Message

Sent: 4/2/2019 4:51:10 PM
To: Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]
CC: Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]
Subject: RE: "If I were still working at the EPA, I would resign"

Fact check below – Copied Schwab to review yellow highlighting on 10/2017 FACA memo

1. "Last week, the Environmental Protection Agency's Clean Air Scientific Advisory Committee met via teleconference to devise a new standard for airborne particle pollution."

Deliberative Process / Ex. 5

2. "Congress established this committee in 1977 to provide unbiased external scientific advice on air-pollutant standards, which are revisited every five years. Congress requires the committee to have seven members, including one from a state agency. But it soon became clear that a seven-member committee would not have sufficient in-depth expertise to make a science-based recommendation. Accordingly, for more than 40 years, the committee has drawn on the expertise of external advisory subcommittees established for each pollutant of concern."

Deliberative Process / Ex. 5 g on

Deliberative Process / Ex. 5 The full line up: Dr. Anthony (Tony) Cox, Cox Associates

Deliberative Process / Ex. 5

3. "That is how it is supposed to work. But last October, Wheeler suddenly and highhandedly terminated the subcommittees working to develop recommendations for the particulate standard, as well as the standard for ozone pollution (which CASAC will review next)."

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

4. "Wheeler has appointed four state agency members to CASAC, an unprecedented majority. All work for Republican governors."

Deliberative Process / Ex. 5

5. "Moreover, Wheeler promulgated a new rule that prohibits scientists funded by the EPA from providing the agency with advice."

Deliberative Process / Ex. 5

6. "I cannot ask President Trump's EPA assistant administrator for research and development to resign. That position remains unfilled."

Deliberative Process / Ex. 5

From: Konkus, John
Sent: Tuesday, April 2, 2019 12:20 PM
To: Woods, Clint <woods.clint@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>
Subject: RE: "If I were still working at the EPA, I would resign"

Yes. Let's consider a fact check. Since the Washington Post opinion editors only selectively fact check.

From: Woods, Clint
Sent: Tuesday, April 2, 2019 12:18 PM
To: Konkus, John <konkus.john@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>
Subject: "If I were still working at the EPA, I would resign"

RE: CASAC PM Panel. This op-ed has multiple factual errors – Let me know if you all want them catalogued.

https://www.washingtonpost.com/opinions/if-i-were-still-working-at-the-epa-i-would-resign/2019/04/02/88e6e2b8-519a-11e9-88a1-ed346f0ec94f_story.html?noredirect=on&utm_term=.769efe69650d

Message

From: woods.clint@epa.gov [woods.clint@epa.gov]
Sent: 3/11/2019 1:44:20 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Fwd: Biogenic Carbon Emission SAB report out
Attachments: EPA-SAB-19-002 .pdf; ATT00001.htm

Begin forwarded message:

From: "DeLuca, Isabel" <DeLuca.Isabel@epa.gov>
Date: March 6, 2019 at 1:15:46 PM EST
To: "Wehrum, Bill" <Wehrum.Bill@epa.gov>, "Woods, Clint" <woods.clint@epa.gov>, "Harlow, David" <harlow.david@epa.gov>, "Dominguez, Alexander" <dominguez.alexander@epa.gov>
Cc: "Millett, John" <Millett.John@epa.gov>
Subject: Biogenic Carbon Emission SAB report out

Hi team,

Just a heads up that the SAB has completed it's peer review of the 2014 biogenic CO2 report (the SAB report is attached) and has posted it online and submitted it to the Administrator. Below is a draft desk statement we could use if we get questions – if you have any edits or concerns with this draft, please let me know.

Thanks,

Isabel

Deliberative Process / Ex. 5

Message

From: woods.clint@epa.gov [woods.clint@epa.gov]
Sent: 4/3/2019 7:48:30 PM
To: Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]
CC: Jones, Lindsey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e1ca93678b0469eb3943c9612a2b7ff-Jones, Lind]
Subject: Re: CASAC nominations list of ecologists

+ Lindsey

On Apr 3, 2019, at 3:41 PM, Dunlap, David <dunlap.david@epa.gov> wrote:

> Yes final list as far as I aware. Plane racing for takeoff. You did no copy Lindsey.
>
> David D. Dunlap
> Deputy Assistant Administrator
> EPA Office of Research & Development
> Office 202.564.6620
>
> On Apr 3, 2019, at 3:40 PM, Woods, Clint <woods.clint@epa.gov> wrote:
>
>> Thanks – That was final list? Lindsey, you, and I should talk about some CASAC stuff in the next week or so.
>>
>> **From:** Dunlap, David
>> **Sent:** Wednesday, April 3, 2019 3:39 PM
>> **To:** Woods, Clint <woods.clint@epa.gov>
>> **Subject:** Fwd: CASAC nominations list of ecologists
>>
>> FYI - These names are ready to post for public comment. Deliberative Process / Ex. 5
>> Deliberative Process / Ex. 5
>>
>> DDD
>>
>> David D. Dunlap
>> Deputy Assistant Administrator
>> EPA Office of Research & Development
>> Office Personal Email / Ex. 6
>>
>> Begin forwarded message:
>>
>>> **From:** "Brennan, Thomas" <Brennan.Thomas@epa.gov>
>>> **Date:** March 25, 2019 at 10:38:50 AM EDT
>>> **To:** "Dunlap, David" <dunlap.david@epa.gov>, "Woods, Clint" <woods.clint@epa.gov>
>>> **Cc:** "Fitzmorris, Amanda" <fitzmorris.amanda@epa.gov>
>>> **Subject: CASAC nominations list of ecologists**
>>>
>>> Hi Clint and David,

Just as a reminder, the CASAC nomination period for ecologists closes on Thursday 3/28.

Here is what I have so far:

Person	City	State	Organization	Address Affiliation	Who Referred
Ex. 5 Deliberative Process (DP)					
Ex. 5 Deliberative Process (DP)					Dr. Tony Cox, CASAC Chair
Ex. 5 Deliberative Process (DP)					
Ex. 5 Deliberative Process (DP)					Dr. Tony Cox, CASAC Chair

Tom Brennan
Acting Director, Science Advisory Board Staff Office
US Environmental Protection Agency

Desk # 202 564 6953
Mobile # 703 581 9300

Appointment

From: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Sent: 4/10/2019 4:31:53 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]

Subject: Call - Tony

Start: 4/15/2019 3:00:00 PM
End: 4/15/2019 3:30:00 PM
Show Time As: Busy

Appointment

From: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Sent: 4/10/2019 4:31:53 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]

Subject: Call - Tony

Start: 4/15/2019 4:30:00 PM
End: 4/15/2019 5:00:00 PM
Show Time As: Busy

Appointment

From: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
Sent: 7/2/2018 1:46:42 PM
To: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Schwab, Justin [Schwab.Justin@epa.gov]

Subject: Pre discussion re: Follow-up call with CASAC chair Dr. Tony Cox
Location: WJC - N 5400

Start: 7/2/2018 4:15:00 PM
End: 7/2/2018 4:30:00 PM
Show Time As: Busy

Message

From: Hamilton, Sabrina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=68D3167C798743848AAFCDFB73BB74F1-SHAMILTN]
Sent: 11/8/2018 8:43:29 PM
To: Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]
CC: Carroll, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e868254d9da47e1ab5831814a7ff2fb-Carroