combined are calculated—that is, when the effects of atmospheric nonlinearity are taken into account—and thus the total results are scaled to match this. The 'marginal sensitivity' lines indicate the gradient of the response obtained by our GEOS-Chem adjoint simulation, and are used for calculations of individual sector and species impacts (where individual perturbations are of smaller size). The difference between the zero intercept of the two lines constitutes the 'interaction' effect. All values are population-weighted means for 2011.

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**Extended Data Table 1 | Primary $PM_{2.5}$, $NO_x$ and $SO_x$ emissions totals for 2005, 2011 and 2018**

| | 2005 | | | | |
|---|---|---|---|---|---|
| | $PM_{2.5}$ | $NO_x$ | $SO_x$ | $NH_3$ | CO |
| Electric power generation | 0.46 | 3.42 | 9.46 | 0.02 | 0.57 |
| Industry | 0.57 | 2.75 | 2.55 | 0.13 | 3.03 |
| Commercial/ Residential | 0.69 | 0.76 | 0.49 | 0.04 | 4.82 |
| Road transportation | 0.27 | 8.17 | 0.16 | 0.14 | 39.3 |
| Marine | 0.07 | 1.30 | 0.45 | 0.00 | 0.18 |
| Rail | 0.03 | 1.01 | 0.07 | 0.00 | 0.11 |
| Aviation (LTO %) | 0.003 (15%) | 0.60 (13%) | 0.06 (15%) | -- | 0.26 (44%) |

| | 2011 | | | | |
|---|---|---|---|---|---|
| | $PM_{2.5}$ | $NO_x$ | $SO_x$ | $NH_3$ | CO |
| Electric power generation | 0.18 | 1.78 | 4.10 | 0.02 | 0.69 |
| Industry | 0.41 | 2.52 | 1.20 | 0.09 | 2.49 |
| Commercial/ Residential | 0.62 | 0.61 | 0.22 | 0.12 | 3.67 |
| Road transportation | 0.19 | 5.10 | 0.03 | 0.11 | 23.1 |
| Marine | 0.02 | 0.60 | 0.05 | 0.00 | 0.11 |
| Rail | 0.02 | 0.77 | 0.01 | 0.00 | 0.12 |
| Aviation (LTO %) | 0.003 (13%) | 0.58 (13%) | 0.05 (13%) | -- | 0.17 (40%) |

| | 2018 | | | | |
|---|---|---|---|---|---|
| | $PM_{2.5}$ | $NO_x$ | $SO_x$ | $NH_3$ | CO |
| Electric power generation | 0.19 | 1.42 | 1.32 | 0.04 | 0.74 |
| Industry | 0.52 | 2.15 | 0.85 | 0.09 | 2.42 |
| Commercial/ Residential | 0.64 | 0.60 | 0.12 | 0.12 | 3.82 |
| Road transportation | 0.11 | 2.38 | 0.01 | 0.08 | 14.0 |
| Marine | 0.01 | 0.37 | 0.002 | 0.00 | 0.09 |
| Rail | 0.02 | 0.67 | 0.001 | 0.00 | 0.14 |
| Aviation (LTO %) | 0.003 (12%) | 0.63 (12%) | 0.05 (12%) | -- | 0.15 (33%) |

Emissions expressed in teragrams per year for each sector for 2005, 2011 and 2018. Emissions for all sectors apart from aviation are derived from EPA's NEI. Aviation emissions are taken from the AEDT inventory[28] (for years 2006, 2010/2012 and 2015) and include emissions that occurred over the contiguous US. The percentages of aviation emissions that occur within around 1 km of altitude (landing and take-off emissions) are given in parentheses, and are the aviations emissions included in our analysis.

**Extended Data Table 2 | Five states with the greatest reduction in annual early deaths between 2005 and 2018**

| By each state | | | | In each state | | | |
|---|---|---|---|---|---|---|---|
| State | 2005 | 2018 | Δ(2005-18) (%) | State | 2005 | 2018 | Δ(2005-18) (%) |
| WV | 1,740 [1,240-2,250] | 745 [540-950] | 1,000 (57%) | AL | 2,080 [1,520-2,640] | 990 [730-1,260] | 1,080 (53%) |
| AL | 2,640 [1,920-3,350] | 1,280 [950-1,610] | 1,350 (51%) | ME | 330 [240-430] | 170 [120-220] | 160 (48%) |
| TN | 2,370 [1,730-3,020] | 1,210 [880-1,550] | 1,160 (49%) | MS | 970 [710-1,220] | 510 [380-640] | 460 (47%) |
| MD | 3,240 [2,250-4,230] | 1,660 [1,140-2,180] | 1,580 (49%) | VA | 3,760 [2,680-4,840] | 2,010 [1,440-2,590] | 1,750 (46%) |
| KY | 2,750 [1,940-3,560] | 1,430 [1,020-1,850] | 1,320 (48%) | WV | 790 [570-1,010] | 420 [310-540] | 370 (46%) |

Data are given in terms of early deaths caused by emissions from each state and in each state. Values in square brackets show 95% confidence intervals.

**Extended Data Table 3 | Early deaths attributable to each sector and species (that lead to $PM_{2.5}$ and/or ozone formation) for 2005, 2011 and 2018**

**(a)**

| Sector | 2005 | 2011 | 2018 |
|---|---|---|---|
| Electric power generation | 24,400 [16,900-31,800] | 12,800 [9,100-16,600] | 8,500 [6,000-10,900] |
| Industry | 22,400 [15,600-29,100] | 19,100 [13,400-24,700] | 18,200 [12,900-23,600] |
| Commercial/residential | 20,400 [14,100-26,800] | 26,800 [18,300-35,400] | 28,200 [19,200-37,300] |
| Road transportation | 37,000 [26,500-47,600] | 30,800 [21,800-39,800] | 18,400 [12,900-23,800] |
| Marine Transportation | 4,600 [3,200-5,900] | 1,500 [1,100-2,000] | 810 [590-1,000] |
| Rail transportation | 2,300 [1,600-2,900] | 2,400 [1,700-3,100] | 2,100 [1,500-2,800] |
| Aviation | 130 [80-200] | 210 [140-270] | 220 [150-290] |
| *Non-linear $PM_{2.5}$ interactions* | *-29,500* | *-28,400* | *-23,500* |
| *Non-linear ozone interactions* | *+17,900* | *+18,000* | *+13,100* |
| Total | 96,600 [74,200-125,000] | 83,300 [62,400-104,200] | 66,100 [49,300-82,900] |

**(b)**

| Species | 2005 | 2011 | 2018 |
|---|---|---|---|
| $NO_x$ | 30,000 [21,300-38,700] | 28,600 [20,500-36,800] | 19,600 [14,000-25,200] |
| $SO_2$ | 21,000 [14,100-28,000] | 9,900 [6,600-13,100] | 4,300 [2,900-5,800] |
| Primary $PM_{2.5}$ | 34,800 [23,200-46,400] | 31,000 [20,600-41,300] | 30,200 [20,100-40,200] |
| $NH_3$ | 14,400 [9,600-19,200] | 16,700 [11,800-23,500] | 17,400 [11,600-23,200] |
| Other | 10,900 [8,000-13,800] | 6,500 [4,700-8,300] | 4,800 [3,500-6,200] |
| *Non-linear $PM_{2.5}$ interactions* | *-29,500* | *-28,400* | *-23,500* |
| *Non-linear ozone interactions* | *+17,900* | *+18,000* | *+13,100* |
| Total | 96,600 [74,200-125,000] | 83,300 [62,400-104,200] | 66,100 [49,300-82,900] |

Values in square brackets are 95% confidence intervals. Only the mean effect is reported for the nonlinear interaction terms.

**Extended Data Table 4 | Alternative CRF application to 2011 early deaths for all sectors, for $PM_{2.5}$ and ozone**

| Pollutant | Study | Mortality end-points | Early deaths |
|---|---|---|---|
| $PM_{2.5}$ | *Ref. 7* | *All-cause* | *55,200 [36,800-73,600]* |
| | Ref. 2 | All-cause | 94,300 [37,700-169,700] |
| | Ref. 50 | All-cause | 66,800 [64,900-68,600] |
| | Ref. 9 | All-cause | 55,200 [36,800-73,600] |
| | Ref. 49 | All-cause | 124,200 [62,100-195,100] |
| | Ref. 51 | All-cause | 55,200 [9,200-101,200] |
| | Ref. 12 | NCD+LRI* | 75,000 [65,500-85,300]** |
| | Ref. 7 | Cardiopulmonary | 38,600 [29,700-48,200] |
| | Ref. 9 | Cardiovascular | 31,200 [14,200-45,400] |
| | Ref. 49 | Cardiovascular | 69,100 [37,200-106,300] |
| | Ref. 51 | Cardiovascular | 87,500 [54,000-123,500] |
| Ozone*** | *Ref. 52* | *Respiratory (MDA8, annual avg.)* | *28,100 [18,700-37,400]* |
| | *Ref. 52* | All-cause (MDA8, annual avg.) | 59,500 [29,800-119,100] |
| | Ref. 50 | All-cause (24-hr avg. warm season) | 32,900 [29,900-35,900] |
| | Ref. 53 | Respiratory (MDA1, warm season) | 9,700 [2,400-16,300] |

Atmospheric nonlinearity is taken into account. The CRFs used to calculate the estimates in the main text are shown in italics. As in the main text, we apply these to the 30-plus population, using corresponding data for disease-specific baseline incidence rates from the WHO for 2012. Uncertainty intervals (in square brackets) reflect the 95% confidence intervals for each CRF.

*The GEMM model health end-point is all nonaccidental deaths, almost all of which are due to noncommunicable diseases (NCDs) and lower respiratory infections (LRIs). We use the all-cause mortality incidence rate from the WHO, excluding all injury-related deaths.

**To estimate the early deaths from the GEMM model, we use the parameters provided in ref.12 for more than >25 years, excluding the Chinese male cohort study, and use the mean population-weighted concentration of $PM_{2.5}$ in the US to determine the local relative risk per unit increase in exposure. The uncertainty intervals here reflect one standard error in parameter $\theta$ of the model.

***Note that the different CRF studies compared here assume different measures of ozone exposure (annual mean 8-hour maximum in ref. [52]; warm-season (April–September) mean in ref. [50]; and warm-season 1-hour daily maximum in ref. [53]). We apply all of these using the annual mean 8-hour maximum ozone exposure. MDA8, maximum daily 8-hour average.

# Attachment 4

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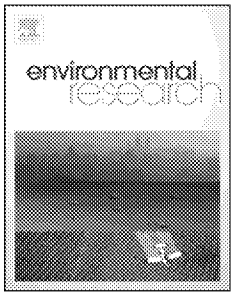


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# Long-term exposure to ozone and children's respiratory health: results from the RESPOZE study.

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## ABSTRACT

**Background**: Although there is evidence on the effects of short-term ozone ($O_3$) exposures on children's respiratory health, few studies have reported results on the effects of long-term exposures. We report the effects of long-term exposure to $O_3$ on respiratory health outcomes in 10-11-year old children.

**Methods**: We conducted a panel study in a sample of the general population of school children in two cities with high average $O_3$ concentrations, Athens and Thessaloniki, Greece. All 186 participating students were followed up intensively for 5 weeks spreading across a school year. Data was collected through questionnaires, weekly personal $O_3$ measurements, spirometry, FeNO and time-activity diaries. Long-term $O_3$ exposure was assessed using fixed site measurements and modeling, calibrated for personal exposures. The associations between measured lung function parameters and lung function growth over the study period, as well as FeNO and the occurrence of symptoms with long-term $O_3$ exposure were assessed through the application of multiple mixed effects 2-level regression models, adjusting for confounders and for short-term exposures.

**Results**: A 10μg/m$^3$ increase in calibrated long-term $O_3$exposure, using measurements from fixed site monitors was associated with lower FVC and $FEV_1$ by 17mL (95% Confidence Interval: 5-28) and 13mL (3-21) respectively and small decreases in lung growth: 0.008% (0.002-0.014%) for FVC and 0.006% (0.000-0.012%) in $FEV_1$ over the study period. No association was observed with PEF, FeNO or the occurrence of symptoms. A similar pattern was observed when the exposure estimates from the dispersion models were employed.

**Conclusions**: Our study provides evidence that long-term $O_3$ exposure is associated with reduced lung volumes and growth.


**Keywords**: ozone; long-term exposure; lung function; school-age children; panel study

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**FUNDING**

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**COMPETING INTERESTS:** None

Online Data Supplement:

This article has an online data supplement

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## INTRODUCTION

Exposure to increased ozone ($O_3$) concentrations in ambient air has been associated with adverse health effects, predominately on respiratory outcomes after short-term exposures [1]. Controlled human exposure studies have demonstrated acute reductions in $FEV_1$, increased airways resistance and an increase in respiratory symptoms [2], superimposed on acute pulmonary inflammation, characterized by neutrophilia and lymphocytosis [2-5]. Epidemiological studies examining the effects of short-term $O_3$ exposure in children have largely focused on asthmatics, or children with symptoms such as wheeze [6], and have reported evidence of decreased lung function (especially $FEV_1$) and increased occurrence of symptoms, such as wheeze, after short-term exposures. A smaller number of studies have examined the impact of short-term $O_3$ exposure in healthy children involving sequential measurements of lung function and ambient $O_3$ measurements, [7-8] providing some evidence of an association between daily outdoor $O_3$ concentrations and decreased lung function. However, there are few cross-sectional, or longitudinal cohort studies investigating the effects of long-term exposure to $O_3$ in children and what results there are, are inconsistent [1,9-12]. This contrasts with a much larger and more consistent evidence base examining the mortality and morbidity effects of long-term exposures to ambient particles, or primary traffic pollutants in adults and children [1]. These studies have reported reduced lung function [11, 13-15], increased symptoms [12] and increased asthma incidence [11,16]. As reduced lung function in early life is associated with poor health and a decrease in life expectancy [15, 17-18] it is essential to understand which pollutant exposures contribute to these early life impacts. To date the impact of long-term exposure to $O_3$ remains largely unexplored.

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We conducted a panel study (Respiratory Effects of Ozone Exposure in children; RESPOZE) in a representative sample of the general population of schoolchildren in the two major cities of Greece, Athens (state capital) and Thessaloniki, characterized by sunny, warm weather, as well as high concentrations of precursor pollutant emissions favoring tropospheric $O_3$ generation and having $O_3$ ambient concentrations among the highest in Europe [19]. We have published elsewhere [20-21] on the effects of short-term exposures on respiratory health from this study. We report here the effects of long-term exposure to $O_3$ on respiratory outcomes in 10-11 year-old children.

## MATERIALS AND METHODS

### Field work design and population sample

Athens and Thessaloniki (population about 3 and 1million, respectively) are the largest cities in Greece. Although the sunny, warm weather in both cities may lead to high $O_3$ concentrations, the emissions of primary pollutants and subsequent ozone scavenging leads to within city contrasts in $O_3$ concentrations. At the first stage of sampling, all state elementary schools (21 schools in Athens and 13 in Thessaloniki), classified as being in "low" or "high" $O_3$ areas based on historical measurements (years 2001 to 2011), located within 2km from a fixed monitoring site were identified and selected. Areas were defined as “high” if the mean $O_3$ value for the period 2001 – 2011 was higher than 50 $\mu g/m^3$. The proximity to monitoring sites permitted good air pollution characterization for regulated pollutants. Students are required to attend the nearest public school to their residence. The selected students lived at a mean distance of 550 meters (standard deviation (SD): 343 meters) from the school they attended. At the second stage, we visited fifth-grade classes (10 to 11-year-old students), informed the children about the project, obtained informed consent from the

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parents of children willing to participate and finalized our sample consisting of 97 children in Athens and 89 in Thessaloniki, with a range of 1-19 students per school. Online Data Supplement **Figures E1a** & **E1b** present a map of the geographical location of the fixed monitoring sites operated by the Ministry of Environment and Energy, the schools included in the study by high/low exposure area at both cities, respectively. All who consented (about 15% of the total number of students) were included in the study. About 60% of children were from the high $O_3$area schools. Participants were racially homogeneous (Caucasian).

Each child was followed for five intensive field work weeks spread across the 2013–2014 academic year. Specifically, students were followed for 2 weeks during fall (October-November), 1 week in winter (February-March) and 2 weeks in spring-summer (April -June). Before the start of the field work, trained interviewers visited the children's families at home and administered a questionnaire including demographic, lifestyle, medical and residential information. During the field work, a team including one pediatrician or pulmonologist and two nurses, visited students at their schools twice for each field work week on the same weekday. At the first visit $O_3$ personal samplers (Ogawa Co., Pompano Beach, FL, USA) and time activity diaries (TAD) were distributed. The self-completed TAD included information on the students' location at 15 min intervals for each day and on self-reported symptoms during the day.

At the second visit the $O_3$ samplers and the TADs, as well as data on fractional exhaled nitric oxide (FeNO) and a 24-hour dietary recall were collected, and spirometry was performed. The study was approved by the Ethics Committee of the National and Kapodistrian

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University of Athens and the Ministry of Education. More details on the study design may be found in Karakatsani et al[21].

**Ozone ($O_3$) exposure assessment**

To estimate long-term exposure to $O_3$, we used both measurements from the fixed sites and estimates from dispersion modeling. Concentrations of daily ambient 8 and 24-hour $O_3$ and 24-hour Particulate Matter with aerodynamic diameter <10μm ($PM_{10}$) were obtained from 6 fixed monitoring sites in Athens and 3 in Thessaloniki for2013-2014 (www.ypeka.gr). Average outdoor $O_3$ concentrations were calculated from the nearest monitors for the period corresponding to each field work period across 2013-2014. More details on the measurements may be found in Grivas et al[22].

The non-hydrostatic meteorological model MEMO [23] and the Eulerian chemical transport model MARS-aero,[24] were used to calculate annual concentrations of $O_3$ and $PM_{10}$ at each student's residential address. Estimates were based on a meteorological classification scheme that uses ten representative days to compose the annual average concentration fields[25]. Model simulations were performed in a nested grid configuration, covering in the case of Athens the entire area of the Attica Peninsula (120×120 $km^2$ coarse grid) at a horizontal resolution of 2 km and the urban areas of Athens and Piraeus (50×50 $km^2$ fine grid) at a horizontal resolution of 500 m. For Thessaloniki ,the coarse grid covers an area of 200×200 $km^2$ with a horizontal resolution of 4 km and the fine grid has an extend of 50×50 $km^2$ with a horizontal resolution of 1 km. High resolution emissions used in the chemical transport model were based, for both cities, on localized emissions inventories for the year 2008 which have been compiled according to the methodology of the (EMEP/EEA air

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pollutant emission inventory guidebook, 2013), while for traffic in particular the COPERT4 [26] methodology was used. For students who had moved during their lifetime, a weighted average of the exposures at each residence was calculated.

Each student had 5 weekly personal measurements of $O_3$. These do not cover a sufficient period to characterize long-term exposure, but were used to calibrate the assessment of long-term exposure, based either on fixed-site monitors, or on modelling, in order to better reflect each student's personal exposure, which is affected by the time spent indoors/outdoors and location. The ratio of each student's personal exposure to the overall mean personal concentrations of all students was calculated. The long-term average exposure attributed to each student based on the measurement or modeling approaches was then multiplied by this ratio to derive individual differences in exposure between children under the same environmental concentrations. To clarify this better, a child spending more time indoors, or in low $O_3$ locations has on average less exposure compared to another spending more time outdoors or in higher $O_3$ locations in a day characterized by the same outdoor concentrations. This is reflected in the ratio of the personal to overall mean personal concentrations and, thus, scaling outdoor measurements by this ratio provides an estimate of exposure corrected for the specific child's average activity profile. We used both the fixed site measurements for 2013-14 to reflect the relatively recent 2-year exposure and the estimates from the dispersion model based in a 2008 emissions inventory to reflect older exposures. These adjusted outdoor measurements are referred to as “calibrated” values.

**Respiratory health outcomes**

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Details of the spirometry performed at the end of each field work week are described in Karakatsani et al[21]. Briefly, Forced Vital Capacity (FVC), Forced Expiratory Volume at 1 second ($FEV_1$) and Peak Expiratory Flow (PEF) were recorded five times for each student. Additionally, as the students' lung function was expected to grow during the > 6-month span of the field work, we also calculated the difference between the fifth measurement in the spring-summer period and the first one in the fall period divided by the value of the first measurement as percentage lung function growth. Some students missed either the first or fifth spirometry and were excluded; thus the analysis for the growth variables was based on 146 children (78.5% of the study sample). There was no difference in mean $FEV_1$ and FVC between the students included in this analysis and those who were not included.

The symptoms "wheezing", "dyspnea" and " fever" were reported at least once by 23, 15 and 31 children respectively. "Cough" was reported by 106 children and "stuffy nose" by 112. We analyzed the number of days per child when "any symptom", compiling the occurrence of any of the above symptoms, or, separately, cough or stuffy nose as well as the number of days of absence from school within a week were reported.

**Statistical analyses**

We compared the two estimates of long-term $O_3$ exposure using Bland-Altman plots and also calculated Spearman correlation coefficients. We applied multiple linear mixed effects 2-level regression models (1st level was a cluster based on the monitoring station nearest to each school and 2nd level was the child), incorporating a random intercept, when investigating $O_3$ effects on weekly spirometry indices, FVC, $FEV_1$ and PEF, as well as log-transformed FeNO levels. Similarly, we applied 2-level (accounting for the same variables)

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mixed Poisson regression models, with random intercept, for the number of days per week with reported symptoms, as well as absence from school. Lung function, i.e. FVC, $FEV_1$, PEF and lung growth variables were used as dependent variables in multiple regression models.

Our main exposure variables were the "calibrated" values of the 2013-14 measurements based on the nearest monitor and the "calibrated" values based on the dispersion model. These exposure variables characterized the long-term exposure to $O_3$ for each student. We applied 3 models with different levels of adjustment for potentially confounding variables: The first ("core") model included sex, father's years of education and city (Athens/Thessaloniki) as time invariant covariates. When mixed models were applied, the model included height (cm) and weight (kg) corresponding to each week of observation, except when FeNO was the dependent variable. In the analysis of growth variables, we adjusted for the child's height and weight difference over the study period. The second ("main") model additionally included mean time spent outdoors per day (hours), corresponding to each week of observation when we applied mixed models and the average of all weeks in the analysis of growth variables, and citrus fruit consumption (yes in any of the questionnaires/no). The third model also included adjustment for $PM_{10}$ levels ($\mu g/m^3$) based on concentrations measured at the nearest fixed monitoring site. Cook's distance was calculated for the final models in order to identify outliers in the predictor variables which may influence the associations with the health outcomes. The assumption of linearity between the exposure indices and outcomes was assessed by fitting a spline of the exposure to the outcome. The plots produced did not indicate violation of the assumption of linearity. Also, terms for $O_3$ and gender and terms for 2 pollutants ($O_3$ and $PM_{10}$) interactions were tested, although the sample size may not have enough power to detect

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interactions. Moreover, we introduced a variable regarding smoking at home (no/yes) in the models exploring $FEV_1$, FVC, PEF and FeNO changes.

In order to distinguish between long-term and short-term effects of $O_3$ on spirometry indices and reported symptoms, we further adjusted all models for short-term exposure effects. To avoid collinearity, we used the difference of each week's $O_3$ measurements from the nearest monitor from the long-term (2013-14) average from the same monitor, to account for short-term (i.e. weekly) fluctuations in pollution levels.

## RESULTS

**Table 1** shows personal and socioeconomic characteristics and respiratory health indices for the students in our sample, by city and between "high"/"low" $O_3$ areas. The mean FVC (L) for all children as recorded in the first spirometry was 2.38 (standard deviation -SD:0.37) and 12 students (one with reported asthma) had FVC <80% predicted. The mean $FEV_1$ was 2.10 (SD:0.32) and 7 students had $FEV_1$<80% predicted. Only 4 students had FVC< 80% predicted across all assessments. Doctor-diagnosed asthma was reported by the parents of 7 (7%) children in Athens and 14 (15%) children in Thessaloniki. Any association with asthma prevalence was not explored due to the small numbers.

**Table 1**. Personal and socio-economic characteristics and respiratory health indices of 97 children in Athens and 89 in Thessaloniki, by city and ozone concentration area*.

| | Athens | Thessaloniki |
|---|---|---|

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| | $O_3$ concentration area (number of children) * | | | |
|---|---|---|---|---|
| | Low (n=37) | High (n=60) | Low (n=32) | High (n=57) |
| **Boys (n, %)** | 22 (59.5) | 28 (46.7) | 14 (43.8) | 29 (50.9) |
| **Age (mean, SD; years)** | 10.3 (0.3) | 10.3 (0.3) | 10.4 (0.4) | 10.4 (0.3) |
| **Height (mean, SD; cm)** | 147.2 (6.7) | 143.5 (7.7) | 145.9 (9.5) | 144.3 (7.3) |
| **Weight (mean, SD; kg)** | 39.5 (7.7) | 38.1 (7.8) | 38.6 (9.7) | 37.7 (7.6) |
| **Father's education (mean, SD; years)** | 14.0 (2.8) | 15.2 (3.7) | 15.3 (3.4) | 14.1 (3.3) |
| **Moved home† (n, %)** | 23 (62.2) | 29 (48.3) | 19 (59.4) | 23 (40.4) |
| **Forced Vital Capacity‡ (mean, SD; FVC, L)** | 2.5 (0.4) | 2.4 (0.3) | 2.4 (0.4) | 2.4 (0.4) |
| **Forced Expiratory Volume in 1s‡ (mean, SD; $FEV_1$, L)** | 2.2 (0.4) | 2.1 (0.3) | 2.1 (0.4) | 2.0 (0.4) |
| **Peak Expiratory Flow‡ (mean, SD; PEF, L/sec)** | 4.6 (0.9) | 4.7 (0.7) | 4.7 (0.8) | 4.3 (0.8) |
| **Forced Vital Capacity growth (mean, SD; FVC, %)§** | 0.083 (0.096) | 0.078 (0.075) | 0.161 (0.063) | 0.090 (0.070) |
| **Forced Expiratory Volume growth (mean, SD; FEV1, %) §** | 0.057 (0.074) | 0.035 (0.072) | 0.140 (0.075) | 0.104 (0.074) |
| **Peak Expiratory Flow growth (mean, SD; PEF, %) §** | 0.064 (0.105) | 0.040 (0.165) | 0.183 (0.133) | 0.172 (0.210) |

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| | | | | |
|---|---|---|---|---|
| **Number of students who reported any symptom at least once (n, %)** | 29 (78.4) | 40 (66.7) | 27 (84.4) | 45 (79.0) |
| **Number of students who reported cough at least once (n, %)** | 21 (56.8) | 30 (50.0) | 24 (75.0) | 31 (54.4) |
| **Number of students who reported stuffy nose at least once (n, %)** | 24 (64.9) | 32 (53.3) | 22 (68.8) | 34 (59.7) |
| **Number of students absent from school at least once(n, %)** | 18 (48.7) | 31 (51.7) | 12 (37.5) | 22 (38.6) |

*The definition of high and low concentration areas was based on fixed site measurements from previous years and used as a basis for the sampling procedure.

†Children that have moved at least once during their lifetime

‡From spirometry performed at school, measured at the first visit

§From spirometry performed at school - difference between the last measurement and the first one divided by the value of the first measurement

**Table 2** shows $O_3$ and $PM_{10}$ concentrations by city and area. As expected, personal $O_3$ measurements were substantially lower than the outdoor concentration, especially in the "high" $O_3$ areas. This reflects the time children spent in indoor environments, as $O_3$ is very low indoors. The mean value of personal and outdoor $O_3$ measurements, as well as model estimates, were higher in the "high" $O_3$ areas of both cities. Athens had higher $O_3$ concentrations. It is worth noting that $PM_{10}$ levels were higher in the lower $O_3$ area only in

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Athens. The estimates of $PM_{10}$ from the dispersion modeling were higher compared to fixed site measurements, probably because the reference year for the emissions used in the model was 2008. During the financial crisis, i.e. after 2010, reduced activity in traffic, industry and shipping was reflected in the measured $PM_{10}$ averages.

**Table 2**. Long-term air pollution concentrations by city and area of high or low $O_3$ concentrations*. Data are presented as mean (SD); median (IQR) and min-max.

| Exposure index | Descriptive measures | Athens | | Thessaloniki | |
|---|---|---|---|---|---|
| | | $O_3$ concentration area (number of children) * | | | |
| | | Low (n=37) | High (n=60) | Low (n=32) | High (n=57) |
| **$O_3$ personal exposure (5-week average; µg/m$^3$)** | Mean (SD) | 8.2 (6.7) | 10.8 (7.8) | 4.7 (4.8) | 5.9 (6.6) |
| | Median (IQR) | 8.4 (4.9) | 10.8 (4.1) | 4.0 (4.3) | 4.6 (4.1) |
| | Min - Max | 2.6 – 17.1 | 3.2 – 21.6 | 1.0 – 11.4 | 1.1 – 14.2 |
| **$O_3$ at fixed sites (24h average for 2013-14‡; µg/m$^3$)** | Mean (SD) | 25.1 (4.8) | 67.9 (7.8) | 38.6 (8.3) | 58.6 (17.0) |
| | Median (IQR) | 21.2 (9.7) | 67.4 (6.3) | 38.2 (10.0) | 72.9 (34.2) |
| | Min - Max | 21.2 – 30.9 | 59.7 – 83.7 | 36.0 – 48.0 | 38.8 – 72.9 |
| **$O_3$ taking into account address history,** | Mean (SD) | 41.2 (3.5) | 63.4 (11.3) | 36.4 (7.3) | 49.0 (15.3) |
| | Median (IQR) | 41.7 (5.9) | 62.8 (14.6) | 35.0 (5.6) | 48.6 (20.8) |
| | | 36.3 – 51.4 | 50.0 – 97.7 | 26.6 – 64.5 | 32.2 – 84.1 |

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| | | | | | |
|---|---|---|---|---|---|
| **dispersion model ($\mu g/m^3$)** | Min - Max | | | | |
| **Calibrated $O_3$exposure from outdoor 24h fixed sites measurements($\mu g/m^3$)[§]** | Mean (SD)<br>Median (IQR)<br>Min - Max | 28.3 (15.4)<br>23.4 (19.7)<br>9.7 – 68.8 | 96.8 (38.0)<br>99.3 (38.0)<br>27.2 – 236.8 | 23.0 (12.7)<br>20.3 (22.0)<br>5.1 – 57.3 | 42.8 (29.1)<br>34.6 (20.8)<br>32.2 – 84.1 |
| **Calibrated $O_3$exposure using outdoor estimates from dispersion models($\mu g/m^3$)[‖]** | Mean (SD)<br>Median (IQR)<br>Min - Max | 44.9 (19.7)<br>43.4 (32.4)<br>12.4 – 94.0 | 89.8 (35.7)<br>87.0 (42.1)<br>22.7 – 215.5 | 21.1 (10.7)<br>20.4 (16.6)<br>4.2 – 47.3 | 36.6 (28.3)<br>26.3 (23.5)<br>7.6 – 136.7 |
| **$PM_{10}$ from fixed sites (24h average for 2013-14[2]; $\mu g/m^3$)** | Mean (SD)<br>Median (IQR)<br>Min - Max | 33.2 (0.7)<br>33.7 (1.3)<br>32.4 – 33.7 | 27.5 (5.0)<br>25.7 (5.0)<br>23.0 – 35.6 | 20.7 (10.4)<br>23.5 (11.5)<br>12.0 – 35.0 | 26.9 (12.4)<br>23.1 (26.6)<br>14.3 – 40.9 |
| **$PM_{10}$ taking into account address history, dispersion model** | Mean (SD)<br>Median (IQR)<br>Min - Max | 91.7 (6.7)<br>91.7 (8.2)<br>73.5 – 104.8 | 48.6 (18.1)<br>44.2 (21.0)<br>20.6 – 96.9 | 70.2 (8.5)<br>72.3 (7.2)<br>38.7 – 81.3 | 55.3 (13.7)<br>57.9 (19.2)<br>27.6 – 78.5 |

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| (μg/m$^3$) | | | | | |
|---|---|---|---|---|---|

*This definition of high and low concentration areas was based on fixed site measurements from previous years and used as a basis for the sampling procedure.

†Five weeks coinciding with the field work period for each student

‡Annual averages of 24 h pollutant concentrations (μg/m$^3$) measured from all fixed monitoring sites during the years 2013 & 2014.

§ (average of personal measurements for each student/overall mean of personal exposures for all students) *24h annual average $O_3$ measurements from fixed sites

||(average of personal measurements for each student/overall mean of personal exposures for all students) *24h annual average estimates of $O_3$ concentrations from dispersion models, taking into account address history

Online Data Supplement **Tables E1a** & **E1b** show Spearman correlation coefficients between personal $O_3$ measurements, those from fixed sites and estimates from dispersion models as well as measurements and model estimates for $PM_{10}$ separately for Athens and Thessaloniki. It was observed that personal $O_3$ measurements were better correlated with the calibrated indices in both cities. Moreover, online Data Supplement **Figures E2a** & **E2b** show Bland-Altman plots for agreement between $O_3$ measurements from fixed sites and estimated concentrations from the dispersion model and for both calibrated estimates using calibrated $O_3$ exposure from outdoor 24h fixed sites measurements and using calibrated $O_3$ exposure using outdoor estimates from dispersion models, for the whole study area. It was observed that the latter display better agreement.

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1 **Figure 1** and the online supplement **Table E2** show the association between lung function
2 indices and long-term exposure to $O_3$ using multiple linear mixed effects 2-level regression
3 models. We found that a10 μg/m$^3$ increase in long-term exposure to calibrated $O_3$, as
4 estimated by measurements from fixed site monitors, was associated with lower FVC and
5 $FEV_1$ by 17mL (95% Confidence Interval (CI):5-28) and 13mL (95%CI:3-21) respectively
6 (P<0.01), which remained unchanged after adjustment for $PM_{10}$ concentrations. No
7 association was observed with PEF. A similar pattern was observed when the exposure
8 estimates from the dispersion models were used: the same exposure increase was
9 associated with lower FVC and FEV by 20mL (95%CI:6-35) and 14mL (95%CI:3-25)
10 respectively (P<0.01). We assessed the potential impact of outliers on the observed
11 associations but found low Cook's D values (<0.023), indicating no influential observations.
12 The results were practically identical when considering short-term $O_3$ effects (**Table E2**).
13
14 **Figure 1** and **supplemental Table E3**show the association of the same long-term $O_3$
15 exposure increase with FVC, $FEV_1$ and PEF and percent growth between the first and last
16 spirometry measurement. When fixed site measurements were used for the exposure
17 estimation, a 10μg/m$^3$ increase in $O_3$ exposure was associated with a decrease by 0.008%
18 (95%CI:0.002-0.014) in FVC growth (P=0.01) and 0.006% (95%CI:0.000-0.012) in
19 $FEV_1$(P=0.06) (corresponding approximately to 20 and 15mL, respectively). No association
20 was observed with PEF. The same pattern of associations was observed when estimates
21 from the dispersion model were used, but these did not reach statistical significance (**Figure**
22 **1&Table E3**).
23
24 **Figure 2** shows the association of FeNO levels with long-term $O_3$ exposure estimate.

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**Table 3** shows the association of long-term $O_3$ exposure with the frequency of occurrence of respiratory symptoms and absenteeism during the study year and **Supplement Table E4** shows the results following adjustment for acute $O_3$ effects. No associations were observed between $O_3$ exposure and FeNO, or occurrence of symptoms/ absenteeism.

**Table 3**. Relative risks (RR) and 95% confidence intervals (CI) in the number of days with respiratory symptoms in each study week associated with an increase of 10μg/m$^3$ in $O_3$ long-term calibrated exposure in 97 children in Athens and 89 in Thessaloniki. Results from Poisson mixed effect regression 2-level (nearest fixed site monitor; child).

| **Long-term $O_3$ Exposure** | **Health outcome** | **Model** | **RR (95% CI)/ P value** |
|---|---|---|---|
| Calibrated exposure from fixed site outdoor measurements for 2013-14* | Any symptom | Core‡ | 1.000 (0.926 , 1.078) / 0.977 |
| | | Main§ | 1.001 (0.926 , 1.082) / 0.980 |
| | | Main+$PM_{10}$+distance‖ | 0.987 (0.920 , 1.059) / 0.720 |
| | Cough | Core‡ | 0.994 (0.911 , 1.084) / 0.886 |
| | | Main§ | 0.993 (0.911 , 1.082) / 0.870 |
| | | Main+$PM_{10}$+distance‖ | 0.974 (0.900 , 1.055) / 0.520 |
| | Stuffy nose | Core‡ | 0.997 (0.897 , 1.109) / 0.959 |
| | | Main§ | 0.995 (0.892 , 1.110) / 0.925 |
| | | Main+$PM_{10}$+distance‖ | 0.985 (0.889 , 1.092) / 0.776 |
| | Absence | Core‡ | 1.004 (0.941 , 1.071) / 0.897 |
| | | Main§ | 1.010 (0.945 , 1.079) / 0.777 |

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| | | | |
|---|---|---|---|
| | | Main+$PM_{10}$+distance[ll] | 0.996 (0.930 , 1.066) / 0.903 |
| Calibrated exposure using outdoor 24h estimates from dispersion models[†] | Any symptom | Core[‡] | 1.022 (0.941 , 1.110) / 0.603 |
| | | Main[§] | 1.024 (0.940 , 1.115) / 0.585 |
| | | Main+$PM_{10}$+distance[ll] | 1.018 (0.927 , 1.118) / 0.705 |
| | Cough | Core[‡] | 1.022 (0.928 , 1.126) / 0.653 |
| | | Main[§] | 1.018 (0.924 , 1.121) / 0.719 |
| | | Main+$PM_{10}$+distance[ll] | 0.999 (0.888 , 1.124) / 0.185 |
| | Stuffy nose | Core[‡] | 1.013 (0.903 , 1.136) / 0.825 |
| | | Main[§] | 1.012 (0.899 , 1.138) / 0.846 |
| | | Main+$PM_{10}$+distance[ll] | 1.008 (0.890 , 1.142) / 0.899 |
| | Absence | Core[‡] | 1.014 (0.942 , 1.092) / 0.708 |
| | | Main[§] | 1.021 (0.946 , 1.102) / 0.589 |
| | | Main+$PM_{10}$+distance[ll] | 1.015 (0.925 , 1.114) / 0.757 |

*(personal measurements/overall mean of personal exposure) *24h annual average $O_3$ measurements from fixed sites

[†](personal measurements/ overall mean of personal exposure) *24h annual average estimates of $O_3$ concentrations from dispersion models, taking into account address history

[‡]adjusting for sex (girls / boys), study area (Athens / Thessaloniki), years of father's education and a clustering by nearest fixed monitoring site variable

[§]adjusting for all variables in model 1plus mean time spent out daily (hours) and citrus fruits consumption (yes/no) and a clustering by nearest fixed monitoring site variable

[ll]adjusting for all variables in model 2 plus exposure to $PM_{10}$ (μg/m$^3$) measurements conducted by the fixed monitoring sites (24h annual average) or estimated $PM_{10}$ (μg/m$^3$)

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concentrations from dispersion models taking into account address history plus distance of children's residence from nearest street

Interactions between $PM_{10}$ and $O_3$, as well as interactions with sex, were not statistically significant (P>0.20 in all models).

The $O_3$ effect remained the same after accounting for the smoking at home variable and remained significant in $FEV_1$ and FVC models.

**DISCUSSION**

In a panel study conducted in a sample of the general population of students in the two largest cities of Greece characterized by high ambient pollutant concentrations [19], we found effects of calibrated long-term $O_3$ exposure using personal measurements, on both lung function and lung function growth. These effects were robust to adjustment to short-term fluctuations in ozone. Specifically, in cross-sectional analysis, we found lower FVC (19ml and 23ml, based on measured and modelled exposure estimate, respectively) and $FEV_1$ (14ml and 16ml), associated with 10μg/m$^3$ higher long-term exposure. Taking advantage of the longitudinal follow up period, we also found a difference of 0.008% in FVC and 0.006% in $FEV_1$ growth over 6 to 8 months per child for the same increase in long-term exposure. We did not find any associations with PEF, FeNO or with symptoms occurrence. The results were robust when adjusting for $PM_{10}$ and for distance of residence to the nearest major road.

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Schwartz,[27] used data from the NHANES cross-sectional survey to evaluate the effects of long-term exposure to $O_3$ based on ambient measurements (median: 64μg/m$^3$) in 1005 subjects aged 6 to 24years. Significant decreases in FVC, $FEV_1$ and PEF were found to be associated with higher long-term $O_3$ concentrations. Raizenne et al,[28] studied children aged 8-12 years in several US and Canadian communities and found an almost 3% decrease in FVC and $FEV_1$ associated with 37μg/m$^3$ increase in $O_3$ concentrations, but no statistically significant association was found with PEF. This decrease in FEV and FVC is relatively consistent with what we report here, as our estimates represent about 5% decrease in lung function per 37μg/m$^3$. Peters et al,[29]reported a cross-sectional analysis on long-term concentrations to several pollutants, and the occurrence of self-reported symptoms but found no $O_3$ effects. In the longitudinal Southern California Children's Health Study, which included several cohorts with recruitment periods between 1992 and 2003, many results have been reported, however associations with lung function and lung function growth were found mainly with traffic related pollutants, rather than $O_3$ based on fixed site ambient measurements [13,30].

Similar studies have been conducted in College students. Kunzli et al,[31] reported the results of a study in 130 Berkeley freshmen where no associations were found of "effective" $O_3$ exposure on $FEV_1$ and FVC, but reported a decrease in $FEF_{75}$%, implying ozone was impacting on the small airways. The "effective" $O_3$ exposure calculation in this study took time spent outdoors by each subject into account, a similar approach to the one adopted in the present study using the "calibrated" estimates. In a follow up of the same study, with more subjects, again no association with $FEV_1$ and FVC was found, but there was a decrease in $FEF_{75}$ and $FEF_{25-75}$. Galizia et al,[32] studied 520 Yale College students with low (<80ppb)

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vs high long-term $O_3$ exposures based on ambient concentrations in places they have lived. Whilst they did not find an association with FVC they did report a decrease in $FEV_1$ of about 3% contrasting the 2 exposure categories. Tager et al,[33]studied 255 Berkeley students, also considering time spent outdoors, and found significant effects of lifetime estimated $O_3$ exposure on $FEV_1$,$FEF_{75}$ and $FEF_{25-75}$.

Several studies have evaluated the association between long-term $O_3$exposure and lung function growth over periods ranging from a few months to several years. In two Austrian studies,[34,35] 2,153 children aged 6-9 years were followed up and lung function growth assessed over approximately three 6-month periods, compared across 3 areas classified according to $O_3$ concentrations. The results showed a decrease in $FEV_1$ and FVC growth over the warm season periods in students residing in medium and high $O_3$ exposure areas compared to low, but not during the winter. The growth deficit reported for the warm months was 19.2ml in FVC and 18.5ml in $FEV_1$, for a change between exposure categories of about 10μg/$m^3$. The period assessed was of similar length to the period we studied, but we were not able to include the hot summer months (July and August) because schools are closed in Greece and many students move outside the cities. However, the growth deficit of 0.008% for FVC, which we report here, is equal to about 20ml covering a period including the winter in Greece. The researchers from the Austrian study found no lung function growth deficits over 3.5 years, perhaps because the deficits in the summers were compensated by rebound growth during the winter period. Hwang et al,[36] conducted a 2 year follow up study in 12 year-old children, in Taiwan. They reported a deficit in lung function growth for FVC of about 55 and 42mL for boys and girls respectively and 59 and

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46mL for $FEV_1$, per IQR (about 20μg/$m^3$) increase in 8-hour $O_3$ exposure, which is comparable to what we have found.

In the RESPOZE study we had five weekly measurements of FeNO, spaced out over the study period, and we have reported elsewhere an association between short-term weekly $O_3$ exposure and increased FeNO [21]. However, in the present analysis we found no association with long-term $O_3$ exposure. Similarly, in the California Children's Health Study a 23-day exposure to $O_3$ was found to be associated with increased FeNO,[37] whilst long-term exposure to $O_3$ was not,[38].

In our study we did not observe an association of long-term exposure to $O_3$ and respiratory symptoms or absenteeism from school. In the California Children's Health Study a decrease in long-term $O_3$ concentrations was associated with a decrease in the frequency of bronchitic symptoms [12]. However, it may be that symptoms are more prevalent in asthmatic children and in our study we had a small prevalence of asthma and of more serious symptoms, therefore it may be possible that we could not detect an effect. Similarly, an association of school absences with $O_3$ exposure and a calculation of the cost of $O_3$-related absences has been reported,[39] which was not observed in our study.

It is interesting to note that our results show a more robust statistical association between long-term $O_3$ exposure and measures of lung volume, particularly FVC, rather than flow (PEF) measurements, suggestive of a more restrictive pattern, consistent with a deficit in lung function growth among children exposed to higher long-term $O_3$ concentrations.

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An advantage of our study are the 5 repeated measurements of lung function and FeNO and the 35 daily recordings of symptoms, leading to more accurate assessment of these health outcomes. The application of mixed models, allowed this advantage to be exploited, by adjusting for time varying covariates such as short-term exposure to $O_3$, height and weight and time spent outdoors. Another advantage of the study is the fact that we were able to use the personal $O_3$ measurements to account for personal variation in exposure. It is known that $O_3$ exposure occurs mainly outdoors and is therefore significantly modified by individual time activity patterns. The personal measurements reflect individual habits and in the present study we had personal measurements over 5-weeks spanning across a school year, giving a good estimate of the usual situation of each student. Also, our study utilized a sample drawn from the general population, which allows a general impact calculation of $O_3$ exposure applicable to the whole population of this age range and was implemented in a location with high $O_3$ concentrations.

Our study also has a number of limitations. It is a rather small study, a disadvantage somewhat compensated for by the repeated measurements study design. The relatively small proportion of students participating among those eligible should also be considered as a limitation. The small sample size and relatively low prevalence of asthma did not allow an assessment of the association of long-term $O_3$ exposure with asthma prevalence. One additional limitation is that although we had personal $O_3$ measurements, we do not have personal measurements for $NO_2$, PM, or acidic vapor, which were found associated with lung function in the CHS [13]. It is known that $O_3$, as a secondary pollutant, often is negatively correlated with primary pollutants and the adjustment of other pollutants in the models is very important. In our study the adjustment to $PM_{10}$ was done using the nearest

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monitoring site, and residual confounding and bias due to the different level of measurement error may be present. $PM_{2.5}$ measurements from fixed sites were very sparse during the study period and could not be used. We checked the correlation between $PM_{10}$ and $PM_{2.5}$ for a longer period. Specifically, the correlation coefficient between the daily average of $PM_{2.5}$ and $PM_{10}$ for 2013-18 was 0.74 for Athens and 0.85 for Thessaloniki. Although this does not necessarily mean that the two PM indices have the same spatial pattern, it shows that the variability of $PM_{2.5}$ is largely reflected by the variability in $PM_{10}$. $NO_2$ ambient concentration measurements were moderately inversely correlated with $O_3$ measurements (rho= -0.54) and would not be expected to lower the $O_3$ health outcome associations if included in a two pollutant model. Acidic vapor was not measured. However, in the CHS [40] its correlation with long-term $O_3$ concentrations across communities was very low (-0.07). Additionally, we adjusted for distance of the student's residence to the nearest major road, as an indirect control for traffic generated pollutants such as $NO_2$ and $PM_{2.5}$. We contend that it is unlikely that the findings are due to chance because of their consistency and robustness.

In conclusion, our study provides evidence that long-term exposure to $O_3$ is associated with reduced lung function and restricted growth. These results enhance the small data base of cross sectional and longitudinal studies assessing the long-term effects of $O_3$.

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Figure legends

Figure 1. Mean change and 95% CI in lung function indices associated with an increase of 10μg/m$^3$ in $O_3$ calibrated long-term exposure* in 97 schoolchildren school children in Athens and 89 in Thessaloniki. Results from 2-level (nearest fixed site monitor; child) mixed effect regression models, regarding spirometry measurements**. Results from multiple linear regression models, regarding lung function percentage growth**.

Figure 2. Mean percent change and 95% CI in exhaled nitric oxide fraction ($F_{eNO}$; ppb) associated with an increase of 10μg/m$^3$ in $O_3$ calibrated long-term exposure* in 97 schoolchildren school children in Athens and 89 in Thessaloniki. Results from 2-level (nearest fixed site monitor; child) mixed effect regression models, adjusting for sex (girls / boys), city (Athens / Thessaloniki), years of father's education, mean time spent outdoors daily (hours), citrus fruits consumption (yes/no), $PM_{10}$ (μg/m$^3$) measurements.

Figure 1 Footnotes

*Fixed sites: (personal measurements/overall mean of personal exposure) X 24h annual average $O_3$ measurements from fixed sites; Dispersion models: (personal measurements/ overall mean of personal exposure) X 24h annual average estimates of $O_3$ concentrations from dispersion models, taking into account address history

**adjusting for sex (girls / boys), height (cm) , weight (kg), city (Athens / Thessaloniki), years of father's education, mean time spent outdoors daily (hours), citrus fruits consumption (yes/no), $PM_{10}$ (μg/m$^3$) measurements (24h annual average). In case of lung function percentage growth, we accounted for height (cm) & weight difference (kg).

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Figure 2 Footnotes

*Fixed sites: (personal measurements/overall mean of personal exposure) X 24h annual average $O_3$ measurements from fixed sites; Dispersion models: (personal measurements/ overall mean of personal exposure) X 24h annual average estimates of $O_3$ concentrations from dispersion models, taking into account address history

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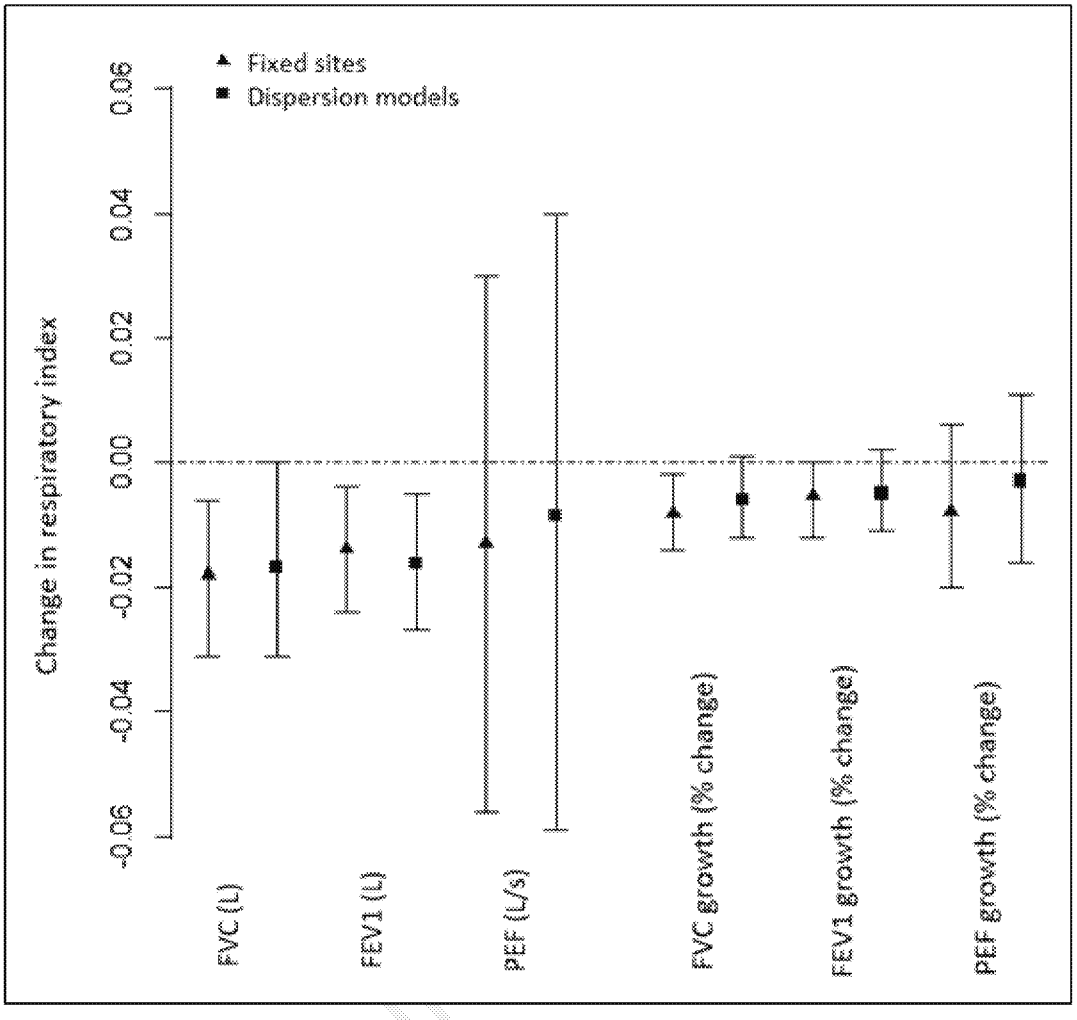

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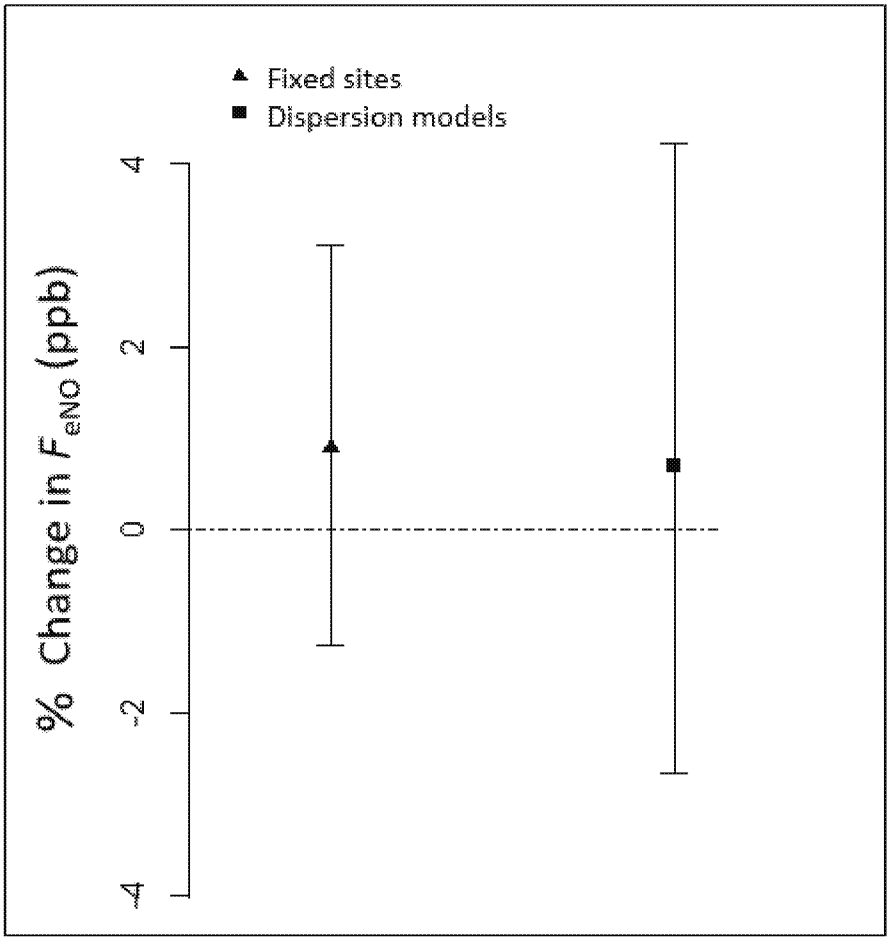


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**Highlights:**

We investigated the effects of long-term exposure to ambient ozone on respiratory health outcomes in children.

This study shows adverse associations between long-term $O_3$ exposure and children's lung development, which may be of clinical relevance for a subset of the general population.

These early life impacts of long-term $O_3$ exposure may provide an explanation for premature mortality and increased morbidity in later life.

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# Attachment 5

EPA-HQ-2021-5551

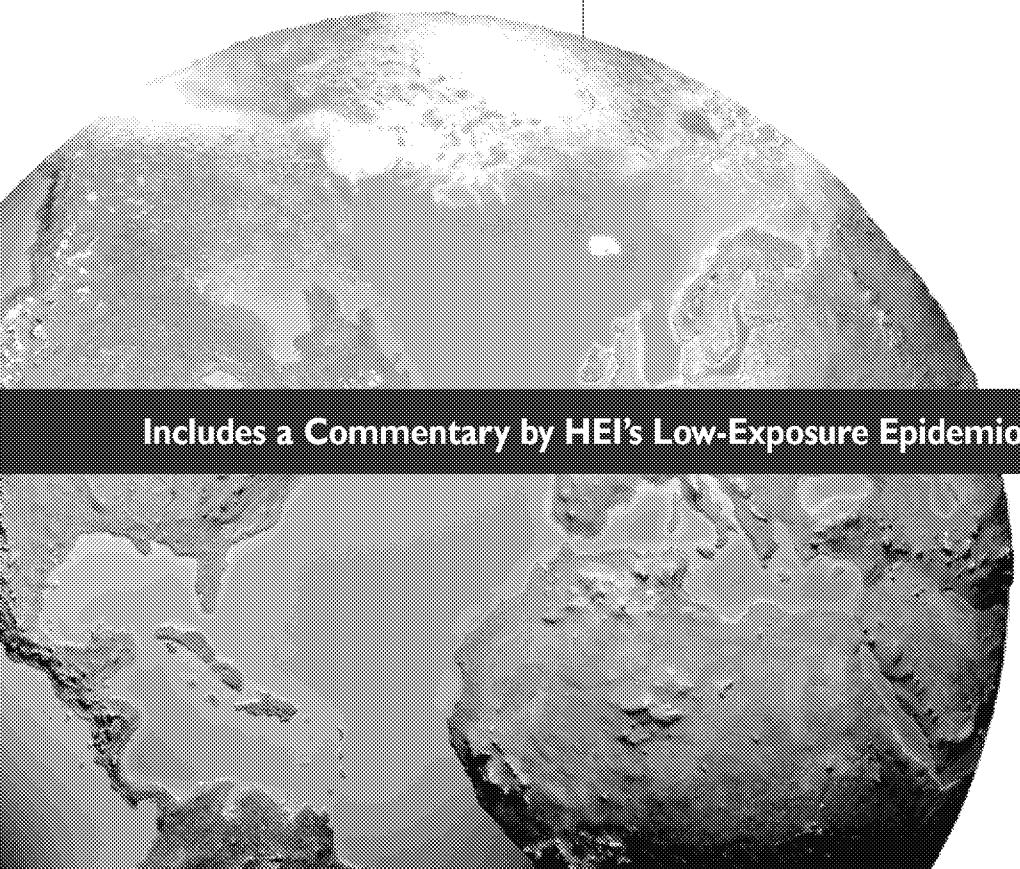
RESEARCH REPORT

HEALTH EFFECTS INSTITUTE

Number 200
November 2019

# Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1

Francesca Dominici, Joel Schwartz, Qian Di, Danielle Braun, Christine Choirat, and Antonella Zanobetti



Includes a Commentary by HEI's Low-Exposure Epidemiology Studies Review Panel

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# Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1

Francesca Dominici, Joel Schwartz, Qian Di, Danielle Braun,
Christine Choirat, and Antonella Zanobetti

with a Commentary by
HEI's Low-Exposure Epidemiology Studies Review Panel

Research Report 200
Health Effects Institute
Boston, Massachusetts

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# ABOUT HEI

The Health Effects Institute is a nonprofit corporation chartered in 1980 as an independent research organization to provide high-quality, impartial, and relevant science on the effects of air pollution on health. To accomplish its mission, the institute

- Identifies the highest-priority areas for health effects research;
- Competitively funds and oversees research projects;
- Provides intensive independent review of HEI-supported studies and related research;
- Integrates HEI's research results with those of other institutions into broader evaluations; and
- Communicates the results of HEI's research and analyses to public and private decision makers.

HEI typically receives balanced funding from the U.S. Environmental Protection Agency and the worldwide motor vehicle industry. Frequently, other public and private organizations in the United States and around the world also support major projects or research programs. HEI has funded more than 340 research projects in North America, Europe, Asia, and Latin America, the results of which have informed decisions regarding carbon monoxide, air toxics, nitrogen oxides, diesel exhaust, ozone, particulate matter, and other pollutants. These results have appeared in more than 260 comprehensive reports published by HEI, as well as in more than 1,000 articles in the peer-reviewed literature.

HEI's independent Board of Directors consists of leaders in science and policy who are committed to fostering the public–private partnership that is central to the organization. The Research Committee solicits input from HEI sponsors and other stakeholders and works with scientific staff to develop a Five-Year Strategic Plan, select research projects for funding, and oversee their conduct. For this study, a special panel — HEI's Low-Exposure Epidemiology Studies Oversight Panel — has worked with the Research Committee in project selection and oversight. The Review Committee, which has no role in selecting or overseeing studies, works with staff to evaluate and interpret the results of funded studies and related research. For this study, a special review panel — HEI's Low-Exposure Epidemiology Studies Review Panel — is fulfilling this role.

All project results and accompanying comments by the Review Committee (or, in this case, the Low-Exposure Epidemiology Studies Review Panel) are widely disseminated through HEI's website (*www.healtheffects.org*), printed reports, newsletters and other publications, annual conferences, and presentations to legislative bodies and public agencies.

# ABOUT THIS REPORT

Research Report 200, *Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1*, presents a research project funded by the Health Effects Institute and conducted by Dr. Francesca Dominici, of Harvard T.H. Chan School of Public Health, Boston, Massachusetts, and her colleagues. The report contains three main sections.

**The HEI Statement,** prepared by staff at HEI, is a brief, nontechnical summary of the study and its findings; it also briefly describes the Low-Exposure Epidemiology Studies Review Panel's comments on the study.

**The Investigators' Report,** prepared by Dominici and colleagues, describes the scientific background, aims, methods, results, and conclusions of the study.

**The Commentary,** prepared by members of the Low-Exposure Epidemiology Studies Review Panel with the assistance of HEI staff, places the study in a broader scientific context, points out its strengths and limitations, and discusses remaining uncertainties and implications of the study's findings for public health and future research.

This report has gone through HEI's rigorous review process. When an HEI-funded study is completed, the investigators submit a draft final report presenting the background and results of the study. This draft report was first examined by outside technical reviewers and a biostatistician. The report and the reviewers' comments were then evaluated by members of the Low-Exposure Epidemiology Studies Review Panel, an independent panel of distinguished scientists who have no involvement in selecting or overseeing HEI studies. During the review process, the investigators had an opportunity to exchange comments with the Review Panel and, as necessary, to revise their report. The Commentary reflects the information provided in the final version of the report.

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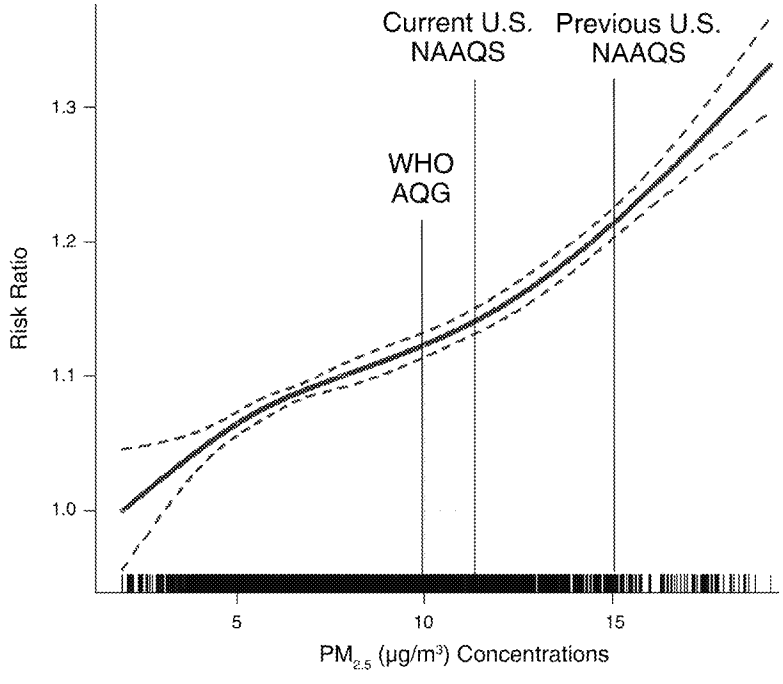
# PREFACE

## HEI's Program to Assess Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution

### INTRODUCTION

Levels of ambient air pollution have declined significantly over the last decades in North America, Europe, and in other developed regions. Despite the decreasing levels of air pollution, recent epidemiological studies report associations between adverse health effects and exposure to air pollution. These studies have found associations between exposure to fine particulate matter, that is, particulate matter ≤2.5 μm in aerodynamic diameter ($PM_{2.5}$*), and mortality at levels below current ambient air quality standards (e.g., Beelen et al. 2014; Crouse et al. 2012; Hales et al. 2012) (Preface Figure 1). In order to improve the science and inform future regulation, it is important to confirm whether associations with adverse health effects continue to be observed as levels of air pollution have declined. It is also important to better understand the shape of the exposure–response function at those low levels.

The growing scientific evidence for effects at levels below current air quality standards and the large overall estimates of the air pollution-attributable burden of




**Preface Figure 1. Shape of the concentration–response function for mortality associated with fine particulate matter in a Canadian Cohort.** (Courtesy R. Burnett). NAAQS = National Ambient Air Quality Standard; WHO AQG = World Health Organization Air Quality Guidelines.

* A list of abbreviations and other terms appears at the end of this volume.

disease, as well as the interest in reducing greenhouse gases, suggest that more stringent air quality standards and guidelines may be considered in the future. For these reasons, there is a need for additional investigation to improve our understanding of exposure–response function(s) for mortality and morbidity at low levels of $PM_{2.5}$, ozone ($O_3$), and other ambient air pollutants. Such studies would inform risk assessors and policy makers regarding exposure–response functions at levels of ambient air pollution currently prevalent in North America, Western Europe, and other high-income regions of the world.

In 2014, HEI issued RFA 14-3, *Assessing Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution,* to solicit studies to address these important questions. The main goals of the RFA were to:

1. Fund studies to assess health effects of long-term exposure to low levels of ambient air pollution, including all-cause and cause-specific mortality and morbidity. Such studies should analyze and evaluate exposure–response function(s) for $PM_{2.5}$ and other pollutants at levels currently prevalent in North America, Western Europe, and other high-income regions. The studies may also address related questions about health effects at low levels of ambient air pollution.
2. Develop statistical and other methodology required for, and specifically suited to, conducting such research including, but not limited to, evaluation and correction of exposure measurement error.

Applicants were asked to pay particular attention to having sufficiently large cohorts and statistical power to detect associations should they exist, having the ability to test various potential confounders of any associations, and developing exposure-assessment approaches and statistical methodology that would enable a robust examination of the associations.

Specifically, applicants were asked to propose studies to:

1. Compare and contrast alternative analytic models and accompanying uncertainty. For example, compare threshold against nonthreshold models, linear against nonlinear models, and parametric against nonparametric models, to characterize the exposure–response function(s) at low levels of ambient air pollution.
2. Explore possible variability in estimates of risk at low pollutant concentrations among populations, and identify possible contributing factors. Such factors could include age, smoking, socioeconomic position, health status, and access to medical care, as well as differences in air pollution sources and time–activity patterns.
3. Develop and evaluate exposure-assessment methods suitable to estimate exposure to low levels of air pollution at various spatial and temporal scales in large study populations, including people who reside in areas not covered by routine ground-level monitoring.
4. Develop, evaluate, and apply statistical methods to quantify and correct for exposure measurement error in risk estimates and in characterization of exposure–response relationships.
5. Develop and validate approaches to assess the effects of co-occurring pollutants on any health effect associations at low ambient concentrations.
6. Develop and validate indirect approaches to correct risk estimates for the effects of important potential confounding variables, such as smoking, in the absence of such data at the individual level.
7. Improve techniques for record linkage and methods for disclosure protection for optimal use of large administrative databases in air pollution and health research.

## STUDY SELECTION

HEI established an independent Low-Exposure Epidemiology Studies Oversight Panel — consisting of outside experts and HEI Research Committee members — to prepare RFA 14-3 and review all applications submitted in response (see Contributors page). Members of HEI's Research Committees with any conflict of interest were recused from all discussions and from the decision-making process. The HEI Research Committee reviewed the Panel's recommendations and recommended three studies for funding to HEI's Board of Directors, which approved funding in 2015.

# Preface

This Preface summarizes the three studies, HEI's oversight process, and the review process for the Phase 1 reports.

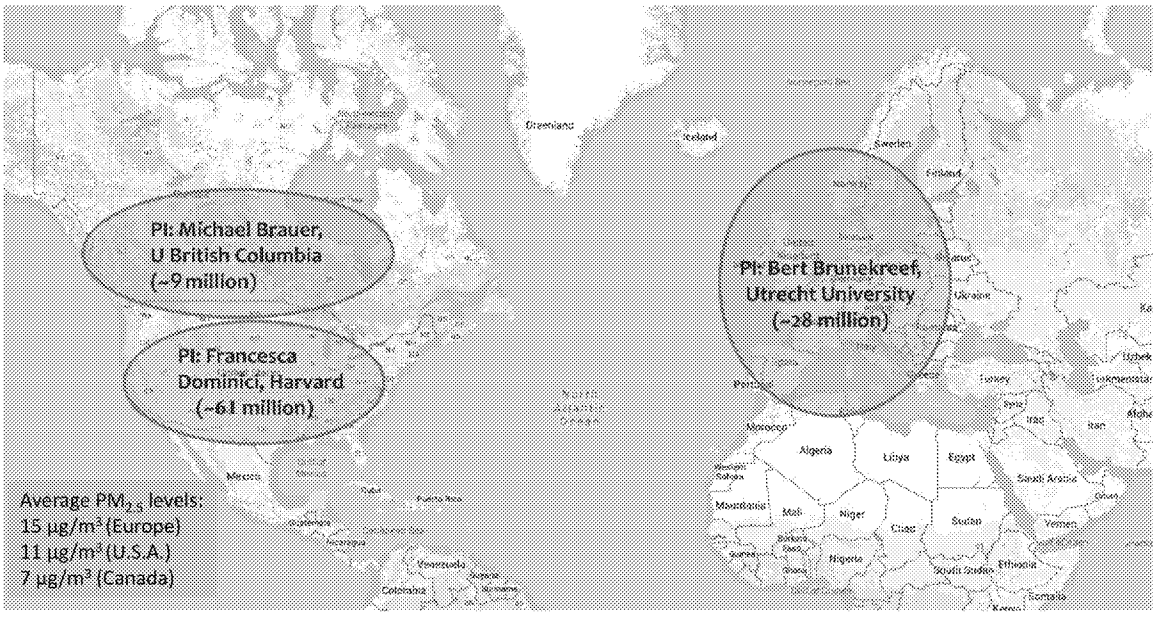
## OVERVIEW OF THE HEI LOW-EXPOSURE EPIDEMIOLOGY STUDIES

After a rigorous selection process, HEI funded three teams, led by Michael Brauer at The University of British Columbia, Canada, Francesca Dominici at the Harvard T.H. Chan School of Public Health, United States, and Bert Brunekreef at the University of Utrecht, the Netherlands, to investigate health effects of exposure to low levels of air pollution in very large populations in Canada, the United States, and Europe, respectively (see Preface Table and Preface Figure 2). The studies included large population cohorts (with detailed individual information about potential confounders for all subjects or for subsets of cohorts), as well as large administrative databases with greater statistical power (albeit with less individual information about potential confounders). Additionally, the three teams employed satellite data and ground-level pollutant measurements, used high-quality exposure-assessment models at high spatial resolutions, and set out to develop and apply novel statistical methods.

The three studies are expected to inform the scientific community and the risk assessors and policy makers regarding exposure–response functions at levels of ambient air pollution currently prevalent in North

**Preface Table.** HEI's Program to Assess Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution

| Investigator (Institution) | Study Title | Phase 1 Report | Phase 2 (Final) Report Expected |
|---|---|---|---|
| **Brauer, Michael** (The University of British Columbia, Canada) | Mortality–Air Pollution Associations in Low Exposure Environments (MAPLE) | Brauer M, Brook JR, Christidis T, Chu Y, Crouse DL, Erickson A, et al. 2019. Mortality–Air Pollution Associations in Low-Exposure Environments (MAPLE): Phase 1. Research Report 203. Boston, MA:Health Effects Institute. | Summer 2020 |
| **Brunekreef, Bert** (Utrecht University, the Netherlands) | Mortality and Morbidity Effects of Long-Term Exposure to Low-Level $PM_{2.5}$, Black Carbon, $NO_2$ and $O_3$: An Analysis of European Cohorts | None | Fall 2020 |
| **Dominici, Francesca** (Harvard University, T.H. Chan School of Public Health, U.S.A.) | Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Pollution | Dominici F, Schwartz J, Di Q, Braun D, Choirat C, Zanobetti A. 2019. Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1. Research Report 200. Boston, MA:Health Effects Institute. | Summer 2020 |




**Preface Figure 2. Geographical areas and populations covered by HEI's research program to assess adverse health effects of long-term exposure to low levels of ambient air pollution.**

America, Western Europe, and other developed regions. The full sets of analyses are expected to be completed in 2020, as discussed in the following sections.

## CANADIAN STUDY (MICHAEL BRAUER ET AL.)

Brauer and colleagues are assessing the relationship between nonaccidental mortality and long-term exposure to low concentrations of $PM_{2.5}$ in four large population-based cohorts, including a careful characterization of the shape of the exposure–response function. The investigators are using Canadian census data and have access to a nationally representative population of approximately 9 million Canadians (ages 25–90 yr) (Preface Figure 2). The Canadian team is developing hybrid models primarily using satellite data, as well as chemical transport models, land-use variables, and routinely collected monitoring data for $PM_{2.5}$. They are also estimating ambient concentrations for nitrogen dioxide ($NO_2$) and $O_3$ for Canada and the United States during the period 1981–2016. Additionally, they will be validating satellite data against ground-based monitors in Canada as part of the SPARTAN network (Snider et al. 2015).

The exposure models are applied to estimate effects of air pollution exposure on all-cause and cause-specific mortality in four Canadian cohorts:

1. About 2.5 million respondents who completed the 1991 census long form of the Canadian Census Health & Environment Cohorts (CanCHEC),
2. About 3 million respondents who completed the 1996 CanCHEC census long-form,
3. About 3 million respondents who completed the 2001 CanCHEC census long-form, and
4. About 540,000 respondents who participated in the Canadian Community Health Survey (CCHS) between 2001 and 2012, and reported individual-level risk factors, including smoking.

## EUROPEAN STUDY (BERT BRUNEKREEF ET AL.)

Brunekreef and colleagues are basing their study on the European Study of Cohorts for Air Pollution Effects (ESCAPE), which started about a decade ago; its results have been published widely (e.g., Beelen et al. 2014). In the current HEI-funded study, the investigators are analyzing pooled data from 10 ESCAPE cohorts (instead of

the cohort-specific approach they used previously). In addition, they are using data from six large administrative cohorts to yield a total study population of approximately 28 million Europeans (Preface Figure 2). They are developing hybrid, Europe-wide and location-specific exposure models that utilize land-use information, dispersion modeling, satellite data, ESCAPE monitoring data, and routinely collected monitoring data for $PM_{2.5}$, $NO_2$, $O_3$, and black carbon at high spatial resolution (residential address level; such detailed information is very difficult to obtain in the United States).

Brunekreef and colleagues are investigating the following health outcomes: all-cause and cause-specific mortality, incidence of coronary and cerebrovascular events, and lung cancer incidence. The incorporation of ESCAPE cohorts with individual covariate information as well as very large administrative cohorts (albeit with less detailed information) will provide new insights in the merits of both approaches.

### UNITED STATES STUDY (FRANCESCA DOMINICI ET AL.)

Dominici and colleagues are evaluating Medicare and Medicaid data for a study population of approximately 61 million Americans (Preface Figure 2). They are developing high spatial resolution (1 $km^2$-grid) hybrid exposure models that incorporate satellite data, chemical transport models, land-use and weather variables, and routinely collected monitoring data for $NO_2$, $O_3$, and $PM_{2.5}$ and its components, for the continental United States during the period 2000–2012. Exposure models will be applied to estimate adverse health effects of air pollution in three cohorts:

1. Medicare enrollees (28.6 million elderly enrollees per year, 2000–2012);
2. Medicaid enrollees (28 million enrollees per year, 2010–2012); and
3. Medicare Current Beneficiary Survey enrollees (nationally representative sample of approximately 15,000 enrollees per year with rich individual-level risk factor information, including smoking).

Dominici and colleagues are analyzing the following health outcomes: time to death, time to hospitalization by cause, and disease progression (time to rehospitalization). They are developing and applying new causal inference methods to estimate exposure–response functions to adjust for confounding and exposure measurement error. Additionally, they are developing tools for reproducible research including approaches for data sharing, record linkage, and statistical software.

## STUDY OVERSIGHT

HEI's independent Low-Exposure Epidemiology Studies Oversight Panel continues to provide advice and feedback on the study design, analytical plans, and study progress throughout the duration of the research program.

Given the substantial challenges in conducting a systematic analysis to assess health effects of long-term exposure to low levels of ambient air pollution, HEI has worked actively (and continues to do so) with the study teams to coordinate their efforts and ensure the maximum degree of comparable epidemiological results at the end of this research effort. To this end, HEI has regularly held investigator workshops and site visits, among other activities. In addition, the studies are subject to HEI's special Quality Assurance procedures, which include an audit by an independent audit team (see *www.healtheffects.org/research/quality-assurance).*

## REVIEW OF PHASE 1 AND PHASE 2 (FINAL) REPORTS

To inform the ongoing review of the U.S. National Ambient Air Quality Standards (NAAQS) for $PM_{2.5}$ and $O_3$ starting in 2018, HEI requested Phase 1 reports from the investigators based on the research completed during the first two years of the Canadian and U.S. studies. Thus, the Phase 1 reports by Drs. Brauer and Dominici provide summaries of results to date, including those published in journal articles.

As is common for major research programs, HEI convened a Low-Exposure Epidemiology Studies Review Panel to independently review the Phase 1 reports by Drs. Brauer and Dominici. The Panel consists of seven experts in epidemiology, exposure assessment, and biostatistics (see Contributors page). Commentaries by the Review Panel accompany the Phase 1 reports. The Panel will also review the final reports of the three studies.

# Preface

The Phase 1 Research Reports provide an opportunity to present the results from the first two years of research in one place and to present the Review Panel's Commentaries, which review the results and evaluate the studies' strengths and weaknesses. The three studies commenced in spring 2016 and are expected to be completed in summer 2020, with final reports published during 2021.

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Snider G, Weagle CL, Martin RV, van Donkelaar A, Conrad K, Cunningham D et al. 2015. SPARTAN: A global network to evaluate and enhance satellite-based estimates of ground-level particulate matter for global health applications. Atmos Meas Tech Discuss 7:7569–7611.

# HEI STATEMENT

## Synopsis of Research Report 200

# Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1

### INTRODUCTION

The levels of most ambient air pollutants have declined significantly in the United States during the last few decades. Recent epidemiological studies, however, have suggested an association between exposure to ambient levels of air pollution — even below the current U.S. National Ambient Air Quality Standards (NAAQS) — and adverse

## What This Study Adds

- This study is part of an HEI program to address questions regarding potential associations between air pollution exposure and health outcomes at low ambient air pollution levels, particularly at levels below the current U.S. national air quality standards.
- Dominici and colleagues developed hybrid, U.S.-wide models using machine learning to estimate outdoor fine particle (particulate matter $\leq 2.5$ μm in aerodynamic diameter, or $PM_{2.5}$) and ozone ($O_3$) concentrations at 1 km × 1 km grids, by combining monitoring, satellite, transport modeling output, and other data.
- They obtained Medicare data for 61 million Americans, ages 65 years and older, who enrolled between 2000 and 2012. Using both cohort and case–crossover designs, they analyzed the association between long-term and short-term outdoor $PM_{2.5}$ and $O_3$ exposures and mortality.
- The investigators report positive associations between nonaccidental, all-cause mortality and $PM_{2.5}$ and $O_3$ at low concentrations, including below the U.S. National Ambient Air Quality Standards (annual 12 μg/m$^3$ for $PM_{2.5}$ and 8-hour 70 ppb for $O_3$).
- These associations were robust to most adjustments for potential confounding by a number of lifestyle and behavioral factors in the cohort analyses. Sensitivity analyses did not meaningfully impact the findings of association.
- HEI's Low-Exposure Epidemiology Studies Review Panel noted, however, that several important issues still need to be addressed by the investigators regarding these results during the remainder of this project. In particular, the potential for confounding by time and the complexities introduced by the use of different spatial scales for the exposure and health data need to be explored in more detail, and the causal inference methods need to be more fully applied.
- The Panel concluded that Dominici and colleagues have conducted an extensive and innovative set of initial analyses in these extraordinarily large air pollution and health data sets. While initial conclusions may be drawn from these analyses, the Panel awaits the further analyses that are underway before reaching full conclusions on the air pollution and public health implications of this important research.

This Statement, prepared by the Health Effects Institute, summarizes a research project funded by HEI and conducted by Dr. Francesca Dominici at the Harvard T.H. Chan School of Public Health, Boston, Massachusetts, and colleagues. Research Report 200 contains both the detailed Investigators' Report and a Commentary on the study prepared by HEI's Low-Exposure Epidemiology Studies Review Panel.

health effects. In view of the importance of such research findings, the Health Effects Institute in 2014 issued a request for applications (RFA 14-3) seeking to fund research to assess the health effects of long-term exposure to low levels, particularly below the NAAQS, of ambient air pollution and to develop improved statistical methods for conducting such research. HEI funded three studies under this program; each study used state-of-the-art exposure methods and very large cohorts. The studies were based in the United States, Canada, and Europe, thus providing a comprehensive cross-section of high-income countries where ambient levels are generally low.

The low-exposure-level studies are scheduled to be completed in 2020. In 2018, in order to inform the ongoing review of the NAAQS for fine particles ($PM_{2.5}$) and ozone ($O_3$), HEI requested Phase 1 reports from the U.S. (Francesca Dominici) and Canadian (Michael Brauer) investigators. HEI's formed a special panel, the Low-Exposure Epidemiology Studies Review Panel, to evaluate the studies' methods, results, conclusions, and their strengths and weaknesses. This Statement focuses on the study by Dr. Francesca Dominici, from the Harvard T.H. Chan School of Public Health, Boston, Massachusetts, and her colleagues, titled, "Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution."

## APPROACH

**Aims:** The aims of the Dominici study were to (1) develop hybrid, high-resolution, exposure-prediction models to estimate long-term exposures to $PM_{2.5}$ and $O_3$ levels for the continental United States; (2) develop and apply causal inference methods; (3) estimate all-cause mortality associated with exposure to ambient air pollution for all U.S. Medicare enrollees between 2000 and 2012 using a cohort (long-term) and a case–crossover (short-term) design; and (4) develop tools for data sharing, record linkage, and statistical software.

**Data and Methods:** Dominici and colleagues developed hybrid air pollution concentration models for the contiguous United States for the period 2000 to 2012, using data from a variety of sources, including satellite data, chemical transport models, land-use and weather variables, and routinely collected air monitoring data from the U.S. Environmental Protection Agency (EPA).

With this large amount of data and using multiple approaches and input variables, the investigators developed a hybrid model to estimate daily $PM_{2.5}$ and $O_3$ concentrations at 1 km $\times$ 1 km grids across the continental United States. Complex atmospheric processes were addressed using a neural network that modeled nonlinearity and interactions. The neural network was trained using data covering the study period, and the predictions were validated against 10% of the EPA air monitors left out of the model. A similar approach was used to estimate and validate a model to predict $O_3$ concentrations during the warm months (April through September) of each study year.

Health data were obtained from the Centers for Medicare and Medicaid Services for all Medicare enrollees for the years 2000 to 2012, which represents more than 96% of the U.S. population 65 years of age and older (see Statement Table). The study obtained records for all Medicare enrollees (~61 million), with 460 million person-years of follow-up and 23 million deaths. They also obtained covariate information from the Medicare Current Beneficiary Survey (MCBS; ~57,000 people), an annual phone survey of a nationally representative sample of Medicare beneficiaries, with information on more than 150 individual-level risk factors, including smoking and body mass index.

Using the Medicare data and cohort and case–crossover designs, they investigated the association between exposure to $PM_{2.5}$ and $O_3$ and all-cause mortality in two-pollutant analyses, including separate analyses for low pollutant concentrations. For the cohort study, they performed survival analyses using the Andersen-Gill method, a variant of the traditional Cox proportional hazards model that incorporates spatiotemporal features by allowing for variation in covariates from year to year. The investigators developed concentration–response curves by fitting a log-linear model with thin-plate splines for both pollutants while controlling for important individual and ecological variables, including socioeconomic status and race. For the case–crossover study, the case day was defined as the date of death, with exposure defined as the mean of the ambient concentration on that day and the day before; this was compared to exposure on three predefined control days. They fitted a conditional logistic regression to all pairs of case and matched control days, thus estimating the relative risk of all-cause mortality associated

**Statement Table.** Key Features of the Dominici et al. Study

| | |
|---|---|
| **Overall** | |
| Medicare study population | 60.9 million |
| MCBS study population | 57,200 |
| Study period | 2000–2012 |
| **Case–Control Study** | |
| Follow-up period | 460.3 million person-years |
| Deaths | 22.6 million |
| $PM_{2.5}$ average concentration | 11.0 µg/m$^3$ |
| $O_3$ average concentration | 46.3 ppb |
| **Case–Crossover Study** | |
| Case days | 22.4 million |
| Control days | 76.1 million |
| $PM_{2.5}$ average concentration | 11.6 µg/m$^3$ |
| $O_3$ average concentration | 37.8 ppb |

with short-term exposure to $PM_{2.5}$ and $O_3$. They also performed subanalyses to explore the health effects at lower levels of exposure.

To assess whether any subgroups within the cohort study were at higher or lower risk of mortality associated with either long-term or short-term air pollution exposure, the investigators fitted the same statistical models to certain population subgroups (e.g., male vs. female and white vs. black). To explore the robustness of the results from the cohort analysis, they performed sensitivity analyses and compared any changes in risk estimates with differences in confounder adjustment and estimation approaches. Finally, since Medicare data do not include information on many important individual-level covariates, the investigators utilized data from the Medicare Current Beneficiary Statement to examine how the lack of adjustment for these risk factors could have affected the risk estimates for the Medicare cohort.

## RESULTS

Dominici and colleagues report overall good performance of the models for estimating $PM_{2.5}$ and $O_3$ concentrations, with overall $R^2$ values of 0.84 and 0.80, respectively. For $PM_{2.5}$, the average annual concentration was 11.0 µg/m$^3$ during the study period, 2000–2012. Performance of the model varied between different geographical regions and seasons; the highest $PM_{2.5}$ concentrations were predicted to be in California and the eastern and southeastern United States, and model performance was better in the eastern and central United States than in the western part of the country. And, the $PM_{2.5}$ model performed best during the summer. For $O_3$, the average of 8-hour daily concentrations during the warm season was 46.3 ppb during the study period. $O_3$ concentrations were highest in the Mountain region and in California and lower in the eastern states. The average concentrations of $PM_{2.5}$ decreased during the study period, but $O_3$ concentrations remained more or less the same. Annual $PM_{2.5}$ and warm-season $O_3$ concentrations were only weakly correlated.

The 2000–2012 cohort of Medicare beneficiaries provided a very large population for studying association with long-term effects of exposure to ambient air pollution. In two-pollutant analyses of long-term effects, Dominici and colleagues report a 7.3% higher risk of all-cause mortality for each 10-µg/m$^3$ increase in annual average $PM_{2.5}$ concentrations and a 1.1% higher risk of mortality for each 10-ppb increase in average $O_3$ concentrations in the warm season. At low concentrations — less than 12 µg/m$^3$ $PM_{2.5}$ and less than 50 ppb $O_3$ — the risk was 13.6% for $PM_{2.5}$ and 1.0% for $O_3$ for each 10-µg/m$^3$ and 10-ppb increase in concentrations, respectively. The concentration–response relationships from the two-pollutant models showed almost

linear curves, with no suggestion of a threshold down to 5 μg/m$^3$ $PM_{2.5}$ and 30 ppb $O_3$.

In subgroup analyses for long-term $PM_{2.5}$ exposure, the investigators found larger estimates of effect among males and among Hispanics, Asians, and particularly African Americans, compared with whites. Individuals with low socioeconomic status, as indicated by eligibility for Medicaid, appear to have a slightly higher risk per unit of $PM_{2.5}$ exposure. For long-term $O_3$ exposure, the subgroup analysis showed that the effect estimates were higher for Medicaid-eligible enrollees and slightly higher for whites, but these analyses also produced puzzling hazard ratios of less than 1 for certain subgroups, including Hispanics and Asians, and particularly for Native Americans, than the overall population.

For short-term exposures, the investigators observed a 1.05% greater risk of mortality in two-pollutant models for a 10-μg/m$^3$ increase in $PM_{2.5}$ concentrations and a 0.51% greater risk for a 10-ppb increase in 8-hour warm-season $O_3$ concentration. (Pollutant levels were averaged over the current and previous day.) At low concentrations (below 25 μg/m$^3$ of $PM_{2.5}$ and below 60 ppb of $O_3$), the associations remained elevated for both pollutants (1.61% for $PM_{2.5}$ and 0.58% for $O_3$). The concentration–response curves showed the relative risk increasing sharply for both pollutants at a relatively low concentration and then leveling out at higher concentrations. The investigators observed evidence of effect modification for several variables, including a higher $PM_{2.5}$–mortality risk for females than for males.

## INTERPRETATION OF RESULTS

In its independent review of the study, HEI's Low-Exposure Epidemiology Studies Review Panel noted that the report by Dominici and colleagues summarizes an impressive amount of work completed in the first part of this HEI project. Particularly strong aspects of this work include the extremely large, national cohort, with high-resolution exposure assessment and development and application of state-of-the-art statistical techniques. The Panel also noted that additional research, including further development of causal methods that would properly allow for the complexities in the design of the studies and nature of the data, is currently ongoing.

**Exposure Assessment:** The use of large, diverse, and existing data sets to generate estimates of $PM_{2.5}$ and $O_3$ concentrations on a 1 km × 1 km national grid for the entire continental United States (~8 million km$^2$) is impressive, and allowed the investigators to estimate concentrations in areas where air monitors are sparse. However, as with any exposure assessment, it is critical to consider the potential for exposure prediction errors.

Despite steps to correct for regional and compositional differences, both geographical and temporal variability in the errors of the concentration estimates persisted in the final estimates for $PM_{2.5}$ and $O_3$. The exposure model was trained by leaving out 10% of EPA air quality monitors. But because these monitors are generally located in areas with high population density, it is possible that the model is prone to larger error in areas with lower population density — which generally have lower $PM_{2.5}$ concentrations and therefore are of greater interest in the context of this study. And, based on earlier work by the researchers that provides the basis for the exposure models used in these studies, it appears that the model may systematically underpredict concentrations for unexplained reasons. The nature, sources, size, and potential impact of the potential errors discussed here are important to understand and deserve attention in future analyses.

**Long-Term Health Effects, Cohort Study:** Using the massive database of all Medicare recipients during 2000 to 2012, and combining it with the equally large exposure predictions, Dominici and colleagues have performed a study with extraordinary statistical power to investigate the association between all-cause mortality and long-term exposure to a range of $PM_{2.5}$ and $O_3$ levels. That they observed an association between annual average concentrations and mortality at higher concentrations was not the new finding of this research, but the findings at low levels, particularly at levels below the current NAAQS, are novel and potentially important.

The greatest challenge to the internal validity of this study, as for all observational studies, is the potential for confounding, which can bias the results. To address such concerns, the investigators performed numerous analyses with some 20 covariates. They also utilized findings from a smaller Medicare cohort that had a much richer set of potential confounding variables to assess the likely impact of having only a limited number of covariates in the main cohort analysis. In addition, to allow for the effects of time-dependent covariates known to vary from year to year, they utilized a variant of the classic Cox proportional hazards model, the Andersen-Gill formulation.

However, this is a complex study. Health and personal characteristics are available for individuals, but ambient air pollutant exposure is estimated at the ZIP code level (averaged from the 1 km × 1 km spatial scale of the prediction model). Additionally, the ZIP code scale is the smallest spatial unit at which individual residential and other covariate information is available. These factors, coupled with confounders that can act at the level of the individual, the community, or the regional environment, result in a complex hybrid model. These issues pose important challenges for the next phase of the work planned by the investigators, and the causal inference methods under development will need to focus on these challenges.

Based on the current results, the Panel offers the following comments most relevant to the cohort analyses.

The investigators performed various analyses to explore the potential impact of confounding; however, the Panel noted several areas with a potential for residual confounding in the cohort study. For example, some results from the subgroup analyses are puzzling, particularly the dramatically higher effect of $PM_{2.5}$ exposure in African Americans and the negative (protective) effects of exposure to $O_3$ for Native Americans, Hispanics, and Asians.

Although the investigators have used the Andersen-Gill formulation to better model time-dependent variables, the Panel's biggest concern relates to the problem of potential for temporal confounding, with both overall nonaccidental mortality and $PM_{2.5}$ levels declining steadily over the period of the study, 2000–2012. Because this is an open cohort (new individuals enter the cohort as they enroll for Medicare), age — which is controlled in the analyses — is not necessarily strongly correlated with calendar time. As a result, confounding could occur because of the contributions of both age and calendar time. The Panel believes that without accounting for confounding by time, the findings of the long-term exposure study should be viewed with caution.

The Panel also has concerns about the impact of the likely exposure misclassification and confounding related to the hybrid nature of the study, but appreciates that exposure measurement error correction methodology for spatially varying pollutants and methods to address confounding in such a complex study setting are still in their infancy. Additionally, the Panel notes that data on individual health-related behaviors, such as smoking, diet, and exercise, do not capture the full extent of variability in the behaviors, such as geographical variability. Finally, the presence of other pollutants — such as $NO_2$ — may also confound the associations between $PM_{2.5}$ and $O_3$ and mortality.

Another important issue in interpretation of these results is related to the very large population studied here, and consequently the very high apparent precision of the results (i.e., the very small confidence intervals). Because the impact of bias and model misspecification is not reflected in standard uncertainty measures, one should be cautious about over-interpreting the narrow confidence intervals. The Panel's comments and concerns about the potential impacts of bias and of unmeasured confounding should be viewed in this broader context.

**Short-Term Health Effects, Case-Crossover Study:** The second study in this report uses a case–crossover design — a variant of the time-series design — to evaluate short-term effects of low-level air pollution in the Medicare population. One advantage this study design has over the long-term design is that it is based on variation in exposure and mortality experienced by an individual over short periods of time (days, rather than years). Therefore, only confounding factors that vary over short periods of time, such as weather, are of potential concern, rather than the much larger array of potential confounders that either do not vary with time or have long-term trends. On the other hand, by design, time-series analyses only address the immediate impact of air pollution on mortality rather than the pollutants' role in the development of chronic morbidity and subsequent mortality.

Dominici and colleagues report a relative risk increase of 1.05% and 0.51% in daily mortality rate for each 10-$\mu g/m^3$ increase in $PM_{2.5}$ and 10-ppb increase in $O_3$, respectively. The concentration–response analyses for $PM_{2.5}$ and $O_3$ suggest a nonlinear relationship, with a steeper slope at low concentrations and flattening at higher concentrations. They have also investigated effect modifications for a range of variables. For example, they report that the mortality effect of short-term exposure to $PM_{2.5}$ is greater in women than in men, in contrast to the finding in the cohort study. The effects in other subgroup analyses were generally not significant, except for Medicaid eligibility. Also, $NO_2$ — another time-varying covariate — was not included in these analyses.

**Causal Modeling:** There is increasing interest in research on casual inference methods because of the challenges in accounting for confounding in the preceding analyses of observational data, and Dominici and colleagues are devoting significant effort to the development and extension of two such methods.

In the first method, the investigators have developed a generalized-propensity-score approach for confounding adjustment along with a regression calibration method to address exposure measurement error in health models. In the second approach, they have developed a new Bayesian causal approach, known as *local exposure–response confounding adjustment*, to estimate exposure–response curves accounting for differential effects of confounders at different levels of exposure. Both of these approaches serve as potentially useful starting points, and the Panel notes that current applications do not address the concerns raised about the long-term and short-term studies — in particular, concerns about residual confounding and impacts of the complex hybrid nature of the study designs — and so it looks forward to the full development and applications of these methods to the health analyses.

**Sharing of Models and Data:** Dominici and colleagues have made a special effort to make available their data, workflows, and analyses, and have posted these at a secure high-performance computing cluster with the objective of developing an open science research data platform. Additionally, the codes and software tools are publicly available from another depository. The investigators' work in these areas will continue. The Panel finds these efforts praiseworthy and encourages the Dominici team to continue sharing the unique resources they have developed.

## CONCLUSIONS

Using very large air pollution model and health data sets, Dominici and colleagues have reported initial results using two types of analysis — a cohort analysis of long-term exposures and a case–crossover analysis of short-term exposures. They and found positive associations of both $PM_{2.5}$ and $O_3$ with all-cause mortality, with associations extending to concentrations below the current NAAQS and with little evidence of a threshold. The investigators also conducted a range of sensitivity analyses and controlled for many confounders; these did not meaningfully change the initial findings of associations. These initial analyses are thorough and comprehensive, and make a valuable contribution to the literature.

As extensive as these analyses are, as noted by the Panel and by the investigators, there are several key questions that need to be investigated further before firmer conclusions can be drawn. Particularly important among these are (1) issues around the potential for confounding by time trends and other variables, including other pollutants such as $NO_2$, and geographical patterns in exposure and health status; (2) impact of the different spatial scales of the variables in both the long-term and short-term analyses, and the resulting complex quasi-ecological (hybrid) nature of the models, with the potential for exposure misclassification and residual confounding; and (3) extension of their work by the development, testing, and application of causal inference methods in the full study population.

Dominici and colleagues have performed a set of extensive and creative analyses in the largest air pollution and health databases to date. While initial conclusions may be drawn from these first analyses, the Panel will wait for the planned extensive further analyses to be completed before reaching full conclusions on the air pollution and public health implications of this important research.

INVESTIGATORS' REPORT

# Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1

Francesca Dominici[1], Joel Schwartz[1], Qian Di[1], Danielle Braun[1,2], Christine Choirat[1], and Antonella Zanobetti[1]

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## ABSTRACT

***Introduction.*** This report provides a summary of major findings and key conclusions supported by a Health Effects Institute grant aimed at "Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Pollution." Our study was designed to advance four critical areas of inquiry and methods development.

***Methods.*** First, our work focused on predicting short- and long-term exposures to ambient $PM_{2.5}$* mass (particulate matter $\leq 2.5\mu m$ in aerodynamic diameter) and ozone ($O_3$) at high spatial resolution (1 km × 1 km) for the continental United States during the period 2000–2012 and linking these predictions to health data. Second, we developed new causal inference methods for exposure–response (ER) that account for exposure error and adjust for measured confounders. We applied these methods to data from the New England region. Third, we applied standard regression methods using Medicare claims data to estimate health effects that are associated with short- and long-term exposure to low levels of ambient air pollution. We conducted sensitivity analyses to assess potential confounding bias due to lack of extensive information on behavioral risk factors in the Medicare population using the Medicare Current Beneficiary Survey (MCBS) (nationally representative sample of approximately 15,000 Medicare enrollees per year), which includes abundant data on individual-level risk factors including smoking. Finally, we have begun developing tools for reproducible research — including approaches for data sharing, record linkage, and statistical software.

***Results.*** Our HEI-funded work has supported an extensive portfolio of analysis and the development of statistical methods that can be used to robustly understand the health effects of long- and short-term exposure to low levels of ambient air pollution. This report provides a high-level overview of statistical methods, data analysis, and key findings, as grouped into the following four areas: (1) Exposure assessment and data access; (2) Epidemiological studies of ambient exposures to air pollution at low levels; (3) Methodological contributions in causal inference; and (4) Open science research data platform.

***Conclusion.*** Our body of work, advanced by HEI, lends extensive evidence that short- and long-term exposure to $PM_{2.5}$ and $O_3$ is harmful to human health, increasing the risks of hospitalization and death, even at levels that are well below the National Ambient Air Quality Standards (NAAQS).

This Investigators' Report is one part of Health Effects Institute Research Report 200, which also includes a Commentary by the Institute's Low-Exposure Epidemiology Studies Review Panel and an HEI Statement about the research project. Correspondence concerning the Investigators' Report may be addressed to Dr. Francesca Dominici, Harvard T.H. Chan School of Public Health, 677 Huntington Ave., Boston, MA 02115; e-mail: *fdominic@hsph.harvard.edu.*

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* A list of abbreviations and other terms appears at the end of this volume.

## INTRODUCTION

In late 2014, HEI issued a Request for Applications (RFA 14-3) seeking proposals to assess health effects of long-term exposure to low levels of ambient air pollution with particular attention to (a) sufficient size and statistical power to detect associations if they exist, (b) the ability to test different potential confounders of these associations, and (c) a variety of approaches to exposure assessment and statistical analysis to enable a robust examination of the associations.

Levels of ambient air pollution have declined significantly over the last decades in North America, Europe, and in other developed regions. Nonetheless, epidemiological studies continue to report associations of adverse health effects with air pollution even at these lower levels, and recently some studies have found associations at levels below current ambient air quality standards (e.g., Crouse et al. 2012; Hales et al. 2012; Shi et al. 2016). In order to inform future risk assessment and regulation, HEI committed funding to examine whether associations with adverse effects continue to be observed as levels of air pollution decline further and what the shape of the ER function is at those low levels, both major uncertainties in current air quality standards decision making.

As air pollution levels continue to decrease and regulatory actions become more costly, the quantification of the public health benefits of cleaner air will be subject to an increased level of scrutiny. Epidemiological analyses of claims data have provided strong evidence of air pollution's adverse health effects, mostly using data from urban areas (Carey et al. 2013; Crouse et al. 2015; Krewski et al. 2009; Ostro et al. 2015; Turner et al. 2016). Yet, significant gaps in knowledge remain, particularly with regard to the health effects of long-term exposure to lower levels of air pollution, and no large study to date has investigated the health effects of long-term air pollution in areas with sparse monitoring (Aim 1).

The estimation of health effects associated with long-term exposure to low levels of air pollution presents key methodological challenges, including: (1) the estimation of an ER within a traditional regression framework does not have a causal interpretation and can be highly sensitive to model choice for both the shape of the ER and the adjustment for confounding; (2) health effects estimation at low exposure levels might be affected by a different set of confounders than at high exposure levels; (3) information on individual-level potential confounders is limited in the administrative data; (4) estimation of the ER must account for potentially larger exposure error at lower exposure levels; (5) identification of effect modifiers is challenged by the large number of possibilities that cannot all be tested individually; and (6) causal estimation of ER in the context of multiple pollutants is virtually nonexistent in the literature. A rigorous treatment of *all* these statistical challenges, under a unifying causal inference framework, is necessary to investigate the health risks associated with low pollution levels and to inform regulatory policy (Aim 2). Additionally, little is known about health effects at low pollution levels, not only on mortality and morbidity outcomes, but also on disease progression in populations thought to be highly susceptible to air pollution — such as low-income adults (Aim 3). Finally, methods for data sharing and reproducibility in air pollution epidemiology are of paramount importance, yet the scientific community lacks tools to make this possible (Aim 4).

This report provides a summary of major findings and key conclusions supported by our HEI-funded project.

## STUDY AIMS

To overcome these challenges, our team structured our work around four specific aims:

***Aim 1: Exposure Prediction and Data Linkage.*** Investigate the health effects of long-term air pollution in areas with sparse monitoring. Apply and extend already developed and evaluated hybrid prediction models that use satellite, land use, emissions, ground monitoring, and weather data in conjunction with chemical transport models to estimate long-term exposures to low levels of ambient $PM_{2.5}$ mass and components, as well as the gaseous air pollutants $O_3$ and nitrogen dioxide ($NO_2$), at high spatial resolution (1 km × 1 km) for the continental United States during the period 2000–2012. Link these predictions to the health data. See Figure 1.

***Aim 2: Causal Inference Methods for Exposure–Response.*** Develop a new framework in Bayesian causal inference to estimate the whole ER that is robust to model misspecification for confounding and accounts for exposure error. Specifically, we aimed to develop methods to: (1) estimate a nonlinear ER, while accounting for exposure error; (2) adjust for measured and unmeasured confounders; (3) adjust for confounding in the context of multiple exposures; and (4) detect effect modification when the multiplicity of possible modifiers precludes testing of each one individually. See Figure 2.

***Aim 3: Evidence on Adverse Health Effects.*** Apply methods developed in Aim 2 to estimate health effects associated with long-term exposure to low levels of ambient air pollution for three dynamic U.S. cohorts: Medicare

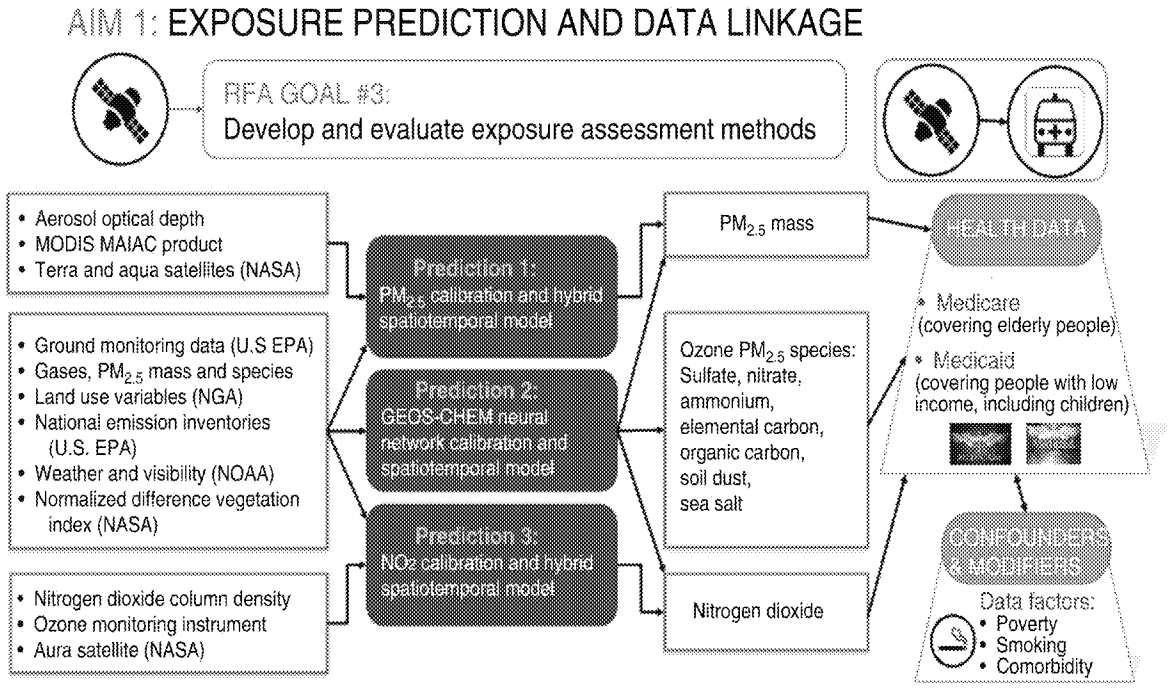


**Figure 1. Overview of Aim 1 showing the type, source, and purpose of national data sets used in our prediction models and the corresponding exposure metrics being assessed.** (U.S. EPA = U.S. Environmental Protection Agency, NASA = National Aeronautics and Space Administration, NGA = National Geospatial-Intelligence Agency, NOAA = National Oceanic and Atmospheric Administration.)

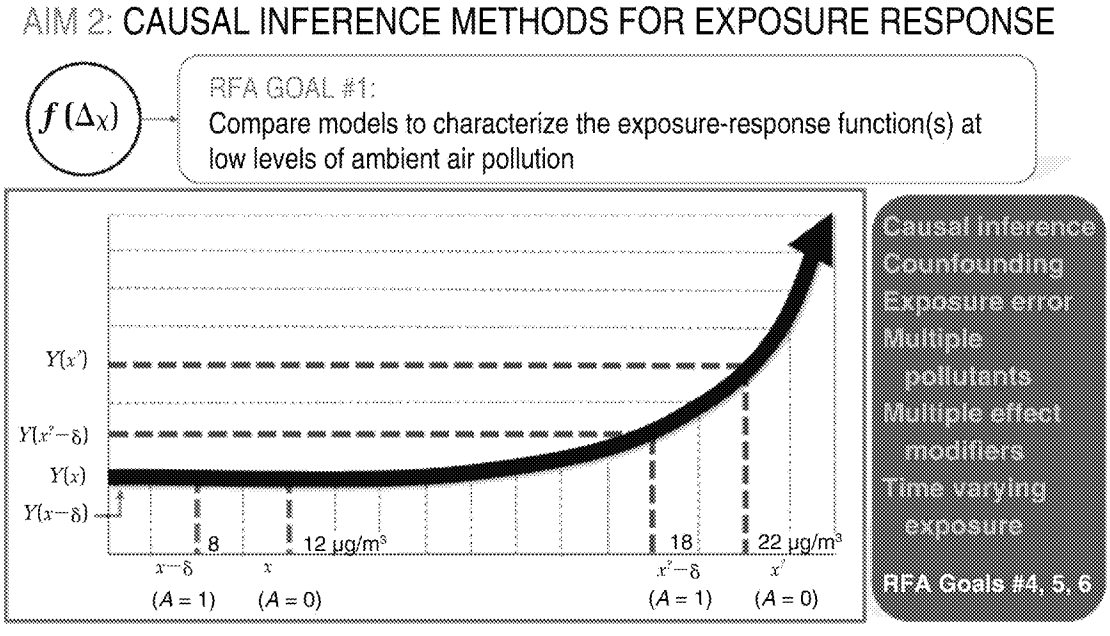


**Figure 2. Overview of Aim 2 showing causal inference methods for exposure–response analysis.** Causal ER defined as a sequence of hypothetical experiments.

enrollees (28.6 million enrollees [≥65 years] per year, 2000–2012); Medicaid enrollees (28 million enrollees per year, including 12 million children and 7 million people with disabilities, 2010–2012); and MCBS enrollees (nationally representative sample of approximately 15,000 enrollees per year with abundant data on individual-level risk factors, including smoking linked to Medicare claims). We aimed to examine the following health outcomes (time is measured from Medicare enrollment): (1) time to hospitalization by cause; (2) disease progression (time to rehospitalization); and (3) time to death. See Figure 3.

***Aim 4: Tools for Data Access and Reproducibility.***

Develop tools for reproducible research including approaches for data sharing, record linkage, and statistical software. Figure 4 provides a visual representation of the connection across the proposed aims.

## METHODS AND STUDY DESIGN

In Aim 1, we addressed Research Objective #3 of the RFA ("Develop and evaluate exposure assessment methods suitable to estimate exposure to low levels of air pollution at various spatial and temporal scales in large study populations, including populations that reside in areas not covered by routine ground-level monitoring"). We assembled and linked a wealth of data sources from satellite and ground monitoring data and applied, compared, and validated prediction models to estimate long-term average levels of $PM_{2.5}$, $PM_{2.5}$ species, $NO_2$, and $O_3$ in a 1 km × 1 km grid for the continental United States. In this aim, we also refined previously developed methods to align gridded exposure to ZIP-code-level exposure including the propagation of the exposure error from grid to ZIP code (location code used by the U.S. Postal Service). We then linked the exposure, health, and confounder data at the ZIP code level (see Figure 1).

In Aim 2, we developed new methods to address Research Objectives #1, 4, 5, and 6 of the RFA ("1. Compare and contrast alternative models and their uncertainty, e.g., threshold/nonthreshold, linear/nonlinear, and parametric/nonparametric, to characterize the ER function(s) at low levels of ambient air pollution. 4. Develop, evaluate, and apply statistical methods to quantify and correct for exposure measurement error in risk estimates and in characterization of ER relationships. 5. Develop and validate approaches to assess the impacts of co-occurring pollutants on health effect associations at low ambient concentrations. 6. Develop and validate indirect approaches to correct risk estimates for the effects of important potential confounding variables, such as smoking, in the absence of such data at the individual level.") We developed several new statistical methods for *causal inference* to estimate the whole ER function. The new methods were designed to overcome several important challenges in the estimation of health effects associated with low-level exposure (see Figure 2).

In Aim 3, we addressed Research Objective #2 of the RFA ("Explore possible variability in effect estimates at low levels among populations, and identify possible contributing factors. Such factors may include age, socioeconomic position, health status, and access to medical care, as well as differences in air pollution sources and time–activity patterns"), providing national evidence on the causal effects of low-level exposure on several outcomes in children, adults with low-income, and adults 65 years and older (see Figure 3).

In Aim 4, we addressed Research Objective #7 of the RFA ("Improve techniques for record linkage and methods for disclosure protection for optimal use of large administrative databases in air pollution and health research"), developing new tools for data access and reproducibility, including statistical software to implement the methods developed in Aim 2 and specific instructions on how to reproduce our analyses (see Figure 4).

This project was approved by the Institutional Review Board of the Harvard T.H. Chan School of Public Health.

## STATISTICAL METHODS AND DATA ANALYSIS

Our HEI-funded work comprises an extensive portfolio of analysis and the development of robust statistical methods that can be used to understand the health effects of long- and short-term exposure to low levels of ambient air pollution. In this section, we provide a high-level overview of this work, as grouped into the following four areas: (1) Exposure assessment and data access; (2) Epidemiological studies of ambient exposures to air pollution at low levels; and (3) Methodological contributions in causal inference; and (4) Open science research data platform.

## EXPOSURE ASSESSMENT AND DATA ACCESS

### PREDICTING AIR POLLUTION: A FLEXIBLE R PACKAGE*

There is strong evidence that ambient exposure to $PM_{2.5}$ increases risk of mortality and hospitalization. Large-scale epidemiological studies on the health effects of $PM_{2.5}$

* A paper describing development of this method (Sabath et al. 2018) was first presented at the 5th IEEE International Conference on Data Science and Advanced Analytics, 1-4 October 2018 and can be found at *arXiv:1805.11534v2 [stat.ML].*

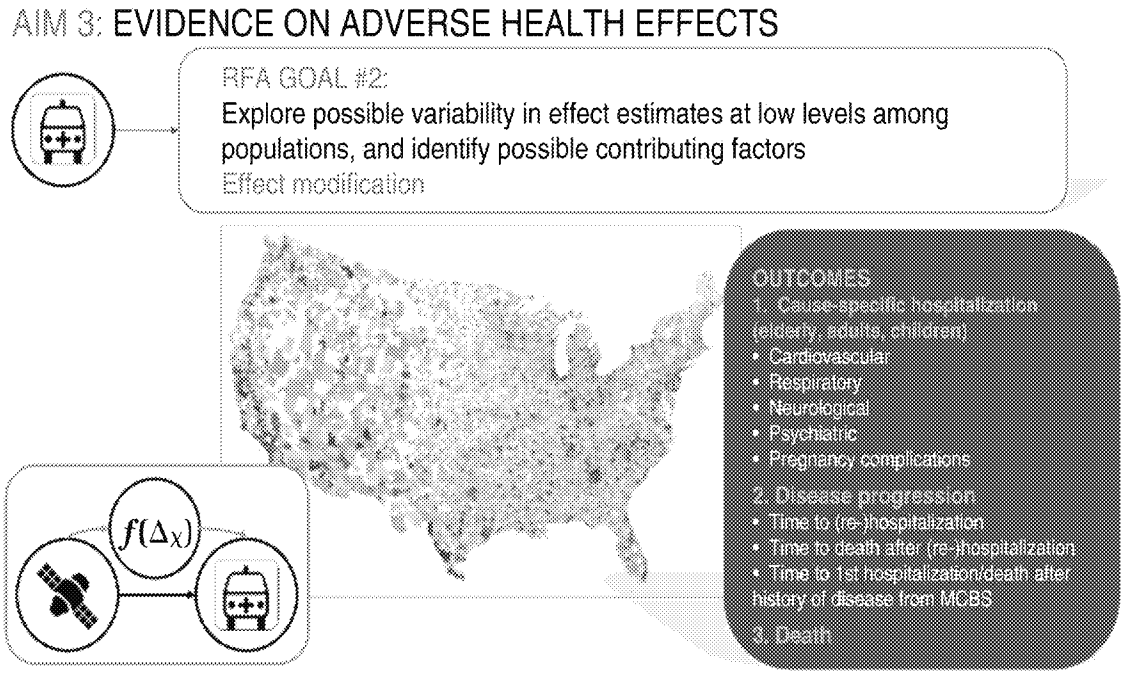


**Figure 3. Overview of Aim 3 to provide national evidence on the causal effects of low-level exposure on several outcomes in children, people with disabilities, pregnant women, adults with low-income, and adults 65 years and older.**

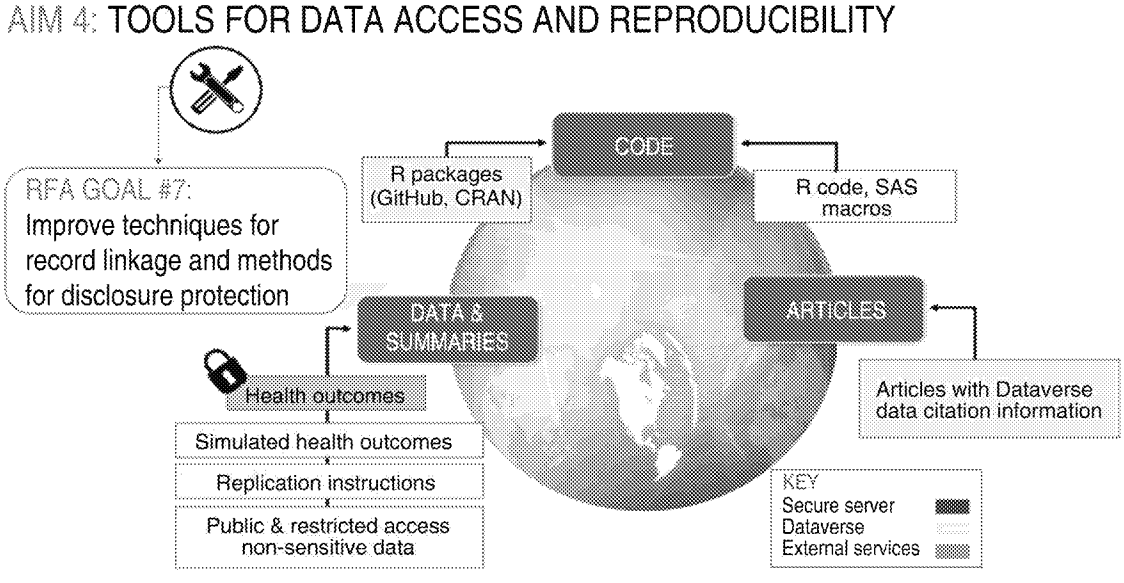


**Figure 4. Overview of Aim 4 to develop new tools for data access and reproducibility, including statistical software to implement the methods developed in Aim 2 and specific instructions on how to reproduce our analyses.**

provide the necessary evidence base for lowering the safety standards and informing regulatory policy. However, ambient monitors of $PM_{2.5}$ (as well as monitors for other pollutants) are sparsely located across the United States, and therefore studies based only on the levels of $PM_{2.5}$ measured from the monitors would inevitably exclude large parts of the population. One approach to resolving this issue has been developing models to predict local $PM_{2.5}$, $NO_2$, and $O_3$ based on satellite, meteorological, and land-use data. This process typically involves developing a prediction model that relies on large amounts of input data and is highly computationally intensive to predict levels of air pollution in unmonitored areas.

Various groups have developed air pollution modeling platforms, with the goal of using information that is available in locations with and without monitors to predict ground level $PM_{2.5}$. A key component used in many of the developed models is satellite-based aerosol optical depth (AOD), a measure of visibility that is associated with levels of particulate matter in the atmosphere. However, these measurements represent particulate matter present in the entire atmospheric column and can't provide a reliable proxy to ground level pollution (Wang et al. 2017). Information from satellite, meteorological and land-use sources is then used to attempt to estimate the levels of $PM_{2.5}$ at surface.

To account for complex atmospheric mechanisms, Di and colleagues (2016; 2017b) used a neural network for its capacity to model nonlinearity and interactions. They employed convolutional layers, which aggregate neighboring information, into a neural network to account for spatial and temporal autocorrelation. We implemented this prediction model to generate daily predictions for the continental United States from 2000 to 2012 for $PM_{2.5}$ and $O_3$ and tested the performance of the model with monitors left out of the original group (see Figure 5). The model developed by Di and colleagues (2016) relied heavily on data from $PM_{2.5}$ monitors to generate predictions of $PM_{2.5}$. They took a data intensive approach, using information

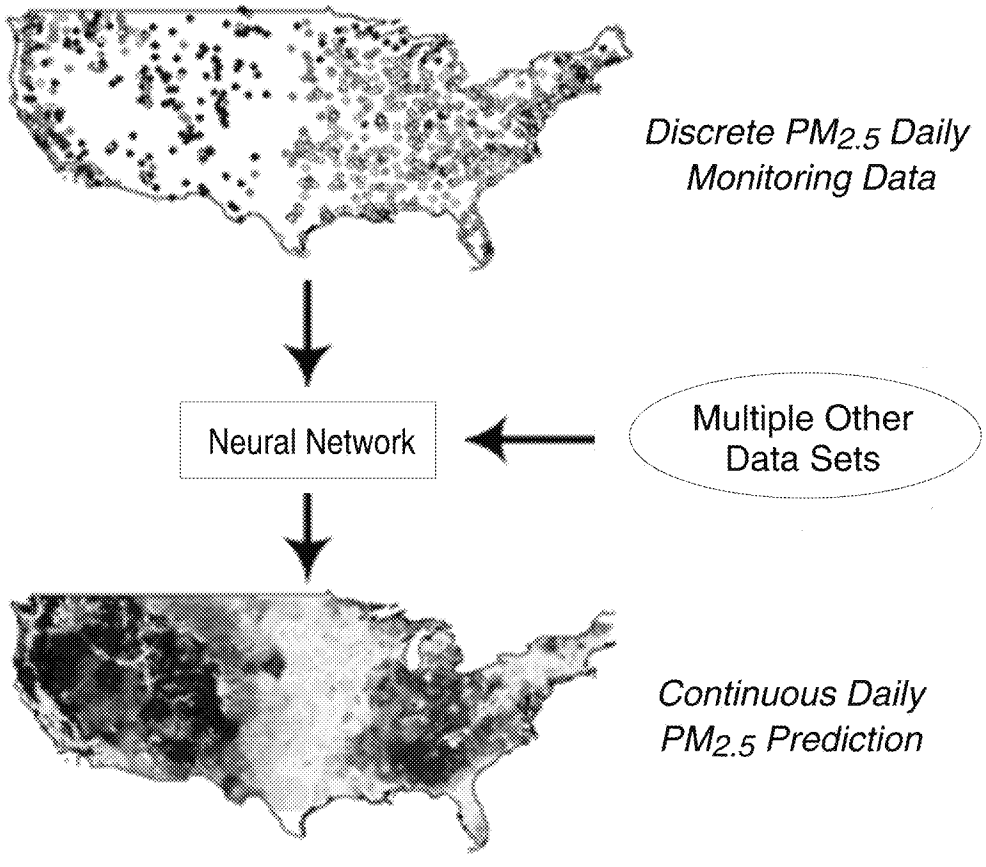


**Figure 5. Distribution of pollution monitors and of predictions taken from the model by Di and colleagues (2016).** Reprinted with permission from Di et al 2016. Copyright (2016) American Chemical Society.

about AOD from the moderate resolution imaging spectroradiometer (MODIS) satellite, surface reflectance data, estimates of both ground level $PM_{2.5}$ and total levels of aerosols distributed throughout the whole atmospheric column from the Goddard Earth Observing System (GEOS-Chem), meteorological data from the North American Regional Reanalysis project, indices of aerosols that could potentially absorb $PM_{2.5}$, and land-use information such as elevation, road density, vegetation coverage, and population density that can serve as reasonable proxies for emissions as well as help capture small scale variations in PM levels.

One key form of data with universal coverage used to help model PM concentrations and other pollutants is the results of chemical transport models (CTMs). CTMs are computationally intensive atmospheric models that model material flows and chemical reactions within the atmosphere. When combined with measurements of AOD, these have been shown to provide more accurate measurements of $PM_{2.5}$ (Pafka 2015; Wang et al. 2017). Multiple approaches also bring in land-use data to further refine the predictions (Di et al. 2016; Wang et al. 2017). These pieces of information were combined using either standard linear-based statistical models or more complex machine learning methods in order to generate predictions. These are typically able to generate predictions at a 1 km × 1 km scale for large regions, such as the continental United States and the whole of North America (Wang et al. 2017).

This model has been applied in health research to determine the effects of low level $PM_{2.5}$. By incorporating these predictions, this research was able to analyze data from underrepresented populations and demonstrate a connection between increased mortality and PM exposure even at low levels (Di et al. 2017a, c).

A unifying factor among all modeling approaches for estimating exposure prediction — including the model used by Di and colleagues — is that they are both data and computationally intensive. In our work, we used data that took up 30 TBs of disk storage in unprocessed form. The inputs for the $PM_{2.5}$ model came from a variety of sources including atmospheric imaging primarily from National Aeronautics and Space Administration (NASA) satellites, meteorological results of chemical-transport model simulations, geographical information, and information on land usage (such as measurements of road density). For example, inputs for the model by Di and colleagues (2016) are shown in Table 1. Di and colleagues developed their software toolkit in Matlab. It is also worth noting that, because our model was optimized to maximize $R^2$ with existing monitoring stations, it raises the possibility of overfitting for monitored areas, and this model training process could also make our model less accurate in unmonitored, primarily rural, areas. In order to eliminate the impact of potential overfitting, we trained our models using cross-validation. To address the issue of the model being potentially less accurate in unmonitored areas, we estimated, as a sensitivity analysis, the distribution of population as a function of the distance to the nearest monitoring site and found that 72.9% and 75.1% of the U.S. population lives within 20 km of $PM_{2.5}$ monitoring sites and $O_3$ monitoring sites, respectively. As a substantial proportion of the U.S. population is located near monitors, our prediction model, which is trained on monitoring stations, would provide accurate estimates for a large proportion of the population.

We have developed a flexible R package called airpred (Sabath et al. 2018) (*https://github.com/NSAPH/airpred*) that allows environmental health researchers to design and train spatio–temporal models capable of predicting multiple pollutants, including $PM_{2.5}$. We utilized the R statistical language together with H2O, an open source big data platform, to achieve both performance and scalability when used in conjunction with cloud or cluster computing systems.

**Table 1.** Data Sources and Resolutions Used in the Di Model[a]

| Input Type[b] | Sources[c] | Spatial Resolution |
|---|---|---|
| Meteorological data | Reanalysis | 0.5° × 0.625° |
| AOD | MAIACUS | 1 km × 1 km |
| Surface reflectance | MOD09A1 | 500 m × 500 m |
| CTMs | GEOS-Chem<br>CMAQ | 12 k × 12 k |
| Absorbing aerosols | OMAERUVd<br>OMAEROe | 0.25° × 0.25° |
| Vegetation | MOD13A2 | 1 km × 1 km |
| Other land use | NLCD | 30 m × 30 m |

[a] Di et al. 2016.

[b] AOD = aerosol optical depth; CTM = chemical transport model.

[c] MAIACUS (Multi-Angle Implementation of Atmospheric Correction with U.S. data) is a new algorithm to retrieve aerosol optical depth data from a satellite. MOD09A1 is the product name of surface reflectance data from a satellite. GEOS-Chem and CMAQ are chemical transport models. OMAERUVd and OMAEROe are two algorithms for retrieving aerosol composition data. OMAERUVd is a near-ultraviolet algorithm, which retrieves ultraviolet aerosol index, and OMAEROe uses a multiwavelength aerosol algorithm, whose outputs include aerosol indexes at the visible and ultraviolet ranges. MOD13A2 is the data product name of normalized difference vegetation index. NLCD (National Land Cover Database) provides land cover for the entire study area at 30 m × 30 m resolution.

With airpred, we ported and extended the Matlab workflow to the open-source R statistical software (R Development Core Team 2011), while explicitly relying on the H2O "big data" software stack, which is known to perform well on laptops as well as on large computer systems, facilitating the use of parallel algorithms and cluster and cloud deployment options to speed processing. The target audience for the package primarily consists of environmental epidemiology researchers and environmental scientists. As R is a common programming language used in these two fields, we chose to implement the prediction platform in the form of an R package. In addition to user familiarity, R also has the advantage of having a large ecosystem of packages available, allowing for the use of systems developed by others rather than needing to develop many utilities ourselves. Additionally, by developing in R, we can potentially release our package on CRAN, a repository of publicly available R packages that can be accessed via built in functions in R. All CRAN R packages are open source as well, which would allow us to ensure that all code used is publicly available. It was crucial to develop a platform that allows for flexibility, as both the model inputs and the statistical models themselves are frequently changing. Given this, we chose to design a system that would allow users to easily change these elements without making any alterations to the back-end code of the package.

Further, it was important to ensure readability and ease of use for any script utilizing the developed package. Therefore, the number of arguments passed directly to functions was minimized, and the package was designed to include only a small number of clearly named functions that users would need to call in order to implement the full workflow. Airpred can be used to replicate the exposure prediction modeling that provides the air pollution exposure estimates used in the work by Di and colleagues (2017a,c), but users can also specify different types of neural networks, with different parameters, or even perform ensemble modeling.

When modeling $PM_{2.5}$ and other pollutants, we must take into account technical limitations at every step of the process. Moving large quantities of data through memory, let alone feeding them into machine learning (e.g., neural networks) or other modeling systems, can quickly run into system limits. Because of this, it is important to take into account not just the methodology of developing prediction models, but the entire workflow, and to treat all work around it as a single prediction platform. The airpred package implements a single prediction platform for modeling air pollution exposure data. It provides a generic framework to (1) process and assemble raw data sets from a variety of sources; (2) train a deep learning model on the assembled data sets; and (3) generate predictions at the requested spatio–temporal scale. The developed R package is flexible and can be applied to any pollutant. Our R code relies on wrappers to the deep learning algorithms developed in the H2O (*www.h2o.ai/*) open-source software for big data analysis and machine learning at scale.

## IMPROVING DATA ACCESS — CREATING AN OPEN SCIENCE RESEARCH DATA PLATFORM

Once we developed the model for estimating exposures to predict $PM_{2.5}$ and $O_3$ for every 1 km × 1 km grid in the United States (Sabath et al. 2018), we then needed to address data access issues in order to enable investigators to link our curated exposure data to confounder data and health data (from Medicaid and Medicare). Particularly because scientific evidence of harmful effects of air pollution is being subjected to unprecedented scrutiny (Dominici et al. 2014; Samet 2011; Zigler and Dominici 2014), data access and reproducibility are central to current debates on how studies can constitute the scientific base to support regulatory decisions.

To address the need for greater data access and reproducibility, and to achieve Aim 1 and Aim 4 of the project, we posted our data, workflows, and analyses to a secure high-performance computing cluster with the objective of developing an open science research data platform (*https://osf.io/2cg6v/*). Our research data platform contains three distinct but complementary parts:(1) nonhealth data (exposure and confounders); (2) health data (Medicare and Medicaid); and (3) analyses, where data from (1) and (2) are merged and statistical tools are used to address the scientific questions of Aim 3.

Exposure data for $PM_{2.5}$ and $O_3$ are available at the daily and annual levels at different levels of spatial aggregation (grid, ZIP code, ZIP code tabulation area, county), with different aggregation methods. In Figure 6, we show the $PM_{2.5}$ predictions from Di and colleagues (2016) for New England in the year 2000 aggregated from 1 km × 1 km grids to the ZIP code level, using (a) area-weighting, (b) population-weighting, and (c) inverse-distance weighting. To promote the dissemination of our results, we created several external-facing interfaces that provide interactive visualization of $PM_{2.5}$ and $O_3$ (e.g., *http://arcg.is/1zTS8S)*. It is important to note that, in order to evaluate the limitations of the data set we used to estimate exposure, we also included in the estimation data from the nearest monitoring sites. While the health effect estimates using air pollution data from proximal monitoring sites were lower than our estimated exposure data, they were still statistically significant. Further, a paper by Wu and colleagues

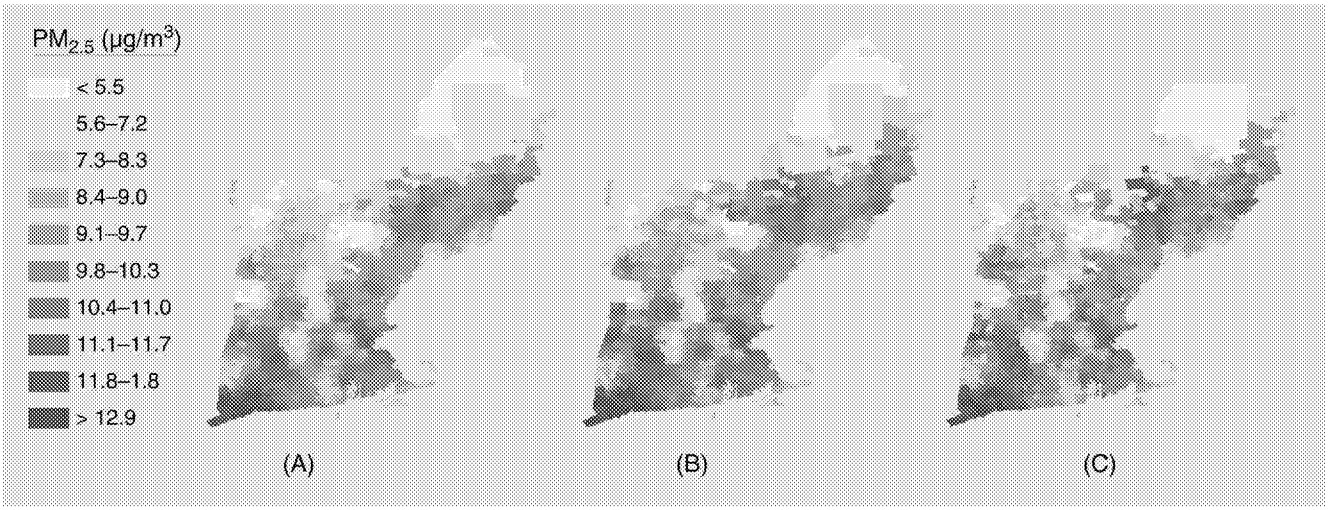


**Figure 6. $PM_{2.5}$ predictions for New England in 2000 from the study by Di and colleagues (2016).** Predictions were aggregated from 1 km × 1 km grids to the ZIP code level using **(A)** area weighting, **(B)** population weighting, and **(C)** inverse-distance weighting.

(2019) deploys novel methods to address the issue of error in air pollution exposure assignment in the context of causal inference. This approach utilizes several different methods to adjust for confounding in causal inference (inverse probability treatment weighting [IPTW] using generalized propensity scores [GPS], GPS matching, and GPS stratification). Using this approach we showed that when adjusting for exposure error, the causal effect of exposure to moderate levels of $PM_{2.5}$ ($8 < PM_{2.5} < 10$ μg/m$^3$) causes a 2.8% (95% confidence interval [CI], 0.6%–3.6%) increase in all-cause mortality compared with low exposure ($PM_{2.5} < 8$ μg/m$^3$).

To ensure the reproducibility of our workflow, we developed software codes and packages that allow investigators to link the already curated exposure and confounder data to Medicare and Medicaid claims data. For investigators who own or wish to purchase their own Medicare and Medicaid claims data, we can provide the exact code that we used to link this claims data to the nonhealth data and that we are using to conduct our own analyses of Medicare and Medicaid data. It allows other investigators to reproduce our analyses, replicate our findings, and conduct new analyses. It also guarantees the reproducibility of our own epidemiological analyses that use Medicare and Medicaid claims data to understand the health impacts of environmental exposures. The research data platform is an asset in increasing the scientific rigor of air pollution epidemiological studies by potentially reducing inconsistency of results across studies.

Our code and software tools are under version control. They are hosted on the GitHub social-coding software platform (National Studies on Air Pollution and Health; *https://github.com/NSAPH/airpred*), and we rely on the open science framework (*https://osf.io/2cg6v/*) to provide a searchable web interface to our data and code resources.

It should be noted that the scale of the research data platform in terms of computation and storage resources allows us to undertake studies on the whole Medicare population, such as two studies described in articles we recently published in the *New England Journal of Medicine* (Di et al. 2017c) and in the *Journal of the American Medical Association* (Di et al. 2017a), described later in this report. These two huge studies are *reproducible*: they rely entirely on publicly available data, which are listed in Table 2. In a recent commentary in *Science*, Cosier (2018) pointed to the importance of our work for promoting open, reproducible evidence that can be used to inform public policy.

**Table 2.** Data Sources[a,b]

| Source | Data Set | Website |
|---|---|---|
| NOAA | Reanalysis meteorological data | *http://www.noaa.gov/* |
| NASA | MAIAC AOD data<br>Surface reflectance data<br>NDVI data<br>OMI Aerosol Index Data | *https://www.nasa.gov/* |
| U.S. Geological Survey | Global terrain elevation data | *https://lta.cr.usgs.gov/* |
| U.S. Census Bureau | Road density, population count, and area | *https://www.census.gov/* |
| MRLC | National Land Cover Dataset | *https://www.mrlc.gov/* |
| GEOS-Chem | Simulation outputs | *http://acmg.seas.harvard.edu/geos/* |
| U.S. EPA | AQS monitoring data ($PM_{2.5}$ and $O_3$) | *https://www.epa.gov/aqs* |
| CMS | Medicare denominator files<br>Medicare Current Beneficiary Survey | *https://www.cms.gov/* |
| CDC | BMI, smoking rate | *https://www.cdc.gov/* |
| Dartmouth Atlas of Health Care | Demographics of the Medicare population | *http://www.dartmouthatlas.org/* |

[a] A detailed list and software codes are available at *https://osf.io/j6hw8/*.

[b] AOD = aerosol optical depth; AQS = air quality system; BMI = body mass index; CDC = Centers for Disease Control and Prevention; CMS = Center for Medicare and Medicaid Services; GEOS-Chem = Goddard Earth Observing System chemical transport model; MAIAC = Multi-angle implementation of atmospheric correction; MRLC = Multi-Resolution Land Characteristics Consortium; NASA = National Aeronautics and Space Administration; NDVI = Normalized Difference Vegetation Index; NOAA = National Oceanic and Atmospheric Association; OMI = ozone monitoring instrument; U.S. EPA = United States Environmental Protection Agency.

## EPIDEMIOLOGICAL STUDIES OF AMBIENT EXPOSURES TO AIR POLLUTION AT LOW LEVELS

### LONG-TERM EXPOSURE TO AIR POLLUTION AND MORTALITY IN THE MEDICARE POPULATION*

There is strong evidence that long-term exposure to air pollution leads to increased mortality. Several studies suggest that long-term exposure to $PM_{2.5}$ results in reduced life expectancy; the National Ambient Air Quality Standard is based on such studies. Evidence for mortality resulting from long-term exposure to $O_3$ is more uncertain, though some studies do suggest reduced survival. However, most air pollution studies have been conducted in urban populations — with higher pollution levels — and evidence is quite limited for any health effects below the standards.

A nationwide cohort study was conducted using all Medicare beneficiaries from 2000 to 2012. Long-term exposure estimates for daily levels of $PM_{2.5}$ and $O_3$ were developed using hybrid prediction models. We found evidence for statistically significant adverse effects of $PM_{2.5}$ and $O_3$ exposures at concentrations below current national standards. This effect was greater for self-identified racial minorities and people with low income.

#### Data and Methods

***Mortality among Medicare Beneficiaries.*** Information about Medicare participants was obtained from the Centers for Medicare and Medicaid Services (CMS) to create a cohort of over 61 million subjects, with a total of over 460 million person-years of follow up. This was an open cohort, where each Medicare subject was followed from the beginning of their first full year of eligibility (age 65 years) during the recruitment period (2000–2012). The outcome of interest was all-cause mortality, and survival

* The following is a summary of an article published in the *New England Journal of Medicine* by Di and colleagues (2017c). A copy of this article, along with a supplementary appendix, is available in Additional Materials on the HEI website, with permission of the publisher.

time was measured from the year subjects entered the cohort until the year of their death (Figure 3).

***$PM_{2.5}$ and $O_3$ Exposure Assessment.*** Long-term exposure estimates were developed using estimated daily levels of $PM_{2.5}$ and $O_3$ at 1 km × 1 km resolution for the continental United States during the period 2000–2012 using hybrid prediction models that use satellite, land use, emissions, ground monitoring, and weather data in conjunction with chemical transport models (see Di et al. 2017c, Figure 1). Annual PM and warm season $O_3$ levels were assigned to each person in the cohort for each calendar year of their inclusion.

### Statistical Analysis

Survival analyses were conducted using a variant of the Cox Proportional Hazards Model, known as the Andersen Gill Model (AG) (Andersen and Gill 1982), which allows for the inclusion of covariates that change from year to year.* The results from this model were used to estimate the hazard ratio associated with a 10-μg/m$^3$ increase in $PM_{2.5}$ and a 10-ppb increase in $O_3$ exposure. In addition, a surface was fitted to describe the combined and potentially synergistic effects of both $PM_{2.5}$ and $O_3$ on mortality using a log-linear model with a thin-plate spline. To investigate the effects of lower exposures, separate analyses were conducted that included only person-years with $PM_{2.5}$ exposures lower than 12 μg/m$^3$ and $O_3$ exposures lower than 50 ppb ("low-exposure analyses"). A series of subgroup analyses was also conducted to consider the potential interaction of pollutants with key covariates.

### Covariate Information

A total of 20 covariates were included in the study, including individual-level covariates, county-level variables, ZIP-code-level variables, three hospital service area–level variables, meteorological variables, and one dummy variable (see Di et al. 2017c, Table 1 and supplementary appendix). Table 3 in this report summarizes the characteristics of the cohort with respect to all of these covariates and provides average levels to which each covariate was exposed in both high and low pollutant regions (for additional information, see supplementary appendix for Di et al. 2017c in Additional Materials on the HEI website). Some of the covariate information was obtained from the MCBS and the Behavioral Risk Factor Surveillance System.

* Note that the use of the AG model is not explicitly discussed in the paper published by Di et al. 2017c.

### Results

The Medicare cohort, with more than 61 million individuals and more than 22 million deaths, had excellent power to estimate the risk of death from air pollution over a range of exposure levels, including those below the current NAAQS (Figure 7). In two-pollutant analyses, a 10-μg/m$^3$ increase in $PM_{2.5}$ was found to be associated with a 7.3% (95% CI, 7.1%–7.5%) increase in mortality for a given ZIP code, and a 10-ppb increase in $O_3$ concentration was associated with a 1.1% increase (95% CI, 1.0%–1.2%) (Table 4). When the analysis was restricted to person-years with exposure to $PM_{2.5}$ of less than 12 μg/m$^3$ and $O_3$ of less than 50 ppb, the same increases in $PM_{2.5}$ and $O_3$ were associated with increases in the risk of death of 13.6% (95% CI, 13.1%–14.1%) and 1.0% (95% CI, 0.9%–1.1%), respectively.

The subgroup analyses described effect modification for a range of variables (see Di et al. 2017c, Figure 2). Specifically, we found an increase in mortality from exposure to $PM_{2.5}$ among male, black, Asian, and Hispanic subgroups. Stratification by Medicaid eligibility (a measure of socioeconomic status) showed a slightly higher estimated risk from $PM_{2.5}$ exposure than in the general population. The effect of $O_3$ exposure on mortality was higher among whites and those eligible for Medicaid, but the risk was also below 1 for certain racial subgroups, suggesting nonlinear interaction effects.

### Discussion

Using an open cohort of all Medicare participants representing more than 96% of the population of older adults in the United States, our survival analysis demonstrated associations between mortality and long-term exposure to $PM_{2.5}$ and $O_3$, even at levels below the NAAQS for $PM_{2.5}$ and $O_3$. Black and Hispanic individuals had a higher risk of death associated with exposure to $PM_{2.5}$ than other subgroups. These findings suggest that lowering the annual NAAQS for $PM_{2.5}$ will produce important public health benefits overall, especially among self-identified racial minorities and people with low income.

***Robustness of Risk Estimates.*** Mortality is influenced by individual-level behavioral risk factors, such as smoking and income, but these data are not included in Medicare claims. To explore the potential impact of such factors, we analyzed the MCBS subsample. The results revealed that the lack of such information did not lead to biased results (see supplementary appendix for Di et al. 2017c in Additional Materials on the HEI website). Our results were also robust to choice of statistical method; we obtained similar risk estimates when individual and

**Table 3.** Baseline Characteristics of the Entire Cohort

| Variable[a] | Entire Cohort | $O_3$ Concentration[b] | | $PM_{2.5}$ Concentration[b] | |
|---|---|---|---|---|---|
| | | ≥50 ppb | <50 ppb | ≥12 μg/m$^3$ | <12 μg/m$^3$ |
| Number of individuals | 60,925,443 | 14,405,094 | 46,520,349 | 28,145,493 | 32,779,950 |
| Number of deaths | 22,567,924 | 5,097,796 | 17,470,128 | 10,659,036 | 11,908,888 |
| Total person-years[c] | 460,310,521 | 106,478,685 | 353,831,836 | 212,628,154 | 247,682,367 |
| Median follow-up years | 7 | 7 | 7 | 7 | 7 |
| **Air Pollutants**[d] | | | | | |
| Average $O_3$ (ppb) | 46.3 | 52.8 | 44.4 | 48.0 | 45.3 |
| Average $PM_{2.5}$ (μg/m$^3$) | 11.0 | 10.9 | 11.0 | 13.3 | 9.6 |
| **Individual Covariates**[d] | | | | | |
| Male (%) | 44.0 | 44.3 | 43.8 | 43.1 | 44.7 |
| White (%) | 85.4 | 86.6 | 85.1 | 82.0 | 88.4 |
| Black (%) | 8.7 | 7.2 | 9.2 | 12.0 | 5.9 |
| Asian (%) | 1.8 | 1.8 | 1.8 | 2.1 | 1.6 |
| Hispanic (%) | 1.9 | 2.0 | 1.9 | 1.9 | 1.9 |
| Native American (%) | 0.3 | 0.6 | 0.3 | 0.1 | 0.6 |
| Medicaid Eligible (%) | 16.5 | 15.3 | 16.8 | 17.8 | 15.3 |
| Age at entry | 70.1 | 69.7 | 70.2 | 70.1 | 70.0 |
| **Ecological Variables**[d] | | | | | |
| BMI (kg/m$^2$) | 28.2 | 27.9 | 28.4 | 28.0 | 28.4 |
| Ever smoker (%) | 46.0 | 44.9 | 46.2 | 45.8 | 46.0 |
| Hispanic population (%) | 9.5 | 13.4 | 8.4 | 8.4 | 10.0 |
| Black population (%) | 8.8 | 7.2 | 9.3 | 13.3 | 6.3 |
| Median household income[e] | 47.4 | 51.0 | 46.4 | 47.3 | 47.4 |
| Median value of housing[e] | 160.5 | 175.8 | 156.3 | 161.7 | 159.8 |
| Below poverty level (%) | 12.2 | 11.4 | 12.4 | 12.5 | 12.0 |
| Below high school education (%) | 32.3 | 30.7 | 32.7 | 35.3 | 30.6 |
| Of owner occupied housing (%) | 71.5 | 71.3 | 71.6 | 68.6 | 73.2 |
| Population density (individual/km$^2$) | 3.2 | 0.7 | 3.8 | 4.8 | 2.2 |
| With LDL-C test (%) | 92.2 | 92.0 | 92.2 | 92.2 | 92.2 |
| With hemoglobin A1c test (%) | 94.8 | 94.6 | 94.8 | 94.8 | 94.8 |
| With ≥1 ambulatory visit (%) | 91.7 | 92.2 | 91.6 | 91.7 | 91.7 |
| **Meteorological Variables**[d] | | | | | |
| Temperature (°C) | 14.0 | 14.9 | 13.8 | 14.5 | 13.7 |
| Relative humidity (%) | 71.1 | 60.8 | 73.9 | 73.7 | 69.6 |

[a] BMI = body mass index; LDL-C = Low-density lipoprotein-cholesterol.

[b] We calculated these summary statistics separately for individuals residing in ZIP codes with average $O_3$ levels below and above 50 ppb and with $PM_{2.5}$ levels below and above 12 μg/m$^3$. The value 12 μg/m$^3$ was chosen as the current annual National Ambient Air Quality Standard (NAAQS).

[c] Total person-years of follow-up in the cohort from 2000 to 2012.

[d] Average values for air pollution levels, ecological variables, and meteorological variables were computed by averaging values over all ZIP codes from 2000 to 2012.

[e] Numbers are presented in U.S. dollars (thousands).

Data from Di et al. 2017c.

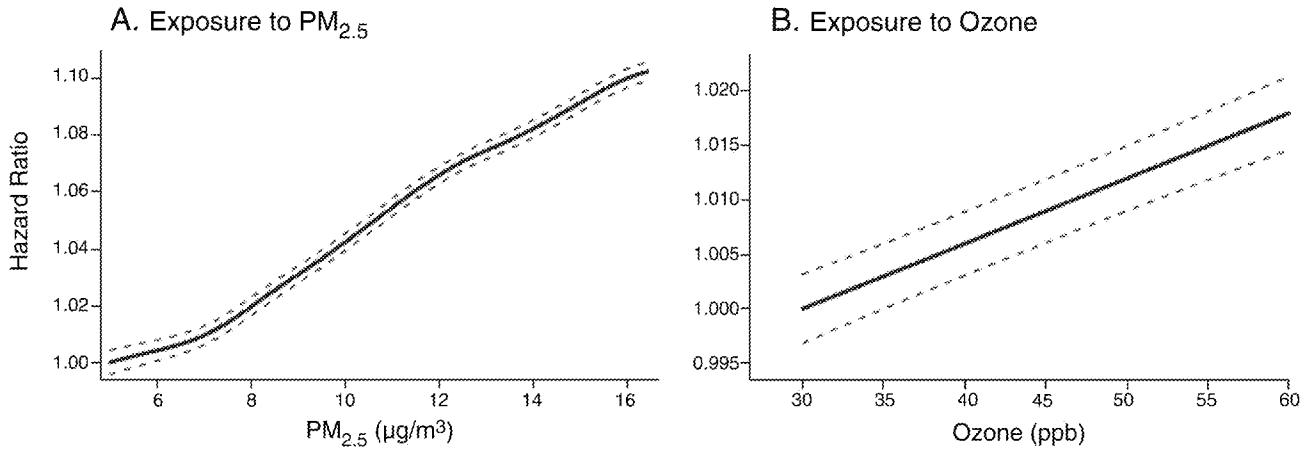


**Figure 7. Concentration–response function of the joint effects of exposure to $PM_{2.5}$ and $O_3$ on all-cause mortality.** (Reprinted with permission from Di et al. 2017c, © 2017 Massachusetts Medical Society.)

**Table 4.** Risk of Death Associated with a 10-µg/m$^3$ Increase in $PM_{2.5}$ or 10-ppb Increase in $O_3$ Exposure[a,b]

| Model | $PM_{2.5}$ HR (95% CI) | $O_3$ HR (95% CI) |
|---|---|---|
| Two-pollutant analysis | | |
| Main analysis | 1.073 (1.071–1.075) | 1.011 (1.010–1.012) |
| Low-exposure analysis | 1.136 (1.131–1.141) | 1.010 (1.009–1.011) |
| Nearest-monitor analysis[c] | 1.061 (1.059–1.063) | 1.001 (1.000–1.002) |
| Single-pollutant analysis[d] | 1.084 (1.081–1.086) | 1.023 (1.022–1.024) |

[a] Reprinted with permission from Di et al. 2017c, © 2017 Massachusetts Medical Society.

[b] Hazard ratios (95% confidence intervals) for a 10-µg/m$^3$ increase in $PM_{2.5}$ and a 10-ppb increase in $O_3$ exposure.

[c] Daily average $PM_{2.5}$ and daily $O_3$ monitoring data were retrieved from the U.S. EPA Air Quality System (AQS). Daily $O_3$ concentrations were averaged from April 1 to September 30 to compute warm-season averages. Individuals were assigned to $PM_{2.5}$ and $O_3$ levels from the nearest monitoring site within 50 kilometers. If there was more than one monitoring site, the nearest one was chosen. Individuals who lived ≥ 50 kilometers away from any monitoring site were excluded.

[d] For the single-pollutant analysis, model specifications were the same as in the main analysis, except that $O_3$ was not included in the model when estimating the main effect of $PM_{2.5}$ and vice versa.

ecological covariates were excluded from the main analysis, the age of entry was categorized more finely, the estimation procedure was varied (generalized estimating equation [GEE] vs. mixed effects), or a different statistical software was used (R vs. SAS).

***Health Effects below NAAQS.*** Our analyses found a significant association between $PM_{2.5}$ exposure and mortality at concentrations below 12 µg/m$^3$, with a steeper slope below that level (Figure 7); this suggests that the health benefit from per unit decreases in $PM_{2.5}$ levels is larger for $PM_{2.5}$ concentrations below the current annual NAAQS than for those above that level. Similar steeper concentration–response curves at low concentrations have been observed in previous studies. Significantly, our analyses (down to about 5 µg/m$^3$) do not provide evidence for a threshold value — the concentration below which $PM_{2.5}$ exposure does not impact mortality.

The $O_3$ standard in the United States is 70 ppb (daily maximum 8-hour average); there is no annual or seasonal standard. Our analyses, based on annual summer average $O_3$ concentrations, found an association with $O_3$ levels, lending support for the establishment of a seasonal or annual $O_3$ standard. We observed larger effect sizes for longer-term $O_3$ exposure, even in locations where $O_3$ concentrations never exceed 70 ppb. The concentration–response curve for $O_3$, using a two-pollutant model, was linear. Finally, the longer-term all-cause mortality results from this study and similar results from other studies (Turner et al. 2016), suggest that the current $O_3$ NAAQS — based only on acute effects from daily respiratory mortality — may underestimate the total health burden of effects from $O_3$ exposure.

***Subgroup Analyses.*** Given the very large sample size, this study afforded an estimation of mortality risk associated with long-term exposure to $PM_{2.5}$ and $O_3$ among predefined subgroups, such as racial minorities and disadvantaged subgroups. We found that the estimated effect size was larger among male, black, and Medicaid-eligible individuals. To determine whether the effect modifications by race and by Medicaid status were independent, we estimated effects in a subgroup of Medicaid-*eligible* whites and in a subgroup of Medicaid-*ineligible* blacks. We found that blacks not eligible for Medicaid continued to have higher $PM_{2.5}$ associated mortality.

Finally, the $PM_{2.5}$ health effect exhibited an urban–rural difference, which may be due to compositional differences (see Table S3 in the supplementary appendix for Di et al. 2017c available in Additional Materials on the HEI website).

***Consistency with Previous Results.*** The 7.3% increase in risk of all-cause mortality observed in this study for each 10-$\mu g/m^3$ increase in $PM_{2.5}$ exposure is within the range of the 13% to 14% increase reported in the Harvard Six Cities Study (Dockery et al. 1993), its extended follow-up study (Krewski et al. 2000), and in other studies. An increased (13.6%) risk for mortality was observed at lower $PM_{2.5}$ concentrations, as reported in the Canadian Community Health Cohort (see Di et al. 2017c for references).

A 10-ppb change in $O_3$ exposure was associated with a 1.1% increase in the risk of all-cause mortality; this result is close to the 2% increase in all-cause mortality reported by other investigators. This study provides substantial additional evidence that long-term $O_3$ exposure is associated with a shortened lifespan.

***Limitations.*** Although our exposure models had very good out-of-sample predictive power, like all epidemiology studies of this nature, we cannot fully rule out exposure assessment error issues. Such errors can attenuate the effect estimates in air pollution studies (Spiegelman 2016).

The potential for measured and unmeasured confounding bias is an intrinsic concern for all observational studies on air pollution and health. In order to mitigate these concerns, we estimated the low-exposure effects using two distinctly different study designs: (1) the AG model (Andersen and Gill 1982) for estimating the effect of long-term exposure to air pollution on mortality, as described in the study by Di and colleagues (2017c); and (2) a case–crossover study model for estimating the effects of short-term exposure to air pollution and mortality (see next section). These two study designs are subject to different types of both measured and unmeasured confounding bias, which we discuss in further detail in the Conclusions section of this report.

We have examined the effects of only two pollutants in this study. Our reasons were that these are both critical criteria pollutants and that their national standards — NAAQS — are currently scheduled for revision. We recently developed ensemble exposure assessment models for both $PM_{2.5}$ and $NO_2$ and updated our $O_3$ model; we expect to include these results in the HEI final report.

Some of the results presented in Figure 2 of the article by Di and colleagues (2017c) for effect modification are puzzling. For example, the protective effect observed for Native Americans, Hispanics, and Asians does not seem biologically based, nor is there an explanation for the difference in hazard ratios for males and females. Given the limits of the regression model for confounding, it is not possible to discern whether these differences may be attributable to model misspecification and/or confounding bias. For these and other reasons, we are developing new methods for causal inference that will give us greater confidence in the results. We plan to apply these new methods to analyze the data so that we may better understand the true effects of ambient air pollution.

## ASSOCIATION OF SHORT-TERM EXPOSURE TO AIR POLLUTION WITH MORTALITY IN OLDER ADULTS*

### Introduction

The evidence for the health effects of short-term exposure to $PM_{2.5}$ and $O_3$ is provided by many studies, though these studies have primarily been conducted in populations living in large, well-monitored urban areas, with relatively high levels of pollutants. The study we describe

* The following is a summary of an article published in the *Journal of the American Medical Association* by Di and colleagues (2017a), which may be viewed at *https://jamanetwork.com/journals/jama/fullarticle/2667069* (open access; courtesy of JAMA).

below was designed to study the health effects of exposure to $PM_{2.5}$ and $O_3$ that included groups living in unmonitored, rural areas. We also sought to shed light on short-term health risks among specific subgroups (e.g., under-represented minorities and those with low socioeconomic status, such as persons eligible for Medicaid).

We have conducted a case–crossover study to investigate all deaths among Medicaid enrollees in the United States during the years 2000 to 2012; our goal was to estimate mortality risk associated with short-term exposures to $PM_{2.5}$ and $O_3$ in the general population and in specific subgroups. We also wanted to estimate the association between daily mortality and exposure levels below the current NAAQS.

## Methods

***Population, Health and Covariate Data.*** All deaths among all Medicare beneficiaries were abstracted from Medicare claims data for the period 2000 to 2012 along with identifying data, relevant covariates, and the date of death. Individuals with an unverified date of death or still living after December 31, 2012, were excluded. A total of 22,433,862 deaths were identified.

Since confounders are, by definition, correlated with exposure, the only covariates included in the model were those which co-vary with daily air pollution levels. These included air and dew point temperatures along with the alternate air pollutant ($O_3$ in the case of $PM_{2.5}$ and $PM_{2.5}$ in the case of $O_3$).

Individual-level and ZIP-code-level covariates that could exhibit little or no change over the course of a month (e.g., age, sex, race/ethnicity, socioeconomic status, smoking, and other behavioral risk factors) were not considered to be potential confounders. However, because these variables may be relevant as effect modifiers, we abstracted age, sex, race, ethnicity, and eligibility for Medicaid from the Medicare and Medicaid records to assess the associations of mortality with $PM_{2.5}$ and $O_3$ concentrations in potentially vulnerable subgroups.

***Exposure: Ambient $PM_{2.5}$ and $O_3$ at the ZIP Code Level.*** Daily ambient levels of $PM_{2.5}$ (24-hour average) and $O_3$ (8-hour maximum in warm season) for all United States at the ZIP code level were estimated using the methods described above. For each subject, ambient concentrations were determined for the "case day," defined as the date of death, and its control days at the ZIP code of residence. For the same person, 3 or 4 control days were chosen and included in the analyses.

***Analysis.*** By fitting a conditional logistic regression to all pairs of case days and matched control days, we estimated the relative risk (RR) of all-cause mortality associated with short-term $PM_{2.5}$ and $O_3$ exposure (pollutant levels were adjusted for each other). Potential for residual weather-related confounding was controlled by using natural splines of air and dew point temperatures with three degrees of freedom. For each case day, daily exposure to air pollution was defined as the mean of the same day of death (lag 0-day) and 1 day prior (lag 01-day). Relative risk increase (RRI) was defined as RR – 1.

We performed subgroup analyses by sex, race, or ethnicity (white, nonwhite, and others), age brackets (≤69, 70–74, 75–84, and ≥85 years), eligibility for Medicaid, and population density at residence (in quartiles). We fitted separate conditional logistic regressions to the data for each subgroup and obtained subgroup-specific estimates of RR and absolute risk difference. Subgroups were compared using a two-sample test for assessing statistically significant differences in the estimated RR between categories.

In order to focus on effects below the current standards, subanalyses were conducted with cases restricted to those occurring on days with daily air pollution concentrations below 25 $\mu g/m^3$ for $PM_{2.5}$ and 60 ppb for $O_3$. This reduced the total number of cases to 20,955,387, a 6.6% decrease. ER curves were estimated between $PM_{2.5}$ or $O_3$ and mortality by replacing linear terms for the two pollutants with penalized splines for both $PM_{2.5}$ and $O_3$.

## Results

These analyses included more than 22 million days with deaths and more than 76 million control days among Medicare enrollees. We found an increase in the daily risk of mortality of 1.05% (95% CI, 0.95%–1.15%) for a 10-$\mu g/m^3$ increase in $PM_{2.5}$ and 0.51% (95% CI, 0.41%–0.61%) for a 10-ppb increase in $O_3$ among older Americans in the two-pollutant model (Table 5). These associations remained significant when examining days below 25 $\mu g/m^3$ for $PM_{2.5}$ and below 60 ppb for $O_3$, but with larger effect size estimates, particularly for both $PM_{2.5}$ and $O_3$ (RRI:1.61% [95% CI, 1.48%–1.74%] and 0.58% [95% CI, 0.46%–0.70%] respectively).

The estimated ER relationships are shown in Figure 8 as the RRI associated with a 10-$\mu g/m^3$ increase in $PM_{2.5}$ or a 10-ppb increase in $O_3$. Note that the increase in RRI rises sharply for both pollutants at a relatively low concentration — consistent with low-exposure analysis — and then levels out. Importantly, neither curve indicates a threshold for mortality at low concentrations.

In subgroup analyses, significant effect modification was observed for some key covariates (Di et al. 2017a, Figures 3 and 4). Thus, higher mortality was observed among

**Table 5.** Relative Risk Increase of Daily Mortality Associated with Each 10-μg/m$^3$ Increase in $PM_{2.5}$ or Each 10-ppb Increase in $O_3$[a]

| Model | Relative Risk Increase% (95% CI) | |
|---|---|---|
| | $PM_{2.5}$ | $O_3$[b] |
| Two-pollutant analysis | | |
| Main analysis[c] | 1.05 (0.95–1.15) | 0.51 (0.41 –0.61) |
| Low-exposure[d] | 1.61 (1.48–1.74) | 0.58 (0.46–0.70) |
| Nearest monitors[e] | 0.83 (0.73–0.93) | 0.35 (0.28–0.41) |
| Single-pollutant[f] | 1.18 (1.09–1.28) | 0.55 (0.48–0.62) |

$PM_{2.5}$ = fine particulate matter; ppb = parts per billion

[a] Adapted with permission from Di et al. 2017a, © 2017 American Medical Association. All rights reserved.

[b] $O_3$ analyses included days from the warm season only (April 1 to September 30).

[c] The main analysis used the mean of daily exposure on the same day of death and 1 day prior (lag 01-day) as the exposure metric for both $PM_{2.5}$ and $O_3$, and controlled for natural splines of air and dew point temperatures with 3 df. The main analysis considered the two pollutants jointly included in the regression model and estimated the percentage increase in the daily mortality rate associated with a 10-μg/m$^3$ increase in $PM_{2.5}$ exposure adjusted for $O_3$ and the percentage increase in daily mortality rate associated with a 10-pph increase in warm-season $O_3$ exposure adjusted for $PM_{2.5}$.

[d] The low-exposure analysis had the same model specifications as the two-pollutant analysis and was constrained for days when $PM_{2.5}$ was below 25 μg/m$^3$ or $O_3$ was below 60 ppb.

[e] $PM_{2.5}$ and $O_3$ monitoring data were retrieved from the U.S. Environmental Protection Agency Air Quality System, which provides the daily mean of $PM_{2.5}$ and daily 8-hour maximum $O_3$ levels at each monitoring site. Daily $O_3$ concentrations were averaged from April 1 to September 30. Individuals were assigned to the $PM_{2.5}$ and $O_3$ levels from the nearest monitor site within 50 km. Those living ≥ 50 km from any monitoring site were excluded.

[f] The single-pollutant analysis estimated the percentage increase in the daily mortality rate associated with a 10-μg/m$^3$ increase in $PM_{2.5}$ exposure without adjusting for $O_3$ and the percentage increase in the daily mortality rate associated with a 10-ppb increase in $O_3$ exposure without adjusting for $PM_{2.5}$.

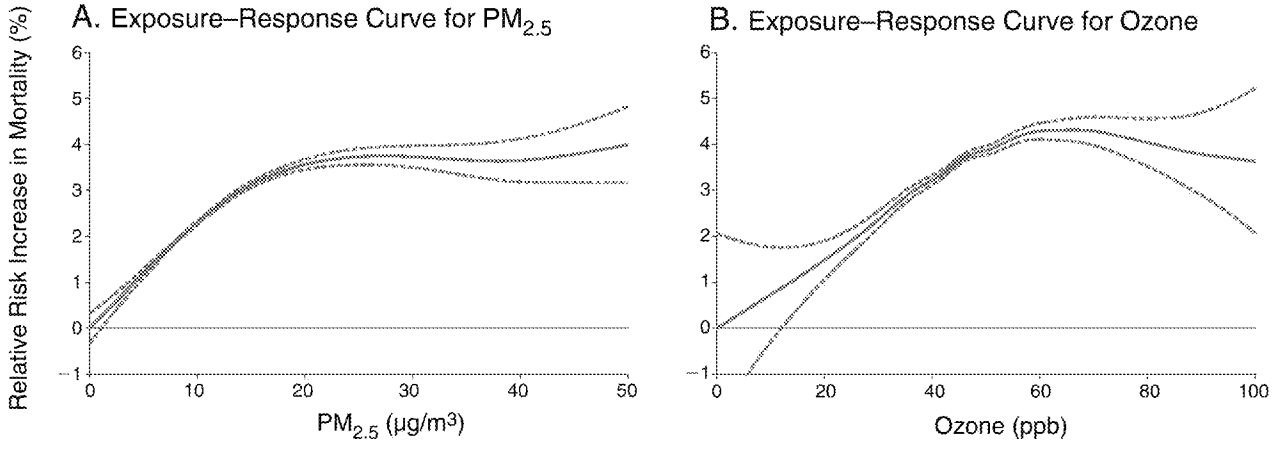


**Figure 8. Estimated exposure–response curves for short-term exposures to $PM_{2.5}$ and $O_3$ (Di et al. 2017a).** A two-pollutant analysis with separate penalized splines on $PM_{2.5}$ (A) and ozone (B) was conducted to assess the percentage increase in daily mortality at various pollution levels. Dashed lines indicate 95% CIs. The mean of daily exposure on the same day of death and 1 day prior (lag 01-day) were used as metrics of exposure to $PM_{2.5}$ and ozone. Analysis for ozone was restricted to the warm season (April to September). (ppb = parts per billion.) (Reprinted with permission from Di et al. 2017a, © 2017 American Medical Association. All rights reserved.)

those eligible for Medicaid (RRI: 1.49% [95% CI, 1.29%–1.70%] $P < 0.001$), those older than 70 years (e.g., for ≥85 years, RRI: 1.38% [95% CI, 1.23%–1.54%, interaction: $P < 0.001$), and among females (RRI: 1.20% [95% CI, 1.07%–1.33%], interaction: $P = 0.02$). The effect estimates for $PM_{2.5}$ increased with age and were higher for black individuals than for white individuals ($P = 0.001$). Similar patterns were observed for $O_3$, but with less contrast between groups.

### Discussion and Conclusion

In this large case–crossover study of all Medicare-recipient deaths between 2000 and 2012, both $PM_{2.5}$ and warm-season $O_3$ exposures were associated with statistically significant increases in mortality. When the analyses were restricted to days with $PM_{2.5}$ and $O_3$ levels lower than the current daily NAAQS levels, the risk of mortality remained statistically significant. Since Medicaid represents a national cohort, it included people living in smaller cities and rural areas that were unmonitored and thus excluded from previous time-series studies; we observed no difference in mortality risks among urban versus rural residents. This study provides evidence that short-term exposures to $PM_{2.5}$ and $O_3$ are associated with increased all-cause mortality, even at levels well below the current daily standards. Certain groups — such as older people, females, and those with lower income — are at an elevated risk.

The results of our study are consistent with the results of a large number of previous studies, conducted on cohorts in both the United States and Europe. Our results showing health effects after exposure to levels below the current NAAQS standards are significant, as are the results showing higher increases in mortality rates in certain subgroups — such as Medicaid-eligible individuals, females, and older individuals.

The strengths of this study are that it is based on the largest cohort among all time-series studies of $PM_{2.5}$ and $O_3$ exposure and health effects; it used state-of-the-art daily exposure assessment techniques for both monitored and unmonitored areas; it had sufficient statistical power to analyze mortality among potentially vulnerable subgroups; and, finally, that it used the case–crossover design, which controls for many confounding factors. Limitations of the study include that the Medicare population comprises individuals 65 years and older, Medicare files do not have information on cause-specific mortality, and there may be some exposure assessment error because exposure was estimated by residential ZIP code and not the exact location of death.

In conclusion, we report that daily $PM_{2.5}$ and warm season $O_3$ levels are associated with a risk of increased mortality, and this risk was observed at levels below the current standards for the two pollutants.

## EXAMINING CAUSAL INFERENCE BETWEEN AIR POLLUTION AND MORTALITY IN THE CONTEXT OF AN ERROR-PRONE EXPOSURE*

Observational studies to estimate the effects of exposure are well-known to be susceptible to sources of bias, particularly exposure measurement error and confounding. We have developed a new approach for estimating causal effects in the presence of exposure error; confounding is adjusted using a GPS. Monitoring data, assumed to be error free, were used as validation data. We then employed a regression calibration (RC)-based adjustment for continuous data for exposure (error prone) and combined it with GPS, thereby adjusting for confounding (RC-GPS). After transforming the corrected continuous exposure into a categorical exposure, we conducted the outcome analysis. We also considered confounding adjustment in the context of GPS subclassification, IPTW, and matching. We found that in simulations with varying degrees of exposure error and confounding bias, as compared with standard approaches that rely on the error-prone exposure, RC-GPS eliminates bias from exposure error and confounding.

To test this approach, we estimated the causal effect of long-term exposure to $PM_{2.5}$ on mortality in New England states for the period from 2000 to 2012 by applying RC-GPS to a rich data platform. We included 2,202 ZIP codes in the main study, covered by 217,660 1 km × 1 km grid cells with yearly mortality rates, yearly $PM_{2.5}$ averages estimated from a spatio–temporal model (error-prone exposure), and several potential confounders. For internal validation, we included a subset of 83 1 km × 1 km grid cells within 75 ZIP codes from the main study with error-free yearly $PM_{2.5}$ exposure data obtained from monitor stations. Under assumptions of noninterference and weak unconfoundedness, we found that exposure to moderate levels of $PM_{2.5}$ ($8 < PM_{2.5} < 10$ μg/m$^3$) causes a 2.8% (95% CI, 0.6%–3.6%) increase in all-cause mortality compared with low exposure ($PM_{2.5} < 8$ μg/m$^3$). (See Wu et al. 2019 for additional details.)

We were also interested in exploring the relationship between the grid of estimated ambient concentration and individual exposures. In this report, we have used ZIP-code-level ambient concentration as a proxy for actual individual exposure. To investigate this, we further downscaled our

* A full description of this study was published in the *Annals of Applied Statistics* (Wu et al. 2019).

updated $PM_{2.5}$ model, from 1 km × km to 100 m × 100 m, with additional downscaling of land-use variables. The refined 100-$m^2$ predictions are quite close to the individual-level exposure estimation that uses the subject's home address. Unfortunately, the Medicare data include only the participant's residential ZIP code.

### ADDRESSING LOCAL CONFOUNDING IN EXPOSURE–RESPONSE ESTIMATION*

To address the issue of confounding, we have developed a Bayesian framework for the estimation of a causal ER curve. This framework, called local ER confounding adjustment (LERCA), allows for different confounders and different strengths of confounding at different exposure levels. It also takes into account model uncertainty regarding confounders' selection and the shape of ER curve. Finally, LERCA enables systematic evaluation of the observed covariates' confounding importance at different exposure levels.

Using simulation studies, we compared LERCA with several state-of-the-art causal inference approaches for ER estimation. In addition, we applied this method to health, weather, demographic, and pollution data for 5,362 ZIP codes during the years 2011 to 2013. (An R package is available at *https://github.com/gpapadog/LERCA*.)

The LERCA approach to flexible estimation of the ER curve in observational studies is innovative because:

- Within a potential outcome framework, it casts the formulation of the ER (and several randomized experiments have been mimicked across exposure levels);
- The experimental configuration is informed by the data;
- It allows for different sets of covariates and confounders at different exposure levels (as is the case with our data example);
- It allows for varying confounding across different levels of the exposure;
- It increases efficiency by performing local covariate selection especially at low exposure levels;
- In the posterior inference on the whole ER curve, it propagates model uncertainty for the experiment configuration and covariate selection; and
- It provides important scientific guidance in terms of which covariates are confounders at different exposure levels.

* A full description of this study will be available in an article by Papadogeorgou and Dominici, submitted for publication.

In addition to its application to the estimation of the health effects of air pollution, the LERCA framework provides a data-driven approach that is applicable to many regulatory settings addressing the safety of potentially harmful substances. The method could be routinely used to assess health effects of low-level exposures to such pollutants as lead, environmental contaminants, radiation, and pesticides.

## DISCUSSION AND CONCLUSIONS

### KEY CONTRIBUTIONS

Our body of work advanced by HEI lends extensive evidence that short- and long-term exposure to $PM_{2.5}$ and $O_3$ is harmful to human health, increasing the risks of hospitalization and death, even at levels that are well below the NAAQS. Specifically, our HEI-funded work has enabled the following scientific contributions:

1. We have conducted the largest study to date on long-term exposure to $PM_{2.5}$ and $O_3$ (a prospective cohort with a time-varying exposure) for the entire Medicare population, with an assessment of the risk of mortality at exposure levels that are always below the NAAQS for yearly average (Di et al. 2017c).
2. We have completed the largest study to date on short-term exposure to $PM_{2.5}$ and $O_3$ (a case–crossover study) for the entire Medicare population, with an assessment of the risk of mortality at exposure levels that are always below the NAAQS for yearly average (Di et al. 2017a).
3. We have advanced the development of an artificial neural network (Di et al. 2017a) and open source R package (Sabath et al. 2018) to estimate daily exposures to $PM_{2.5}$ and $O_3$ for 11 million 1 km × 1 km grids for the continental United States.
4. We have developed new methods for causal inference to propagate the error in the exposure predictions into the health effects estimation using GPSs (Wu et al. 2019).
5. We have developed new methods for causal inference to estimate a causal ER function allowing a different set of confounders at different levels of exposure (*https://arxiv.org/abs/1806.00928*).

### STRENGTHS

There are several factors that contribute to the strengths of this work:

***Nation-Wide Analyses at an Unprecedented Scale.*** We conducted two nation-wide cohort studies (Di et al. 2017a, 2017c), allowing us to examine the health effects of air

pollution exposure at a scope, scale, and level of specificity beyond any previous studies. Our studies, which included claims data from the entire U.S. Medicare population from 2000–2012, included over 460 million person-years of follow up. Health data were linked to highly defined air pollution exposure predictions ($PM_{2.5}$ and $O_3$) for every 1 km × 1 km scale within the United States, allowing our team to examine the long- and short-term effects of air pollution exposure from a unique and unprecedented perspective.

***Two Different Study Designs.*** Each of our nationwide studies uses different study designs. Di and colleagues (2017c) used a prospective cohort design, allowing us to link $PM_{2.5}$ and $O_3$ exposure data to health outcomes and mortality data derived from Medicare claims (from 2000–2012). In Di and colleagues (2017a), we used a case–crossover design to examine all deaths of Medicare participants in the continental United States from 2000–2012 and to estimate the mortality risk associated with short-term exposures to $PM_{2.5}$ and $O_3$ in the general population as well as in subgroups. Although we used two different study designs, both studies provided consistent evidence of a significant increase in mortality risks as levels of $PM_{2.5}$ and $O_3$ exposure increase, even at levels well below the NAAQS.

***Numerous Sensitivity Analyses.*** Because Medicare claims do not include individual-level data on behavioral risk factors (such as smoking and income), which could impact mortality and thus be important confounders, we conducted multiple sensitivity analyses to assess potential confounding bias. Specifically, we used the MCBS (a nationally representative sample of approximately 15,000 Medicare enrollees per year with high-quality data on individual level risk factors, including smoking) to analyze the influence of potential confounding factors (i.e., age of entry in Medicare; body mass index; current smoking status; smoking history; income). We found that these additional individual-level variables, which were available to only part of the Medicare population, had little effect on the mortality and hospitalization risks of exposure to $PM_{2.5}$ for the entire Medicare population. In addition, we found that our results are robust regardless of the statistical methods used, obtaining similar risk estimates when we: (a) excluded individual and ecological covariates from the main analysis (Additional Materials, Table S2, available on the HEI website); (b) finely categorized age at entry (3- and 4-year rather than the 5-year categories used in the main analysis [see Di et al. 2017c, Figure S3]) (c) varied the estimation procedure (GEE vs. mixed effects) (Additional Materials, Di et al. 2017c, Table S3 and S4); and (d) used different statistical software (R vs. SAS) (see Di et al. 2017c Tables S3 and S4). Finally, we found that our results were consistent with other results published in the literature (see Di et al. 2017c, Figure S6).

In addition, we conducted sensitivity analyses of our air pollution prediction model, obtaining $PM_{2.5}$ and $O_3$ concentration data from the U.S. EPA Air Quality System (AQS) and matching it to each individual, based on the nearest monitoring site within a distance of 50 kilometers (see Additional Materials, section S.1 of the supplementary appendix for details).

***Development of New Methods for Causal Inference.*** In order to address significant methodological gaps limiting the current environmental epidemiological literature, we developed two novel methods. First, we developed a new approach to comprehensively assess the causal impact of exposure error overall by estimating causal effects when the exposure is measured with error and the confounding adjustment is performed via a GPS. Using categorical GPS is a critical advancement over the more commonly used binary propensity score confounding adjustment approaches. Second, we developed a Bayesian framework to estimate a causal ER curve called LERCA to account for: (a) different confounders and different strengths of confounding at the different exposure levels; and (b) model uncertainty regarding the selection of confounders and the shape of the ER curve. Also, LERCA provides a principled way of assessing the observed covariates' confounding importance at different exposure levels.

***Serious Effort to Develop Open Source Software and Increase Reproducibility and Transparency.*** Through our HEI-funded work, we have made enormous strides in advancing a framework and a set of tools needed to support greater data access, transparency, and reproducible research through an open science research data platform. To ensure the reproducibility of our workflow, we developed software codes and packages that allow investigators to link the already curated exposure and confounder data to Medicare and Medicaid claims data. For investigators who own or wish to purchase their own Medicare and Medicaid claims data, we can provide the exact code that we have used to link this claims data to the nonhealth data that we are using to conduct our own analyses of Medicare and Medicaid data. It allows other investigators to reproduce our analyses, replicate our findings, and conduct new analyses. It also guarantees the reproducibility of our own epidemiological analyses that use Medicare and Medicaid claims data to understand the health impacts of environmental exposures. Ultimately, the research data platform we have developed is an asset in increasing the scientific rigor of air pollution epidemiological studies by potentially reducing inconsistency of results across studies.

## LIMITATIONS

### Measured and Unmeasured Confounding Bias

The possibility of measured and unmeasured confounding bias is real in all observational studies on air pollution and health. To mitigate the potential impacts of measured and unmeasured confounding bias, we purposely estimated the health effects of low exposure to $PM_{2.5}$ and $O_3$ on mortality using two very distinct study designs: (1) using the AG model for estimating the effect of *long-term* exposure to air pollution on mortality (Di et al. 2017c); (2) using a case–crossover study for estimating the effect of *short-term* exposure to air pollution and mortality (Di et al. 2017a). These two study designs are subject to different types of both measured and unmeasured confounding bias. In the AG model we need to worry about unmeasured time trends and measured and unmeasured confounders that vary spatially. On the other hand, the case–crossover study is not subject to confounding bias by time trends nor by spatially varying covariates because it exploits the day-to-day variation in air pollution and mortality within each location (ZIP code) and because it leverages matching methods. Conducting both of these studies in parallel was an enormous undertaking. It was a serious attempt to see if we could obtain consistent results when analyzing the data in two completely different ways, knowing that each study would be subject to different sources of bias.

In fact, when applied to the same data, these two study designs, which use two totally different statistical analyses, both reported statistically significant associations, including at low levels of exposure. This increases our level of confidence that, overall, short- and long-term exposures to air pollution are both harmful to human health. The AG model, although less than perfect, has the following features compared with a standard Cox model: (1) The Medicare cohort is a dynamic cohort where new enrollees enter into the cohort every year. In the AG model, follow-up years are defined as the number of years since one participant enters the Medicare program until he or she dies or the study ends (in 2012). (2) To account for the dynamic nature of the cohort, the AG model formulation has the advantage of creating different strata of the population for each follow-up time. In other words, in the AG model, we control for follow up by design. This formulation is similar to a log-linear Poisson model with follow up included as a factor term in the model, except it is parametrized differently; the risks for each follow-up year are proportional in the Poisson model, but not in the AG model. However, we do have multiple calendar years of entry and, although related, follow-up year is not identical to calendar year. The AG formulation captures the effects of air pollution from both spatial and temporal variations. The model estimates a single coefficient for both $PM_{2.5}$ and $O_3$ by combining information across all strata. The overall estimate is therefore a combination of contributions *that could potentially be vulnerable to confounding by time trends and others that are not.* (3) Extensive sets of measured spatial confounders are available in the data sets; however, most temporal confounders are unmeasured and thus impossible to adjust for by direct inclusion into the AG model. Inclusion of a year as a linear term to adjust for unmeasured confounding bias due to the time trends in the AG model is inadequate as it will eliminate all the temporal variation in the data and result in an over adjustment. Since $PM_{2.5}$ declined between 2000 and 2012, and in addition, the trend has high collinearity with year, it is extremely hard to disentangle the effect of $PM_{2.5}$ from time trends based on the current methodology. It is also the reason that we are currently conducting sensitivity analyses using newly developed causal inference approaches.

We are currently conducting sensitivity analyses and have made enormous progress toward increasing the computational efficiency of fitting statistical models for the continental United States population. As detailed later in our planned analyses, we are developing an approach to reanalyze the same data used in our earlier study (Di et al 2017c), but with two important modifications: (1) we adjust for measured confounding bias using a causal inference approach using a GPS model; and (2) we adjust for unmeasured confounding bias, such as time trend, by including time into the GPS model. The results of these sensitivity analyses will be presented at the end of the study period and in the final HEI report.

### Need for Further Application of New Causal Inference Methods in National Epidemiological Studies

The development of new methods for causal inference in the context of these massive data sets whose data vary in space and time is a highly complex endeavor. In this report we described two of our studies — by Wu et al. (2019) and Papadogeorgou and Dominici (unpublished results) — that used new methods. We examined the methods' theoretical properties, tested them in simulation studies, and applied them to a subset of the entire U.S. Medicare data set, specifically focusing on the New England region. However, we recognize that these methods have not yet been developed in the context of the same study designs as those used in our earlier studies (Di et al. 2017a,c). Indeed, we are working on extensions to allow us to apply these methods to the exact same study designs as those used in our previous national cohort studies. We will continue to

develop these causal inference methods further for spatio–temporal data and to scale up the computations for the continental United States.

### Need for Formal Propagation of the Exposure Error in Health Effects Estimation

These two national studies do not account for a formal propagation of the exposure error into the health effects estimation. Addressing exposure error is a key priority, and we have attempted to address this issue in three ways: (1) validate the accuracy of our predictions; (2) conduct extensive sensitivity analyses that use only data observed from the monitors; and (3) develop new statistical methods that are purposely designed to propagate the error associated with the prediction of air pollution exposure into the estimation of causal effects of air pollution in health. As detailed in Wu and colleagues (2019), this is a complex problem. The complexity of this task is due to the fact that, in the context of causal inference methods, error in the exposure will affect the regression coefficient measuring the health risks of air pollution exposure (as in any measurement error model), but it will also affect the propensity score model used in the causal inference analysis. In the study by Wu and colleagues (2019), we have detailed an innovative and well-validated approach to overcome these challenges. Although our work so far is limited to the setting where the exposure is categorical and has only been applied to the New England region, we are working on extending it to the continuous setting and applying the approach to the continental United States.

### Mobility Bias

Both of these national epidemiological studies are potentially impacted by mobility bias and we are working towards a better understanding this issue. We have found that approximately 21% of Medicare recipients changed residential ZIP code at least once between 2000 and 2012. It could thus be possible that older people who are healthy are more likely to move to more rural, less polluted areas; or that older people with health problems may tend to move into cities to have better access to medical care. Since we update exposure level for each participant every year, their moving will not affect our exposure assessment. We are conducting analyses of long-term effects of $PM_{2.5}$ on mortality separately among the movers and the nonmovers. So far, we have been able to link exposure data to 10,679,150 movers and 52,746,548 nonmovers (unpublished results).

## NEXT STEPS

### Update the Exposure Estimation for PM, $O_3$, and $NO_2$ to 2016

We have updated our $PM_{2.5}$ exposure assessment to 2016 using an advanced modeling strategy. For the new model, we fit an ensemble model using a generalized additive model accounting for geographic differences to combine $PM_{2.5}$ estimates from three separate machine learning models; neural network, random forest, and gradient boosting. The three machine learning models complement each other; combining them using a generalized additive model provides an overall better model fit. Predictor variables in the three models included satellite data, meteorological variables, land-use variables, elevation, simulation outputs from chemical transport models, reanalysis data sets, and other data sources. Using the ensemble model, we predicted daily $PM_{2.5}$ from 2000 to 2016 at every 1 km × 1 km grid cell in the continental United States. Model training results for daily predictions from 2000 to 2016 indicated good model performance with a 10-fold cross-validated $R^2$ of 0.86. For annual estimates, the cross-validated $R^2$ was 0.89. The final model demonstrated good performance up to 100 μg/m$^3$. This work is completed, and a manuscript has been submitted to *Environment International*. A similar approach is being implemented for $O_3$.

In addition to $PM_{2.5}$ exposure estimates, we also estimated daily $NO_2$ concentrations from 2000 to 2016 in a similar ensemble model-based approach. Similarly, an ensemble model was fit using a generalized additive model to combine estimates from three machine-learning models; neural network, random forest, and gradient boosting, to obtain overall estimates of daily $NO_2$ concentrations. Predictor variables of the three machine-learning $NO_2$ models included $NO_2$ column concentrations from the satellite, land-use variables, meteorological variables, and other data sources. Using the ensemble model, we predicted daily $NO_2$ at 1 km × 1 km grid cells in the continental United States. The mean 10-fold cross-validated $R^2$ was 0.77, ranging from 0.67 to 0.79. The spatial $R^2$ ($R^2$ between monitored and predicted annual averages) was between 0.75 to 0.83, with a mean spatial $R^2$ of 0.82, indicating a good model performance at the annual level (unpublished results).

To summarize, compared with the existing model, our new ensemble $PM_{2.5}$ model performed noticeably better at the annual level. The existing model underestimated $PM_{2.5}$ concentrations at high concentrations. Our new ensemble model does improve model performance at high concentrations of $PM_{2.5}$. Furthermore, it is worth high-lighting that by

using the two new ensemble models we were able to estimate the uncertainty in the predictions (monthly standard deviation of the difference between daily monitored value and daily predicted value).

### Applying New Causal Inference Methods to Same Data Used to Complete Prospective National Medicare Cohort Study

We are working on conducting causal inference analyses of the same data (for all the United States) and same study design as in Di and colleagues (2017c). Within this work, we are comparing various state-of-the-art approaches for causal inference to adjust for measured confounding. More specifically, we are comparing approaches using GPS models (IPTW, matching, doubly robust approaches) as well as nonparametric doubly robust approaches. In addition to adjusting for measured confounding, we are also exploring various approaches to adjust for unmeasured confounding by including time as a covariate in the GPS model. These planned analyses would more robustly explore methods to adjust for measured and unmeasured confounders by applying the innovative causal inference methods our group has been developing for Medicare data of the continental United States. In addition to our national Medicare cohort studies, we have begun applying new causal methods to Medicaid data from 2010 to 2011. Our first project using this cohort is to determine the short-term effects of $PM_{2.5}$ exposure on cardiovascular disease outcomes in this population. This is a new data set for our group to work with. We are using this first project to understand the challenges in analyzing such a complex data set, which includes varying amounts of data availability by state and differing eligibility criteria by state. Our first manuscript using this data is almost complete and will be presented at the next HEI meeting.

### Discovering Heterogenous Groups under a Causal Inference Framework

We are developing causal inference methods for the de novo discovery of vulnerable subgroups and the estimation of air pollution effects within subgroups. Traditional air pollution health studies that seek to identify effect modifiers first select a priori a rather small set of these potential modifiers to test (either at the individual or area level) and then either (1) fit a regression model with one term for the exposure main effect and an additional interaction term between the exposure and each individual potential effect modifier, or (2) fit separate regression models stratified by the levels of a single potential modifier at a time. Recent studies have attempted to reduce the number of regression models by first identifying patterns across multiple modifiers, employing factor analytic techniques, and subsequently testing for potential modification by these composite factors (Achilleos et al. 2017; Kioumourtzoglou et al. 2016). Nonetheless, the current approaches have many limitations:

1. The potential effect modifiers to be tested are selected a priori, leading to the possibility of omitting key factors of vulnerability.
2. Inclusion of an interaction term in a regression model does not permit assessment of higher-order interactions (i.e., when a vulnerable subgroup is characterized by co-occurrence of multiple factors, which is likely among low income populations).
3. Although factor analytic and clustering approaches (Hastie et al. 2009; James et al. 2000) try to address this limitation, they are unsupervised approaches (i.e., one must first classify the population into subgroups and separately assess whether the risk varies by these previously identified subgroups). Thus, these approaches do not allow subgroup discovery based on the outcome and could potentially mask the characteristics of the truly vulnerable subgroups for the specific outcome of interest.
4. Previous techniques require solely continuous or categorical variables as inputs, which is not always the case when multiple modifiers are being evaluated.
5. The current epidemiological literature lacks state-of-the-art approaches to: (a) test for heterogeneity of air pollution effects across subgroups in a way that does not rely on strong parametric assumptions; (b) quantify the evidence of heterogeneity in a way that is not affected by residual or unmeasured confounding bias; (c) eliminate the multiple comparison problem; and (d) allow both continuous and categorical potential modifiers simultaneously as inputs. The new methods that we are developing are designed to overcome these limitations.

As part of our planned analyses, which are also summarized in a paper by Lee and colleagues (In press. *https://arxiv.org/pdf/ 1802.06710.pdf*), we developed a new approach for causal inference to discover *de novo subgroups of the population that experience causal effects of air pollution on mortality that are statistically significantly higher or lower than the population average.* The methods developed in this paper try to overcome the limitations of model misspecification, described as a limitation of Di and colleagues (2017c). More specifically, in this new approach for causal inference we split data into two subsamples, a training and a test sample: (a) in the training sample we use matching to eliminate measured confounding bias and consider a data-driven search for de novo discovery of subgroups that could have exposure effects that differ from the population mean; and then

(b) using the test sample, we quantify evidence of effect modification among the subgroups with nonparametric randomization-based tests. Because we first match and then test for effect modification using a nonparametric approach, we argue that this modeling design is more rigorous and less susceptible to false positive results for effect modification that could be driven by residual confounding bias. Via simulation studies and theoretical arguments, we demonstrate that since we discover the subgroups in the training set, hypothesis testing on the test set can focus on these subgroups only, thus substantially increasing the statistical power of the test. We have applied our method to the data from 1,612,414 Medicare beneficiaries in the New England region of the United States for the period 2000 to 2006. We find that low-income seniors 81–85 years and seniors over 85 years have statistically significant higher causal effects of exposure to $PM_{2.5}$ on 5-year mortality rates compared to the population mean. Scaling up this approach to the continental United States is challenging, but we intend to tackle this challenge as a primary goal of our planned analysis. The novel methods that we are developing, which will be generalizable and applicable to other analyses, will allow a granular joint identification of several potential effect modifiers.

**Spatial Confounding and Analysis of Geographic Regions**

In our completed work to date, we did not use geographic groups since we were interested in the overall effect of air pollution at the national level. However, it would be helpful for future analyses to study regional differences of the health effects of ambient air pollution. Such analyses could address residual confounding by geography. Further, it would be valuable to consider alternate geographic groupings to account for confounding (e.g., geographic areas that map more closely with patterning of disease rates in the United States, such as the so-called stroke belt in the southeastern United States).

## IMPLICATIONS OF FINDINGS

Several critical factors position the scientific community at an unprecedented moment to accelerate scientific discovery and inform data-driven environmental and public health strategies. These factors include: incredible technological advances in how we collect data (from satellites, sensors, power plants, and electronic medical records); nearly unlimited computational power; and the development of new statistical methods that allow data to be analyzed in an unbiased, highly principled way to assess causality. However, in order to fully leverage these advancements to understand the impacts of long-term exposure to low levels of air pollution, we needed to address several existing gaps. Through our HEI-funded work, our team has fundamentally advanced the paradigm for scientific inquiry by: (a) developing a flexible R package called airpred (Sabath et al. 2018) that enables environmental health researchers to design and train spatio–temporal air pollution exposure models capable of predicting multiple pollutants, including $PM_{2.5}$; (b) developing new causal inference methods designed to account for exposure error and to improve ER estimation in order to account for differential confounding at different exposure levels. Together, these tools stand to significantly increase scientific rigor and advance evidence on the causal impacts of exposures to low levels of ambient pollution at a level or robustness not previously possible. The findings generated from our HEI-funded study have been, and will continue to be, impactful to the scientific community, policy makers, and the public.

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Additional Materials contain the *New England Journal of Medicine* article by Di and colleagues (2017c) and the related supplementary appendix. It is available on the HEI website, *www.healtheffects.org/publications,* with permission from the publisher.

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## ABOUT THE AUTHORS

**Francesca Dominici,** PhD, is co-director of the Harvard Data Science Initiative and Clarence James Gamble Professor of Biostatistics, Population, and Data Science at the Harvard T.H. Chan School of Public Health. Her research areas include (1) linking massive and heterogeneous data sets to estimate health effects of environmental contaminants (air pollution, noise) and climate change; (2) developing statistical methods for the analysis of large and complex data to overcome the many sources of bias; (3) developing methods for causal inference to adjust for confounding bias and detect treatment effect heterogeneity; (4) applying newly developed methods to massive data sets to extract new knowledge regarding important questions in environmental health science, health-related impacts of climate change, and comparative effectiveness research; (5) leading the management and the analysis of several administrative databases, including Part A CMS files and SEER-Medicare, which are linked to air pollution and weather and socioeconomic data. She is an expert in Bayesian methods, longitudinal data analysis, confounding adjustment, causal inference, and Bayesian hierarchical models and data science and has extensive experience in the development of statistical methods and their applications to environmental epidemiology, implementation science and health policy, outcome research and patient safety, and comparative effectiveness research. She has authored more than 180 peer-reviewed publications and is a principal investigator, together with Dr. Xihong Lin, of an NCI P01 project titled "Statistical Informatics for Cancer Research." She is

also principal investigator of several U.S. EPA, National Institutes of Health, and HEI funded projects aimed at developing statistical methods and conducting nationwide epidemiological studies on the health effects of air pollution, and she oversees the management and analysis of several administrative databases, including Medicare and Medicaid claims data, which are linked to air pollution and weather and socioeconomic data. She is a permanent member of the National Institutes of Health study section of Biostatistical Methods and Study Designs, has served on a number of National Academies committees, and has recently been appointed as a member of the Radiation Effects Research Foundation Board of Councilors — a cooperative Japan–U.S. Research Organization focused on the study of health effects of radiation in the survivors of the atomic bombings of Hiroshima and Nagasaki. Dr. Dominici has received numerous recognitions, including the 2016 Janet L. Norwood Award for Outstanding Achievement in Statistical Sciences in 2016 and the 2015 Florence Nightingale David award, which is sponsored jointly by the Committee of Presidents of Statistical Societies and the Caucus for Women in Statistics. She was also awarded the 2013 Mathematics for Planet Earth Award Lecture, hosted by the Statistical and Applied Mathematical Sciences Institute; 2009 Diversity Recognition Award at Johns Hopkins University; the 2007 Myrto Lefkopoulou Distinguished Lectureship Award, Department of Biostatistics, Harvard T.H. Chan School of Public Health; 2007 Gertrude Cox Award, Washington, D.C., chapter of the American Statistical Association and RTI International; 2006 Mortimer Spiegelman Award, statistics section of the American Public Health Association; and Dean's Lecture at the Bloomberg School of Public Health in 2007.

**Joel Schwartz,** PhD, is professor of Environmental Epidemiology in the Department of Environmental Health at the Harvard T.H. Chan School of Public Health. He has more than 30 years of experience in the fields of epidemiology, exposure modeling, and biostatistics, including development of spatiotemporal statistical models that use satellite data to predict air pollutant concentrations. He is a worldwide expert and one of the most prolific scientists in the field of environmental epidemiology. He has extensive expertise in epidemiological methods and analyses looking at the health consequences of exposure to pollutants. His air pollution work has examined both acute and chronic effects of air pollution exposure. Recent research has established that exposure to fine combustion particles in the air at concentrations well below current standards are associated with a range of adverse health effects, from increased respiratory symptoms to increased hospital admissions to increased deaths. This work has led to a tightening of the U.S. air quality standards. He has done considerable work on health effects of $O_3$ exposure. He has several international collaborations underway in this area. His recent work has been focused on the cardiovascular effects of air pollution, and on factors which modify the response to air pollution. This work has suggested that people with diabetes are more susceptible, for example. He is also an expert in methods for causal inference and regression spline models, nonparametric smoothing, and generalized additive models. Dr. Schwartz also has extensive expertise in the use of cost–benefit analysis to make environmental decisions. He has developed benefit methodologies for assessing the benefits of lead control and has applied those methodologies to the decision to remove lead from gasoline, and recently, in collaboration with colleagues at the Centers for Disease Control, to a decision to revise their screening recommendations for children. He is also involved in cost–benefit analysis of air pollution control.

**Qian Di,** ScD, was a postdoctoral fellow in the Department of Environmental Health at Harvard T.H. Chan School of Public Health during the course of this study. He is currently assistant professor at the School of Medicine, Tsinghua University, Beijing, China. His work focuses on modeling, predicting air pollutants and temperature with high temporal and spatial resolutions, and working with health data to estimate health effects of air pollution and other environmental factors.

**Danielle Braun**, PhD, is a research scientist in the Department of Biostatistics at the Harvard T.H. Chan School of Public Health and Department of Computational Biology, working with Dr. Francesca Dominici, and also in the Dana-Farber Cancer Institute working with Dr. Giovanni Parmigiani. Her research focuses on the statistical development of methods in causal inference and risk prediction. She has worked extensively on measurement error, causal inference, comparative effectiveness research, risk prediction, genetic epidemiology, survival analysis, and frailty models. She has been mentoring undergraduate and graduate students for over four years and co-leads the BayesMendel lab along with Professor Parmigiani, leading many recent projects and working closely with PhD students on their theses.

**Christine Choirat,** PhD, was a senior research scientist in the Department of Biostatistics, Harvard T.H. Chan School of Public Health, Institute for Quantitative Social Science, Harvard University during the course of this study. She is currently chief health data scientist at Swiss Data Science Center, ETH Zürich and EPFL, Switzerland. A trained data scientist, Choirat has over 15 years of experience in computational statistics and in industry-standard software

development. Her research focuses on quantitative methods applied to economics, management, decision theory, and psychology, with a special emphasis on experimental approaches. She leads a big data acquisition, fusion, and archiving effort assembling a national database of ambient air quality monitoring, air pollution predictions, weather, population demographics, and Medicare/Medicaid hospitalization and mortality outcomes. She is a project lead of the popular statistical software, Zelig (*http://zeligproject.org/*), a suite of open-source R packages that facilitate using and interpreting a wide variety of statistical models through a user-friendly common interface. She has extensive experience in data repositories such as the Dataverse (*http://dataverse.org/*), and in fostering community engagement via the administration of User Groups (*https://groups.google.com/forum/#!forum/zelig-statistical-software*). She is co-author of genTB, an analysis tool for *Mycobacterium tuberculosis* genomic data.

**Antonella Zanobetti,** PhD, is a principal research scientist in the Department of Environment Health at the Harvard T.H. Chan School of Public Health. Her research focuses on the health consequences of exposure to air pollutants and climate change. Her interests are shaped by her background and training in both epidemiology and statistics and by her extensive experience developing and applying statistical methods for epidemiological investigations. Her work has contributed substantially to our understanding of air pollution and climate change-mediated health impact and is focused in three main areas: (1) examination of the impact of short- and long-term exposure to air pollution on mortality and morbidity and on cardiovascular disease in panel and longitudinal studies, (2) development of innovative statistical methodologies to examine emerging issues in environmental epidemiology, such as gene–environment interactions, epigenetics, and susceptibility and vulnerability, and (3) assessment of the health consequences of extreme temperatures and other weather parameters on mortality and morbidity. Dr. Zanobetti has recently been recognized in Thomson Reuters 2015 list of the most highly cited researchers, ranking in the top 1% of scientists cited in her field.

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# COMMENTARY

## HEI's Low-Exposure Epidemiology Studies Review Panel

Research Report 200, *Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1*, F. Dominici et al.

## INTRODUCTION

This Commentary was prepared by the HEI Low-Exposure Epidemiology Studies Review Panel for the study "Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Pollution." This special Panel was convened to review HEI-funded studies on the health effects of exposure to low levels of ambient air pollution. The Commentary includes the scientific and regulatory background for the research, the Panel's evaluation of the Phase 1 report from the investigator team led by Dr. Francesca Dominici, and the Panel's conclusions. It is intended to aid the sponsors of HEI and the public by highlighting both the strengths and limitations of the study and by placing the Investigators' Report into scientific and regulatory perspective.

## SCIENTIFIC AND REGULATORY BACKGROUND

The setting of ambient air quality standards — at levels considered adequate to protect public health — is a central component of programs designed to reduce air pollution and improve public health under the U.S. Clean Air Act (U.S. CAA*) and similar measures in Europe and around the world. Although the process for setting such standards varies, they all contain several common components:

- Identifying, reviewing, and synthesizing the scientific evidence on sources, exposures, and health effects of air pollution;
- Conducting risk and policy assessments to estimate what public health effects are likely to be seen at different levels of the standard;
- Identifying and setting standards based on scenarios considered in the risk analysis;
- Air quality monitoring to identify geographical areas that do not meet the standards; and,
- Implementing air quality control interventions to reduce ambient air concentrations to meet the standards.

### SETTING NATIONAL AMBIENT AIR QUALITY STANDARDS UNDER THE U.S. CAA

The U.S. CAA requires that in setting the National Ambient Air Quality Standards (NAAQS), the U.S. Environmental Protection Agency (U.S. EPA) Administrator review all available science and set the NAAQS for all major ("criteria") pollutants (including ozone [$O_3$], particulate matter [PM], and nitrogen dioxide [$NO_2$]) at a level "requisite to protect the public health with an adequate margin of safety." In practice, since 2008 that review has had two principal steps:

1. Synthesis and evaluation of all new scientific evidence since the previous review in what is now called an *Integrated Science Assessment*. This document reviews the broad range of exposure, dosimetry, toxicology, mechanism, clinical research, and epidemiology evidence. It then — according to a predetermined set of criteria (U.S. EPA 2015) — draws on all lines of evidence to make a determination of whether the exposure is causal, likely to be causal, or suggestive for a series of health outcomes.
2. Assessment of the risks based on that science is then conducted in a *Risk and Policy Assessment*. This further analysis draws on the Integrated Science Assessment to identify the strongest evidence — most often from human clinical and epidemiological studies — of the lowest concentration levels at which health effects are observed, the likely implications of such levels for health across the population, and the degree to which the newest evidence suggests that there are effects observed below the then-current NAAQS for a particular pollutant.

Dr. Francesca Dominici's 4-year study, "Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Pollution," began in March 1, 2016. The Phase 1 draft Investigators' Report from Dominici and colleagues was received for review in October 2018. A revised report, received in February 2019, was accepted for publication in March 2019. During the review process, HEI's Low-Exposure Epidemiology Studies Review Panel and the investigators had the opportunity to exchange comments and to clarify issues in both the Investigators' Report and the Review Panel's Commentary. As the principal investigator of this study, Dr. Francesca Dominici, who is a member of the HEI Research Committee, was not involved in its selection for funding or in the oversight process.

This document has not been reviewed by public or private party institutions, including those that support the Health Effects Institute; therefore, it may not reflect the views of these parties, and no endorsements by them should be inferred.

* A list of abbreviations and other terms appears at the end of this volume.

The Risk and Policy Assessment also examines the uncertainties around estimates of health impact and the shape of the concentration–response curve, especially at levels near and below the then-current NAAQS. Although a range of possible shapes of the concentration–response curves has been considered, including whether there is a threshold at a level below which effects are not likely, the U.S. EPA's conclusions in these reviews thus far have not found evidence of a threshold (although studies to date have not always had the power to detect one) (U.S. EPA 2004, 2013). Also, although the standard is set, according to statute, to protect public health with an adequate margin of safety, it has been generally understood that there are likely additional health effects below the NAAQS, although their presence and magnitude are more uncertain.

Both of these documents are subjected to extensive public comments and reviewed by the Clean Air Scientific Advisory Committee (CASAC), which was established under the U.S. CAA. CASAC is charged with peer-reviewing the documents — which includes providing guidance to the Administrator on the strength and uncertainties in the science and advising on alternative scenarios for retaining or changing the NAAQS.

## EVOLUTION OF THE NAAQS

The reviews of the criteria pollutants have been ongoing for nearly 50 years, since the passage of the Clean Air Act Amendments of 1970. As the science has evolved, each subsequent review has examined the strength of the evidence for retaining or tightening the NAAQS. Although the process has frequently resulted in a decision to retain the then-current NAAQS, the NAAQS of both $O_3$ and fine PM (particulate matter $\leq 2.5$ µm in aerodynamic diameter, or $PM_{2.5}$) have seen substantial revisions, especially over the last 20 years:

***$O_3$*** Starting in 1997, the NAAQS was converted from a 1-hour maximum standard to a standard averaged over 8 hours. In 1997, the NAAQS was set at 80 ppb; subsequently in 2008 it was lowered to 75 ppb, and then in 2015 to 70 ppb. Although there was epidemiological evidence of effects at or near these levels, the changes relied heavily on a series of carefully conducted human controlled-exposure studies.

***$PM_{2.5}$*** In 1997, based on dosimetric and biological information suggesting that fine particles less than or equal to 2.5 µg in diameter ($PM_{2.5}$) were a more appropriate indicator than $PM_{10}$, the U.S. EPA for the first time proposed and established a NAAQS for $PM_{2.5}$. It set the annual standard at 15 µg/m$^3$ in part as a result of the new long-term cohort evidence of association of $PM_{2.5}$ with adverse health effects (Dockery et al., 1993; Pope 1995) That was subsequently further reviewed in 2006 with no change and again in 2012, when the NAAQS, based on additional epidemiological evidence, was reduced to 12 µg/m$^3$ (U.S. EPA 2016).

## IMPACT OF THE NAAQS

With the establishment of these standards, a host of national and regional regulatory actions began to reduce emissions from electric power plants, factories, motor vehicles, and other sources. As a result, there has been a steady and marked decline in ambient concentrations, so that much of the United States now attains the NAAQS (see, for example, the trend in $PM_{2.5}$ concentrations in the Commentary Figure.)

## ADVENT OF RECENT STUDIES OBSERVING ASSOCIATIONS BELOW THE NAAQS

As the data on levels of $PM_{2.5}$ improved over the course of the first decade of this century, new studies began to emerge starting in 2012 (e.g., in Canada and New Zealand) suggesting that associations of $PM_{2.5}$ and mortality could be observed down to levels well below the NAAQS of 12 µg/m$^3$ (Crouse et al. 2012; Hales et al. 2012). These studies found robust associations, with some evidence of even steeper slopes of effect at the lowest levels, findings which, if replicated in other populations and by other investigators, could change the basis for future determinations of the levels at which to set the NAAQS and other air quality standards.

At the same time, they posed several questions, for example:

- Would the results be robust to the application of a range of alternative analytic models and their uncertainty?
- Could other important determinants of population health, such as age, socioeconomic position, health status, and access to medical care, as well as differences in air pollution sources and time–activity patterns, modify or confound the associations seen?
- Would the results change if risk estimates corrected for the effects of important potential confounding variables, such as smoking, in the absence of such data at the individual level?
- What might be the effects of co-occurring pollutants on health effect associations at low ambient concentrations?

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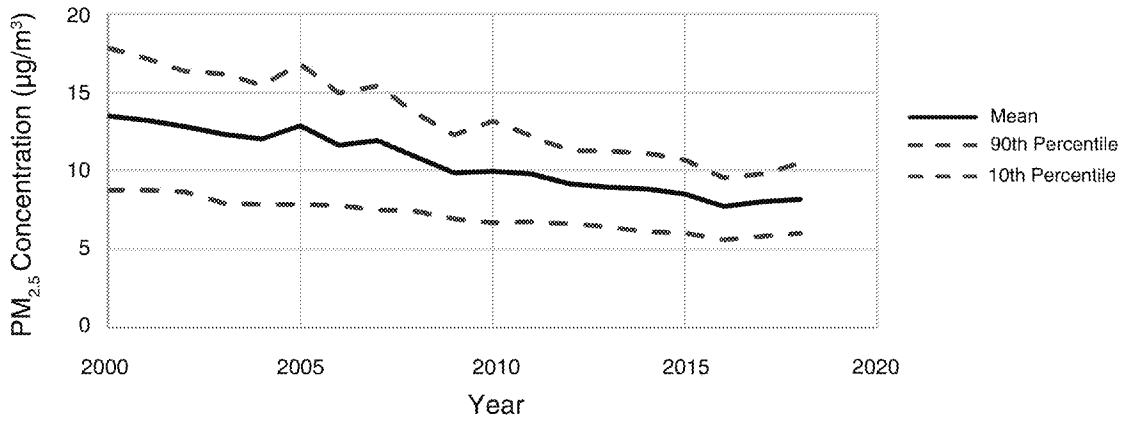


**Commentary Figure. Trends in $PM_{2.5}$ concentration from 2000 to 2018 (seasonally weighted annual average) as monitored by the U.S. EPA (data from U.S. *EPA; www.epa.gov/air-trends/particulate-matter-pm25-trends).***

As described in the Preface in this volume, the advent of these studies and the desire to address these important questions formed the basis for HEI's decision in 2014 to issue a Request for Applications (RFA 14-3), which sought and ultimately supported this study by Dr. Dominici and colleagues and two other studies that make up HEI's program to Assess Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution.

The Dominici research project encompasses a number of goals, which are addressed in nationwide exposure assessment and health impact studies, and causal modeling. Undergirding these studies is an effort to make the methods and data from this project available to the scientific community. The following evaluation is based on the initial results of the study described in the Phase 1 Investigators' Report.

## SUMMARY OF THE STUDY

### SPECIFIC AIMS

The full Dominici project, a four-year study funded by HEI, which began in 2016, has an expansive set of aims; however, for the purposes of this Phase 1 report, a subset of their overall aims is summarized as follows.

***Aim 1: Exposure Prediction and Data Linkage*** Estimate long-term exposures to low levels of ambient $PM_{2.5}$ mass and the gaseous air pollutant $O_3$ by employing and extending hybrid prediction models that use satellite, land-use, emissions, ground-monitoring, and weather data, in conjunction with chemical transport models, at a high spatial resolution (1 km × 1 km) for the continental United States.

***Aim 2: Causal Inference Methods for Exposure–Response*** Develop a new framework in Bayesian causal inference to estimate the concentration–response function that is robust to model misspecification for confounding and accounts for exposure error.

***Aim 3: Evidence on Adverse Health Effects*** Estimate mortality associated with exposure to ambient air pollution for all U.S. Medicare enrollees between 2000 and 2012 (61 million adults, 65 years of age and older) and a representative subsample of Medicare participants with detailed personal information from the Medicare Current Beneficiary Survey (MCBS) (57,200 adults), using a cohort (long-term) and a case–crossover (short-term) design.

***Aim 4: Tools for Data Access and Reproducibility*** Develop approaches and tools for data sharing, record linkage, and statistical software.

This commentary focuses in more detail on Aims 1 and 3, comprising initial results from the exposure and health effects research that have been published in peer-reviewed journals (Di et al. 2017a, 2017c; the latter can be found in Additional Materials on the HEI website). Aims 2 and 4 (causal modeling and more advanced statistical analyses and data access) are discussed briefly here as this research is still in its initial stages; the Panel does offer some

comments on this research, with suggestions for the conduct of these further analyses.

## EXPOSURE AND HEALTH EFFECTS STUDIES

### Data and Methods

The investigators amassed very large amounts of data from many different sources and used them for their analysis.

***Ambient Air Pollution Concentrations*** Since the emphasis in this study was to study the entire older U.S. population — including people living in rural, low ambient air pollution concentration areas — the investigators developed air pollution concentration models for the 48 contiguous states, relying on research that they had completed before the current study began. They estimated ambient $PM_{2.5}$ concentrations for the period 2000 to 2012 using the following sources of data for their exposure model (for details, see Di et al. 2016):

1. Air monitoring data were obtained from the U.S. EPA Air Quality System (AQS), used in both model building and for cross-validation.
2. Aerosol optical depth (AOD) data were obtained from the moderate resolution imaging spectroradiometer (MODIS).
3. Surface reflectance data were also obtained from MODIS (MOD09A1).
4. Chemical transport model outputs were derived from the widely used GEOS-Chem model, which employs meteorological inputs and emission inventories to simulate atmospheric components. Total $PM_{2.5}$ was defined as the sum of nitrate, sulfate and ammonium ions and elemental carbon, organic carbon, sea salt aerosol, and dust aerosol. In addition to producing ground-level $PM_{2.5}$ estimates, the GEOS-Chem model is also useful for calibrating AOD because, being a three-dimensional model, it simulates vertical distribution of aerosols.
5. Meteorological data were obtained from the North American Regional Reanalysis project; the variables used included air temperature, accumulated total precipitation, downward shortwave radiation flux, accumulated total evaporation, planetary boundary layer height, low cloud area fraction, precipitable water for the entire atmosphere, pressure, specific humidity at 2 meters, visibility, wind speed, medium cloud area fraction, high cloud area fraction, and surface reflectance.
6. Aerosol index data were taken from the absorbing aerosol index measured by the ozone monitoring instrument (OMI), onboard the Aura satellite. These data are used to correct for the presence of other absorbing aerosols in the air (such as those from biomass burning and desert dust).
7. Land-use terms were obtained as previously described by Kloog and colleagues (2012). These terms represent emissions and can help inform small spatial scale variations; land-use data incorporate a variety of variables (such as population and road densities, emissions inventory, elevation, percentage urban, etc.).
8. In the regression models, the investigators also used regional and dummy variables to account for regional and temporal variability due to differences in meteorology and aerosol composition.

For estimating $O_3$ concentrations, the investigators used the same information for their models as listed for $PM_{2.5}$, supplemented by the following sources of data (see Di et al. 2017b):

1. Satellite-based $O_3$ measurements obtained from the OMI onboard the Aura satellite and used to calculate vertical distribution of $O_3$ levels.
2. Ozone vertical profile obtained through using an approach similar to that used for modeling $PM_{2.5}$. The GEOS-Chem model was used to estimate $O_3$ levels at different layers, and a scaling factor was used to calibrate satellite-based estimates to ground level $O_3$.
3. Ozone precursors (such as nitrogen oxides [$NO_x$], carbon monoxide, methane, and volatile organic compounds (VOCs), were estimated by the inclusion of AQS daily measurements of sulfur dioxide, $NO_2$, $NO_x$, and VOCs into the $O_3$ model, followed by the use of distance–decay functions from air quality monitors and other approaches.

With this large amount of data and using multiple approaches and input variables, the investigators developed a hybrid model to estimate daily $PM_{2.5}$ and $O_3$ levels at a 1 km × 1 km grid level. Complex atmospheric processes were addressed using a neural network that modeled nonlinearity and interactions. Spatial correlation was addressed using convolutional layers in the neural network, which aggregate nearby information and can simulate autocorrelation. The neural network was trained for the study period for the United States and tested against 10% left-out monitors. They then used the neural network to produce daily $PM_{2.5}$ levels (Di et al. 2016). Essentially the same approach was used to estimate and validate a model to predict daily $O_3$ concentrations during warm months (April 1 to September 30) (Di et al. 2017b).

***Health Outcomes and Analyses*** Health data for this study were obtained from the Centers for Medicare and Medicaid Services (CMS), after applying through the Research Data Assistance Center (ResDAC) (*www.resdac.org*). The investigators obtained information on all Medicare beneficiaries for the years 2000 through 2012, which represents more than 96% of the U.S. population 65 years of age or older. This is an open cohort where individuals enter when they enroll in Medicare at or after age 65 and stay until death. Individuals with an unverified date of death were excluded. For each beneficiary, the following data were extracted: the date of death (if applicable), age at year of Medicare entry, calendar year of entry, sex, race, ethnicity, ZIP code of residence, and Medicaid eligibility (a proxy for low socioeconomic status (SES); note that these individuals were eligible for both Medicare and Medicaid). Thus, all deaths among Medicare recipients during 2000 to 2012 were captured. In all, the cohort had about 61 million persons, with 460 million person-years of follow-up and 23 million deaths.

Medicare data contain little information about individual-level covariates. Therefore, the investigators also obtained data from the MCBS, which is an annual phone survey of a nationally representative sample of Medicare beneficiaries and contains information on more than 150 potential individual confounders, including data on individual risk factors (e.g., smoking, body mass index [BMI], and income). Information on a sample of more than 57,000 enrollees was obtained for the period 2000 through 2012. Dominici and colleagues also analyzed data for a cohort of ~32,000 beneficiaries from the MCBS-Medicare database, which links data from MCBS interviews with Medicare claims data, and also contains information on confounders (see Di et al 2017c, Supplementary Appendix, Section 5, found in Additional Materials on the HEI website; and Makar et al. 2017). The Commentary Table is a summary of the potential confounders that were used during this study.

The investigators used both cohort and case–crossover designs to analyze the association between exposure to $PM_{2.5}$ and $O_3$ and all-cause mortality in the Medicare cohort from 2000 to 2012. For the cohort study, they performed survival analyses using the Andersen-Gill (AG) method (Andersen and Gill 1982), a variant of the traditional Cox proportional hazards model that incorporates spatiotemporal features by allowing for covariates to vary from year to year. They estimated hazard ratios associated with a 10-μg/m$^3$ increase in $PM_{2.5}$ and a 10-ppb increase in $O_3$ exposure using this model in two-pollutant analyses.

The investigators developed concentration–response curves for air pollution levels and mortality by fitting a log-linear model with thin-plate splines of both pollutants while controlling for all individual and ecological variables that they had used in their main analyses (details in Di et al. 2017c, Supplementary Appendix, Section 7, found in Additional Materials). In view of the objective of this research, they explored the health effects at lower ambient concentrations by conducting separate analyses that included only person-years with $PM_{2.5}$ exposures lower than 12 μg/m$^3$ and $O_3$ exposures lower than 50 ppb.

To assess if any subgroups within the Medicare cohort were at higher or lower risk of mortality associated with air pollution, the investigators fitted the same Cox model as above for certain subgroups (e.g., male vs. female, white vs. black, and Medicaid eligible vs. Medicaid ineligible). To explore the robustness of the results, they performed sensitivity analyses and compared any changes in risk estimates with differences in confounder adjustment and estimation approaches. Finally, since Medicare data do not include information on many important individual-level covariates, the investigators utilized data from the MCBS. Using individual-level data (such as smoking status, BMI, and income) and data on many other covariates from the MCBS, they examined how the lack of adjustment for these risk factors could have affected the risk estimated for the Medicare cohort (Di et al. 2017c, Supplementary Appendix, Section 5, found in Additional Materials ).

For the case–crossover study, the case day was defined as the date of death; the daily exposure to air pollution for the case day was defined as the mean of the ambient concentration on that day and the day before (i.e., mean of lag 0-day and lag −1-day). For each person, they compared daily air pollution concentration on the case day versus daily air pollution exposure on control days, which were chosen (1) on the same day of the week as the case day, to control for potential confounding effect by day of week; (2) before and after the case day to control for time trend; and (3) in the same month as the case day to control for seasonal and subseasonal patterns. They fitted a conditional logistic regression to all pairs of case and matched control days, thus estimating the relative risk of all-cause mortality associated with short-term $PM_{2.5}$ and $O_3$ exposure (Di et al. 2017a).

The investigators controlled for potential residual confounding by weather-related factors by using natural splines of air and dew point temperatures with 3 degrees of freedom. For subgroup analyses, the investigators used information on sex, race, or ethnicity (white, nonwhite, and others), age categories (≤ 69, 70–74, 75–84, and ≥85 years), eligibility for Medicaid, and population density at residence (in quartiles). Subgroup-specific estimates of relative risk and absolute risk difference were obtained by fitting separate conditional logistical regression models to

**Commentary Table.** Characteristics of Potential Confounders and Variables[a]

| Potential Confounder / Model Covariate | Variable Level | Variable Type | Data Source[b] |
|---|---|---|---|
| Age<br>Age at entry | Individual | Categorical (5-year) | Medicare |
| Race<br>White<br>Black<br>Asian<br>Hispanic)<br>Native American | Individual | Binary and continuous (% of population) | Medicare and U.S. Census, ACS |
| Sex<br>Sex | Individual | Binary | Medicare |
| Smoking<br>Ever smoker (%) | Ecological (county to ZIP code) | Proportion | BRFSS (2000–2012) |
| Obesity<br>BMI | Ecological (county to ZIP code) | Continuous | BRFSS (2000–2012) |
| Diet<br>Not included | n/a | n/a | n/a |
| Exercise<br>Not included | n/a | n/a | n/a |
| Socioeconomic status — individual level<br>Medicaid eligibility | Individual | Binary | Medicaid Statistical Information System |
| Socioeconomic status — community level<br>Median household income<br>Median value of housing<br>% owner occupied<br>% below poverty level (age >65)<br>% below high school education (age >65)<br>Population density | Ecological (ZIP code) | Continuous | U.S. Census, ACS |
| Access to health care<br>% with LDL-C<br>% with HgbA1c test<br>% with ≥ 1 visit | Ecological (ZIP code) | Continuous | Dartmouth Atlas of Health Care |
| Meteorological<br>Temperature<br>Relative humidity | Area (32 km × 32 km) | Continuous | North American Regional Reanalysis data |
| Regional dummy variable<br>10 geographical regions with similar $PM_{2.5}$ chemical profile | Regional | Categorical | GEOS-Chem 3D global chemical transport model |

[a] Based on information in Di et al. 2017c, Supplementary Materials (available in Additional Materials on the HEI website).

[b] American Community Survey (ACS); Behavioral Risk Factor Surveillance System (BRFSS); n/a = not applicable.

the data for each subgroup. To test for statistically significant differences in estimated relative risk and the absolute risk difference between categories within each subgroup (e.g., male vs. female), they used a two-sample test, based on the point estimate and standard error. They explored the health effects at lower levels of exposure by performing subanalyses with cases restricted to those occurring on days with daily air pollution concentrations below 25 μg/m$^3$ for $PM_{2.5}$ and 60 ppb for $O_3$.

**Key Findings Reported by the Investigators**

***Exposure Assessment*** Dominici and colleagues reported overall good performance for the $PM_{2.5}$ prediction model, with $R^2$ of 0.84 (range 0.78 to 0.88) (Di et al. 2016). During the course of the study, annual $PM_{2.5}$ concentrations ranged from 6.2 to 15.6 μg/m$^3$ (5th and 95th percentiles, respectively). The average annual $PM_{2.5}$ concentration was 11.0 μg/m$^3$ during the study period, 2000–2012. The model performed better in the eastern and central United States and less well in the western United States (Di et al. 2016, Supplementary Appendix Table S4). The highest $PM_{2.5}$ concentrations were predicted to be in the eastern and southeastern United States and in parts of California. The $R^2$ values were lower after 2010, apparently as $PM_{2.5}$ ambient levels decreased in the eastern United States ($R^2$ in 2000 and 2001 of 0.86 and 0.84 vs. 0.81 and 0.74 in 2011 and 2012). In addition, the model performed better during the summer — when $PM_{2.5}$ levels often tend to peak — followed by autumn, spring, and winter (mean $R^2$ values of 0.88, 0.84, 0.84, and 0.80, respectively) (Di et al. 2016, supplementary materials).

The $O_3$ prediction model performed similarly well, with an overall $R^2$ of 0.80 (Di et al. 2017b).* The average of 8-hour, daily, warm-season $O_3$ concentrations across the country during the study period ranged from 36 to 56 ppb (5th and 95th percentiles, respectively), with an average of 46.3 ppb during the study period. The investigators found a west–east gradient in the $O_3$ level, with the model performance being the best in the middle Atlantic, south Atlantic, east north Central, west south Central, and the Pacific States regions. Model performance was not affected by the year, so no year-to-year trend in model fit was observed. Seasonal trends in model performance were also apparent, with the $R^2$ being highest in the autumn, followed by summer, spring, and winter ($R^2$ values of 0.75, 0.71, 0.68, and 0.67, respectively). $O_3$ concentrations were the highest in the Mountain region and in California and were lower in the eastern states. Annual $PM_{2.5}$ and warm-season $O_3$ concentrations were only weakly correlated, with a Pearson correlation coefficient of 0.24.

***The Cohort Study*** The 2000–2012 cohort of Medicare beneficiaries, with about 61 million enrollees and 23 million deaths, provided a very large population to study association with the long-term exposure to ambient air pollution, including at concentrations below the current NAAQS for both $PM_{2.5}$ and $O_3$. In two-pollutant analyses, Dominici and colleagues report a 7.3% (95% confidence interval [CI], 7.1% to 7.5%) higher risk of all-cause mortality for each 10-μg/m$^3$ increase in annual average $PM_{2.5}$ concentrations and a 1.1% (CI, 1.0% to 1.2%) higher risk of mortality for each 10-ppb increase in annual average $O_3$ concentration in the warm season (Di et al. 2017c). At low concentrations — less than 12 μg/m$^3$ for $PM_{2.5}$ and less than 50 ppb for $O_3$ — the risk was 13.6% (CI, 13.1% to 14.1%) for $PM_{2.5}$ and 1.0% (CI, 0.9% to 1.1%) for $O_3$. Thin-plate-spline regression analysis for concentration–response relationship in two-pollutant models produced almost linear curves, with no suggestion of a threshold down to 5 μg/m$^3$ of PM and 30 ppb of $O_3$ (see Figure 7 in the Investigators' Report and Supplementary Appendix, Section 5 of Di et al. 2017c, found in Additional Materials).

In subgroup analyses for $PM_{2.5}$, the investigators found larger estimates of effect among males and among Hispanics, Asians, and particularly African Americans compared with whites. Individuals with low SES, as indicated by eligibility for Medicaid, appear to have a slightly higher risk per unit of air pollution (Di et al. 2017c, Supplementary Appendix, Table S3, found in Additional Materials). For long-term $O_3$ exposure, the subgroup analysis showed that the effect estimates were higher for Medicaid-eligible enrollees and slightly higher for whites, but these analyses also produced hazard ratios of less than 1 for certain subgroups, including Hispanics and Asians, and particularly for Native Americans, than the overall population.

***The Case–Crossover Study*** The case–crossover analyses comprised more than 22 million deaths (case days) and more than 76 million control days among Medicare enrollees between 2000 and 2012, again a very large population. For short-term exposures, the investigators observed a 1.05% (95% CI, 0.95% to 1.15%) greater risk of mortality in two-pollutant models for a 10-μg/m$^3$ increase in $PM_{2.5}$ concentrations, and 0.51% (CI, 0.41% to 0.61%) for a 10-ppb increase in average 8-hour warm-season $O_3$ concentration (pollutant levels were averaged over the current and previous day) (Di et al. 2017a). At low concentrations (<25 μg/m$^3$ of $PM_{2.5}$ and <60 ppb of $O_3$), the associations remained elevated for both $PM_{2.5}$ and $O_3$, with relative risk

*Note that this publication reports the $R^2$ as 0.76 [range 0.74 to 0.80]; presumably this is because the authors improved the model after publication of the earlier article (Di et al. 2017b).

increases (RRI) of 1.61% (95% CI, 1.48% to 1.74%) and 0.58% (CI, 0.46% to 0.70%), respectively. In exposure–response curves, the relative risk increase rises sharply for both pollutants at a relatively low concentrations and then levels out at higher concentrations (see Figure 8 in the Investigators' Report).

In subgroup analyses for the case–crossover study, significant effect modifications were reported for several variables. For $PM_{2.5}$, the investigators observed higher mortality risk for females and individuals who were older (age >70 years), black, or eligible for Medicaid (i.e., lower SES) (Di et al. 2017a, Figure 3). For $O_3$, there was much less contrast between groups, except for age where the older group had a significantly higher risk of mortality (0.69 for ≤69 years vs. 1.83 for ≥85 years) (Di et al. 2017a, Figure 4).

## REVIEW PANEL EVALUATION

This report by Dominici and colleagues summarizes an impressive amount of work completed in the first part of this project. There are several particularly strong aspects of this work: The investigators amassed an extremely large cohort by compiling a very large amount of data on health and related factors across the continental United States from national databases (Medicare and others). They also estimated U.S.-wide air pollution concentrations at high spatial resolution (with 1 km × 1 km grids) and temporal resolution (enabling daily averages). Finally, they developed and applied state-of-the-art statistical techniques to the assessment of health effects of low levels of air pollution.

The Panel's evaluation of this report was made challenging by the nature of the report submitted; the Phase 1 study report was largely compiled from the initial published reports, as well as from some as-yet-unpublished methodological work. The Panel has therefore expanded the focus of this review to include — in addition to the Investigators' Report — some of this recently published work (in particular, Di et al. 2017a and 2017c; the latter can be found in Additional Materials on the HEI website). Di and colleagues have provided many details in the supplemental materials of the two publications. Additionally, the Panel communicated with the investigators during the course of the review. In response to comments from the Panel, the investigators added an additional discussion to the Investigators' Report of limitations and plans for future work.

As stated earlier, the Phase 1 report represents a snapshot of the ambitious work undertaken by the investigators. Much work, including further development of causal methods that would properly allow for the complexities in the design of the studies and nature of the data is currently ongoing. As a whole, this work is likely to represent an important contribution to the literature on the health impacts of air pollution on older adults in the United States. The current report represents a high-quality and thorough investigation of some of the most challenging problems in environmental health.

### EXPOSURE ASSESSMENT

The use of large, diverse, and existing data sets to generate estimates of $PM_{2.5}$ and $O_3$ concentrations on a 1 km × 1 km national grid for the entire continental United States (~8 million km$^2$) is impressive, both in terms of the vast amount and variety of data assembled and the tremendous computational requirements for the analysis (Di et al. 2016, 2017b). The methods developed should prove valuable to researchers studying air pollution and health, especially because the investigators have made efforts to make their modeling approach publicly available for others to use.

Using a hybrid model, Dominici and colleagues estimated $PM_{2.5}$ and $O_3$ concentrations in areas where monitors are sparse, allowing estimates for a larger number of ZIP codes, and thus individuals, to be included within the analyses. However, as with any exposure assessment, it is critical to consider the potential for prediction errors, particularly those that may be systematic, and the implications for the interpretation of the associated epidemiological results. Specific strengths and weaknesses of the exposure assessment are discussed below.

First, Dominici and colleagues used U.S. EPA ground-monitoring data to cross-validate their exposure models. Regional and monthly dummy variables were used in the model in an attempt to account for regional and daily variations related to differences in meteorology and aerosol composition (Di et al. 2016). However, both geographical and temporal variability in the errors of the concentration estimates remained in the final estimates for both $PM_{2.5}$ and $O_3$, as discussed earlier. The source(s) and impact of such variability are not understood and deserve attention.

Second, because U.S. EPA monitors are located for the purpose of compliance with NAAQS, they are generally placed in the more populated, urban areas where air pollution levels are higher. Consequently, the rural areas — where population density is lower and lower pollutant concentrations are found — are not as intensively monitored, and the model may be more prone to larger error in such areas. Further, rural ZIP codes generally cover much larger areas than urban ZIP codes. The potential impact of this on exposure estimates can be seen, for example, in the lower $R^2$ values for $PM_{2.5}$ estimates for the Mountain region (see Di et al. 2016, Figure 1). Although only about 25% of the U.S. population lives 20 km or farther away

from the nearest monitoring station — primarily in rural areas — these are the residents of potentially greatest interest, in the context of this study, because of their lower exposures to pollutants; therefore, the nature, size, and potential impact of these errors are important to understand.

Third, based on the relationship between the model predictions and observed $PM_{2.5}$ and $O_3$ levels (see Di et al. 2016, Figure 5, and Di et al. 2017b, Figure 6), it appears that the model may systematically underpredict concentrations (i.e., produce predictions below the 1:1 line). The impact of such underprediction may be important and should be explored in future research. (Both curves show much greater uncertainty at high pollutant concentrations, but few people live in such high-concentration areas.)

Finally, though the Panel recognizes that the investigators were building a very large, national-scale model with a resolution of 1 km × 1 km, the model does not capture fine scale variability in ambient concentrations. Thus, the model at this scale does not capture local, high gradients in concentrations, such as those along roadways or near major point sources. The exposure estimation for those living in the vicinity of such areas is probably underestimated (for $PM_{2.5}$) or overestimated (for $O_3$, because of local area scavenging), though typically $PM_{2.5}$ and $O_3$ levels tend to be more uniform at urban and regional scales than pollutants such as $NO_2$, which exhibit higher spatial variation.

Using input from disparate sources to develop a model at the national scale, with a 1 km × 1 km resolution, is a major accomplishment, though the model has its limitations. The Panel has noted that the investigators are taking steps to improve their models — by using three different machine-learning models that complement one another — and extending their models to the year 2016. In addition to updating the $PM_{2.5}$ and $O_3$ models, they are also modeling $NO_2$ (see the "Next Steps" section in the Investigators' Report). The application of the improved and additional models for epidemiological analysis should prove useful and may shed greater light on the exposure–response relationships described in these two studies.

## HEALTH EFFECTS: COHORT STUDY*

Using the massive database of all Medicare recipients during 2000 to 2012, and combining it with the equally large exposure predictions, Dominici and colleagues have performed a study with unsurpassed power to investigate the association between all-cause mortality and long-term exposure to a range of $PM_{2.5}$ and $O_3$ levels. That they observed an association between annual average concentrations and mortality at higher concentrations was not the new finding of this work, but the findings at low levels, particularly at levels below the current NAAQSs, are novel and potentially important.

The greatest challenge to the internal validity of this study, as for all observational studies, is the potential for confounding, which can bias the results. To address such concerns, the investigators performed numerous analyses with some 20 covariates (Commentary Table) (for details, see Di et al. 2017c, Supplementary Appendix, available in Additional Materials on the HEI website). They also utilized findings from a smaller Medicare cohort that had a much richer set of potential confounding variables to assess the likely impact of having only a limited number of covariates in the main cohort analysis. To allow for the effects of time-dependent covariates that are known to vary from year to year, the investigators utilized a variant of the classic Cox proportional hazards model — the AG formulation (Andersen and Gill 1982).

However, this is a complex study. Health and personal characteristics are available for individuals, but ambient air pollutant exposure is estimated at the ZIP code level (averaged from the 1 km × 1 km spatial scale of the prediction model). Additionally, the ZIP code scale is the smallest spatial unit at which individual residential and other covariate information is available. These factors, coupled with confounders that can act at the level of the individual, the community, or the regional environment, result in a complex hybrid model. These issues pose important challenges for the next phase of the work planned by the investigators, and the causal inference methods under development will need to focus on these challenges. Based on the current results, the Panel offers the following comments.

### Temporal Confounding

Although the investigators have used the AG formulation of the Cox proportional hazards model to better represent time-dependent variables, the Panel's biggest concern relates to the problem of the potential for temporal confounding, with both the overall nonaccidental mortality and the $PM_{2.5}$ levels declining steadily over the period of the study, 2000 to 2012. Since this is an open cohort (new individuals enter the cohort as they enroll for Medicare), age — which is controlled in the analyses — is not necessarily strongly correlated with calendar time. As a result, confounding can occur due to the contributions of both age and calendar time. In this study, however, there was no adjustment for calendar time, and age was included in the models using five-year categories. Although the Panel understands that there are computational challenges to

* A copy of the article by Di and colleagues (2017c), along with its Supplementary Appendix, is available in Additional Materials on the HEI website, with permission of the publisher.

including a finer resolution for age, the supplementary materials accompanying the article by Di and colleagues (2017c, Supplementary Appendix, found in Additional Materials) show that the hazard ratio drops from 1.07 when a five-year age category is used to 1.05 when it is replaced with a three-year age category. This suggests that this question is unresolved and deserves more attention. Similarly, the Panel acknowledges that disentangling secular trends from any possible causal effect of $PM_{2.5}$ on mortality can be challenging and that including year in the models may over-adjust for exposure by removing true variability over time. Regardless, the inability to adequately account for potential bias due to temporal trends introduces a large element of uncertainty in interpreting the study's findings to date.

In summary, the Panel believes that, without accounting for confounding by time, the findings of the long-term exposure study should be viewed with caution. The Panel is glad to note that the investigators acknowledge these limitations and looks forward to the development of appropriate causal inference techniques and their application to the Medicare data set.

### Potential for Residual Confounding

Dominici and colleagues have performed various analyses to explore the possible sources of residual confounding; however, as discussed below, the Panel identified several areas with a potential for residual confounding in the cohort study that need resolution.

***Subgroup Differences*** Some results from the subgroup analyses are puzzling, as acknowledged by the investigators' team: for example, the dramatically higher effect of $PM_{2.5}$ in African Americans and the negative (protective) effects of $O_3$ for Native Americans, Hispanics, and Asians. It is possible that these observations reflect true intergroup differences; alternatively, it may be more likely that the subgroup designation serves as a surrogate for other risk factors not fully considered, resulting in residual confounding. Model misspecification is another possibility.

***Spatial Differences*** Another issue here is the different scales at which the exposure and health models operate. The Panel has concerns about the impact of the likely exposure misclassification and confounding related to the spatial differences between aggregated summaries of exposures (1 km × 1 km) and residential locations (at the ZIP code level). The Panel appreciates that the health and covariate data are available only as aggregated ZIP-code-level values and looks forward to the results of the planned analyses in the Final Phase 2 report, in which the investigators plan to explore exposure measurement error in the health analyses using a causal-inference framework. The Panel is also aware that the exposure measurement error correction methodology for spatially varying pollutants in multipollutant research is in its infancy (e.g., Bergen et al. 2016; Szpiro and Paciorek 2013), and even more so in the causal inference framework — as duly acknowledged by the investigators — so it is not surprising that Dominici and colleagues did not yet address this in their extensive work.

***Smoking, Diet, and Exercise*** Data on individual health-related behaviors, which are well known for affecting survival time, were available only at the ZIP code level. Some of the information — for example, binary variables for smoking behavior — does not capture the full extent of the variability in the behaviors. The Panel understands the complexity of these factors and the difficulty in finding data on a national scale to include in the model. However, some of these behaviors are known to vary regionally, and it is conceivable that one or the other is geographically correlated with $PM_{2.5}$ or $O_3$. For example, residents of the southeast have some of the highest $PM_{2.5}$ exposure levels and also have the highest rates of obesity in the United States (Centers for Disease Control and Prevention 2019).

***Socioeconomic Status (SES)*** The investigators appropriately consider a variety of measures of SES at the individual and community level; these measures represent a number of factors that might increase mortality risk. They include baseline health status, diet, exercise, psychosocial stressors, risk of violent crime, risk of exposure to chemical and microbial contaminants, and access to medical care. The only measure of individual-level SES available for the entire cohort is Medicaid eligibility status, which produced a fairly small difference in hazard ratios (eligible 1.080 vs. noneligible 1.075) (Di et al. 2017c, Supplementary Appendix, Table S3, found in Additional Materials). To the extent that Medicaid eligibility is an imperfect measure of the relevant aspects of SES, additional sources for residual confounding may be present.

The issues with individual-level SES notwithstanding, neighborhood SES factors — not individual SES — have been reported to be the more important confounders affecting air-pollution-associated mortality (Hajat et al. 2013; Makar et al. 2017). The investigators used four different and reasonable measures of community SES: median household income, median housing price, percentage below poverty level, percentage of homes owner-occupied, and percentage below high school education. They report that none of these had a significant correlation with the observed outcomes (Di et al. 2017c, Supplementary Appendix, found in Additional Materials). The adjustment for neighborhood

SES partly addressed concerns about the limitations of accounting only for individual-level SES, so the inclusion of these additional SES-related factors in the analyses is a strength of this study.

***Cohort vs. Case–Crossover Analysis*** The Panel was not persuaded by the claim made in the "Limitations" section of the Investigators' Report that estimating effects in both the case–crossover and cohort analyses provides some assurance against confounding. At best, this provides evidence that PM does affect mortality. However, the nature of the confounders and the effects being estimated (Eftim and Dominici 2005; Künzli et al. 2001; Rabl 2003) are so different that consistency of findings across the two designs provides essentially no assurance against confounding.

### Precision of Effect Estimates

Another issue to consider is related to one of the major strengths of the study: the extremely large number of observations. Statistical methods have been developed in light of the limitation that an entire population is generally not available for study, so one must study a sample of the population. Statistical methods related to the estimation of different parameters (e.g., bias) and related inferences (e.g., CIs and *P* values) are based on the premise that study participants are sampled from a larger existing or theoretical population. The Dominici study represents a growing trend in the new "Big Data" era in that the *entire* Medicare population of more than 60 million individuals has been studied. Though this enormous sample gave the study unprecedented power to investigate effects, it also raises questions about interpretation of the very narrow CIs and other comparative statistics reported for the cohort. In this situation, bias and model misspecification are likely to be more critical concerns than sampling variability. Because the impact of bias and model misspecification is not reflected in standard uncertainty measures, one should be cautious about overinterpreting the narrow CIs, as the interval width is driven by the very large sample size (see Meng 2018), and the Panel's comments and concerns about the potential impacts of bias and of unmeasured confounding should be viewed in this broader context.

### Other Pollutants

Dominici and colleagues have looked at mortality associations with both $PM_{2.5}$ and $O_3$; this is another strength of this study. However, other pollutants may also confound the associations between $PM_{2.5}$ and $O_3$ and mortality. The Panel looks forward to the results of ongoing work to strengthen the current exposure models (e.g., using data from the IMPROVE network) and to the inclusion of a $NO_2$ model and possibly PM composition.

## HEALTH EFFECTS: CASE–CROSSOVER STUDY*

Long-term studies are typically considered more important for risk and burden assessments as well as policy making, though short-term studies have played an important role as well in the development of air pollution epidemiology science and its applications to policy. The second epidemiology study in this report uses a case–crossover design — a variant of the time-series design — with the Medicare population to evaluate short-term effects of air pollution exposure. One advantage that this design has over the study of long-term health effects is that it is based on variation in exposure and mortality over short periods of time (days, rather than years). Therefore, only confounding factors that vary over short periods of time, such as weather, are of potential concern, rather than the much larger array of potential confounders that either do not vary with time or have long-term trends. On the other hand, by design time-series analyses address only the immediate impact of air pollution on mortality rather than the role of pollutants in the development of chronic morbidity and subsequent mortality. The two designs are both valuable analyses but address different sets of covariates and different questions.

Dominici and colleagues report an RRI of 1.05% (95% CI, 0.95%–1.15%) and 0.51% (0.41%–0.61%) in daily mortality rate, respectively, for each 10-$\mu g/m^3$ increase in $PM_{2.5}$ and 10-ppb increase in $O_3$ (Di et al. 2017a). The concentration–response analysis for $PM_{2.5}$ and $O_3$ suggests a nonlinear relationship, with a steeper slope at low concentrations and flattening at higher concentrations (see Figure 8, Investigators' Report). The investigators have provided the effect estimates for concentrations below 25 $\mu g/m^3$ for $PM_{2.5}$ and 60 ppb for $O_3$, which are the concentrations of interest for this study and below which the curves are linear.

In addition to the main findings, the authors have investigated effect modification for a range of variables. For example, they report that the mortality effect of short-term exposure to $PM_{2.5}$ is greater in women than in men (RRI of 1.20 vs. 0.86; Di et al. 2017a, Figure 3), in contrast to the finding in their cohort study. There is again a clear age effect, particularly for $O_3$ exposure, with older individuals having a significantly higher RRI. The effects in other subgroup analyses were generally not significant, except for Medicaid eligibility. An important group of time-varying covariates not fully included in these models is copollutants, such as $NO_2$.

* The paper by Di and colleagues (2017a) may be viewed at *https://jamanetwork.com/journals/jama/fullarticle/2667069* (courtesy of JAMA).

## SHARING OF MODELS AND DATA

From the inception of this project, the Panel was glad to note that the investigators planned to make available their methods, models, and data with other investigators. To facilitate this, they have posted their data, workflows, and analyses to a secure high-performance computing cluster with the objective of developing an open science research data platform (*https://osf.io/2cg6v/*). Additionally, the codes and software tools are available from the location *https://github.com/NSAPH/airpred*. The investigators' efforts in this area — to make both models and data available — will continue.

***Model*** With an interest in making their model widely available, the investigators developed a flexible R package so that interested environmental health scientists may design and train spatiotemporal models that can predict air pollutants, including $PM_{2.5}$ (Sabath et al. 2018). This is accomplished via neural network tools to produce exposure predictions with high spatial (1 km × 1 km grids) and temporal (enabling daily averages) resolution. The adoption of the R platform — as opposed to the less user-friendly MATLAB platform used by Di and colleagues (2016, 2017b) in their work and on which the airpred package is based — is a major strength since it is likely to promote wider use of the modeling tools by other environmental health researchers. The use of an open source big data platform (H2O) for better computational efficiency and hence scalability is also another major strength. The R package airpred has the flexibility to allow specification of "different types of neural networks, with different parameters, or even to perform ensemble modelling."

***Data*** In their research, Dominici and colleagues have made use of a great deal of data generated by public sources, including the National Aeronautics and Space Administration, the U.S. EPA, and the CMS; data from most of these sources are in the public domain and readily available to anyone. The one exception is the Medicare data, which the investigators are prohibited from sharing under terms of access of the data from CMS. However, these data are available from ResDAC; following an application, payment of fees, and commitments to protect personal data and other requirements, any investigator can access this information. For their part, the investigators have developed codes and packages to allow others to link the curated exposure and confounder data to the Medicare data, and they are prepared to provide the appropriate code and instructions.

The investigators' commitment to making their data and methods publicly available is noteworthy and welcomed; it enables other investigators to access the data, to test different approaches to the analysis, and to move the science forward.

## CAUSAL INFERENCE MODELS

In addition to the research discussed earlier, Dominici and colleagues note in their report the importance of, and are devoting significant effort to, the development and extension of methods for causal analysis, an area where they have considerable expertise. This work is increasingly important because of the challenges in accounting for and analyzing all the covariates in the preceding analyses of observational data, and they have made some strides in this direction. The Investigators' Phase 1 report includes only a relatively brief summary of this work — understandably still in progress — so interested readers are advised to go to the referenced papers, which the HEI Review Panel reviewed for details (Wu et al. 2019; Papadogeorgou and Dominici, forthcoming publication; see also Makar et al. 2017). The causal modeling work so far has taken two different directions, described and discussed as follows:

***Regression Calibration*** In the first method, the investigators have developed causal inference approaches based on regression calibration (RC) to account for exposure prediction errors (Wu et al. 2019). A generalized propensity score approach is utilized for confounding adjustment along with the RC to address exposure measurement error. The development of approaches to handle exposure measurement error and confounding in the causal setting would be an important advance given that environmental exposures are almost always prone to error (whether obtained through direct monitoring or via exposure modeling) and confounding bias is a persistent concern in observational studies. Hence, this research is potentially innovative and significant.

However, in its current form this work has several potential limitations that might lower its effectiveness in the setting of ambient air-pollution-related models for which the method is primarily intended. For example:

- It is not immediately clear whether $PM_{2.5}$ concentrations monitored inside a grid cell are error-free exposures for that grid cell, as the investigators assume. Ideally, one would use more flexible methods to allow for the possibility of such errors.
- Given that the internal validation study for the RC step is based on data from monitored locations (likely higher pollution locations compared with nonmonitored locations), it is very likely this sample will be systematically different from the main study sample. Specifically, this situation might violate some of the

assumptions such as "transportability" (i.e., the relationship between true (X) and error-prone (W) exposures, conditional on covariates (D), would be the same in the validation study where X is observed and in the main study in which it is not). The extensive simulation study does not appear to address this issue. Moreover, it doesn't grapple with the complexities of air pollution exposure, the impact of the complicated exposure modeling that produces the exposure estimates and their associated measurement error, or the complicated spatial structures of exposure, outcome, and covariates. This raises questions about the usefulness of this method in the real context of the epidemiological analyses performed in this study.

- The investigators focus on settings for which they have a continuous monitoring data (with error), yet they convert the continuous values into a categorical scale, likely because of technical challenges. It is important that future work attempt to develop similar methods, but for continuous exposure, which is more useful for the ultimate intended application.

***Local Exposure–Response Confounding Adjustment*** In the second method, Dominici and colleagues have developed a new Bayesian causal approach known as local exposure–response confounding adjustment (LERCA), to estimate exposure–response curves accounting for confounding bias under low exposure settings (Papadogeorgou and Dominici, forthcoming publication). This work recognizes and addresses the potentially differential effects of confounders at different levels of exposure and also the model uncertainty associated with confounder selection. The development of an R package to implement the approach, the simulation study to assess performance, and the application to a large data set are some of the notable strengths.

Developing a preliminary directed acyclic graph would be informative in the design and interpretation of models such as the LERCA model. With that as a starting point — a Bayesian prior in essence — the investigation can use the models to inform our understanding of these relationships and modify the underlying conceptual model in what will likely be an ongoing, iterative process. The LERCA model has great potential as a useful new statistical tool, but it is not entirely clear what public health concerns about the data motivated the investigators to develop this specific model, and why differential confounding at different levels of exposure would be expected. It seems at least as likely that confounding might differ for different levels of the confounders given that, unlike the presumed effects of $PM_{2.5}$, these are often not directly causal or have nonmonotonic relationships. Housing value, for example, does not directly cause disease or hospitalization and, as a surrogate for other factors with strong regional variation, is likely to have a complex relationship with this outcome. Temperature has a U-shaped relationship with biological stress and its role as a confounder is likely to vary strongly with temperature level.

A common limitation of both these approaches stems from the different spatial refinement of the data, in other words, between ambient air pollution concentration estimates (at 1 $km^2$, which are then aggregated to the ZIP code level) and data on health and other covariates (available at the ZIP code level). Neither of the new techniques appears to try to deal with this complexity. This continues to raise questions of exposure error and confounding that potentially affect the primary analyses, a limitation which the investigators specifically note as well. As this work proceeds, a clarification and better understanding of these issues and their impact would be important to the successful completion of the full analyses in this project.

Fully exploring and explaining the observed relationships between air pollution and mortality will necessarily be an iterative process, and the Panel was glad to learn that the investigators plan to spend considerable efforts in this direction in their future work. However, although promising, the current state of methods development is only the first step and may not be a match for the complexity in study design (particularly its hybrid nature), exposure measurement error, and modeling structure of the analysis that has been published using traditional regression-based methods. The investigators have also indicated their plan to develop less computationally intensive methods for analyzing the entire air pollution and health database; it will be informative if the causal models can be applied to those large data sets using these more efficient methods. Given that each of these models relies on assumptions (e.g., accurate measurement of confounders and their full and appropriate specification) to make them mathematically tractable, it is important that the potential impact of these assumptions be explicitly and carefully considered in any interpretation of results as these methods are applied to the larger data sets.

## CONCLUSIONS OF THE PANEL'S EVALUATION OF THE PHASE 1 INITIAL ANALYSES

Dominici and colleagues have conducted an extensive and innovative set of initial analyses in these extraordinarily large air pollution and health data sets. They have conducted two distinct types of analyses: a cohort-based analysis of long-term exposures and a case–crossover-based analysis of short-term exposures. They report positive

associations of both $PM_{2.5}$ and $O_3$ with all-cause mortality, with associations extending to the lowest concentrations and with little evidence of a threshold in these initial analyses. These findings met the criteria for statistical significance, although, as noted earlier, it is important to not overinterpret the statistical robustness of results derived from such a very large data set (Meng 2018). To their credit, the investigators also conducted a range of sensitivity analyses, and they also attempted to control for many key potential confounders in their cohort study that were available in the larger data set, as well as in the smaller Medicare Beneficiaries Survey; in all the analyses to date, these further analyses did not meaningfully change the initial findings of associations.

These initial analyses do make a valuable contribution to the literature; however, while these analyses are thorough and extensive, there is still more work to be done to understand fully the importance of the findings. The investigators are well aware of many of the issues brought up in this commentary and acknowledge them, both in the "Introduction" section and in the "Limitations" section of their Investigators' Report. The Panel was also glad to note that the investigators are proceeding, in completing their project for HEI, with additional analyses and are also developing a less computationally intensive analytic approach in the full cohort. As noted in their discussion of limitations, there are several important analyses that will need to be undertaken before firmer conclusions can be drawn from these studies. Key among important further analyses are:

- *Further analyses of measured and unmeasured confounders*: While the investigators applied the data available on confounders and adopted the AG approach, which offered some advantage over the traditional Cox proportional hazards method in addressing some confounding due to time-dependent covariates, significant questions remain. The Panel discussed these in some detail and would like to highlight here some that will need to be further analyzed:
  - *Potential confounding by time trends*: With air pollution and death rates having declined over the course of the cohort analyses, the degree to which potential confounding of the results may have been affected by time was not adequately analyzed in these initial analyses. The investigators have acknowledged this and indicated they plan to further analyze this important question, by conducting sensitivity analyses using a newly developed causal inference approach.
  - *Potential confounding by other pollutants*: Other air pollutants may also confound the estimates of exposure and effects seen in these analyses. The investigators did test the potential influence of $O_3$ exposure on PM effects — and vice versa — which was an important strength of their work. In addition, they are now developing an exposure model for $NO_2$ that will allow adjustment for this pollutant in their final models.
  - *Analysis of spatial confounding and geographical patterns:* As the Panel noted earlier and the investigators acknowledge, the current analyses are conducted at a national level, without fully addressing potentially significant geographical variation in air pollution (both concentrations and composition) and the underlying health status (i.e., variability in $PM_{2.5}$ levels and substantial diversity in levels of obesity across different regions).
- *Spatial scales and the hybrid model:* There are several spatial scales of the many variables in both the long-term and short-term analyses, and the resulting complex quasi-ecological (hybrid) nature of these analyses make it difficult to fully understand the implications of these. For example, as the Panel noted earlier — and despite the considerable efforts by the investigators to estimate exposure accurately — there are some potential sources of error that may affect results. These include, though may not be limited to, (1) potential underestimation of rural concentration levels due to the relative paucity of ground monitors for evaluation and training in those areas; and (2) the potential differences between exposures estimated at a 1-$km^2$ grid but then applied to health data at the ZIP code level. Although it may not be possible to fully eliminate exposure error from an observational study such as this, the investigators will greatly enhance their final efforts by making every effort to quantify these errors and ideally to account for them in the health analyses.
- *Development, testing, and application of causal inference methods in the full population:* As noted earlier, these analyses would benefit from rigorous application of causal inference methods to the full cohort. To their credit, the investigators have taken initial steps toward developing two such methods and continue to work on them. Properly developed and applied, these methods can also address concerns about residual confounding. The Panel has noted some important questions about these and recommends that the methods be fully evaluated and then applied.

The investigators are to be congratulated for a set of extensive and creative analyses conducted in the largest air pollution and health database to date. While initial conclusions may be drawn from these first analyses, the Panel will wait for the planned extensive further analyses

to be completed before reaching full conclusions on the air pollution and public health implications of this important research.

## ACKNOWLEDGMENTS

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# ABBREVIATIONS AND OTHER TERMS

| | |
|---|---|
| AG | Andersen Gill |
| AOD | aerosol optical depth |
| AQS | air quality system |
| BMI | body mass index |
| CASAC | Clean Air Scientific Advisory Committee |
| CI | confidence interval |
| CMS | Centers for Medicare and Medicaid Services |
| CTM | chemical transport model |
| df | degrees of freedom |
| ER | exposure–response |
| GEE | generalized estimating equation |
| GEOS-Chem | Goddard Earth Observing System (chemical transport model) |
| GPS | generalized propensity score |
| IPTW | inverse probability treatment weighting |
| LERCA | local exposure–response confounding adjustment |
| MCBS | Medicare Current Beneficiary Survey |
| MODIS | moderate resolution imaging spectro-radiometer |
| NAAQS | National Ambient Air Quality Standards |
| NASA | National Aeronautics and Space Administration |
| NDVI | normalized difference vegetation index |
| $NO_2$ | nitrogen dioxide |
| NOAA | National Oceanic and Atmospheric Administration (U.S.) |
| $NO_x$ | nitrogen oxides |
| $O_3$ | ozone |
| OMI | ozone monitoring instrument |
| PM | particulate matter |
| $PM_{2.5}$ | particulate matter $\leq 2.5$ µm in aerodynamic diameter |
| RC | regression calibration |
| RC-GPS | regression calibration-generalized propensity score |
| ResDAC | Research Data Assistance Center |
| RR | relative risk |
| RRI | relative risk increase |
| SES | socioeconomic status |
| U.S. CAA | U.S. Clean Air Act |
| U.S. EPA | U.S. Environmental Protection Agency |
| VOC | volatile organic compound |

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RESEARCH
REPORT

Number 200
November 2019

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/15/2021 10:05:27 PM
**To**: Campbell, Ann [Campbell.Ann@epa.gov]
**Subject**: CSAPR Update Action Memo_031521.doc
**Attachments**: CSAPR Update Action Memo_031521.doc

Appointment

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 3/3/2021 5:15:39 PM
**To**: Mercado Violand, Fernando [MercadoViland.Fernando@epa.gov]

**Subject**: Accepted: Climate Cluster Happy Hour with Secretary of Energy Jennifer Granholm

**Start**: 3/5/2021 11:00:00 PM
**End**: 3/6/2021

**Recurrence**: (none)

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/4/2021 2:16:39 AM
**To**: Dunham, Sarah [Dunham.Sarah@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]
**Subject**: Feb 3 2021 Light-duty Vehicle Options Paper_revised per OAR comments_clean.docx
**Attachments**: Feb 3 2021 Light-duty Vehicle Options Paper_revised per OAR comments_clean.docx

This looks good to me. I made a comment on the first page that we should resolve and once we do we can send it to Dan. Thanks.

Message

**From**: Goffman, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23474D598E8D4EDFA9214A5991F2935B-GOFFMAN, JO]
**Sent**: 2/12/2021 12:40:12 AM
**To**: Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Grundler, Christopher [grundler.christopher@epa.gov]
**CC**: Carbonell, Tomas [Carbonell.Tomas@epa.gov]; Nunez, Alejandra [Nunez.Alejandra@epa.gov]
**Subject**: RE: Heads Up

Thanks to you both for your vigilance and action. Really appreciate it. And, no worries. Have a good evening.

Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency

**From:** Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>
**Sent:** Thursday, February 11, 2021 7:34 PM
**To:** Grundler, Christopher <grundler.christopher@epa.gov>
**Cc:** Goffman, Joseph <Goffman.Joseph@epa.gov>; Carbonell, Tomas <Carbonell.Tomas@epa.gov>; Nunez, Alejandra <Nunez.Alejandra@epa.gov>
**Subject:** Re: Heads Up

Thank you for taking care of this so quickly Chris. Your folks went above and beyond in cleaning everything up. Not a big slip up but always good to have an abundance of caution.

On Feb 11, 2021, at 6:42 PM, Grundler, Christopher <grundler.christopher@epa.gov> wrote:

**Ex. 5 Deliberative Process (DP)**

Chris

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–

Christopher Grundler, Director
Office of Atmospheric Programs
U.S. Environmental Protection Agency
202.343.9140 (o)
734.645.5221 (m)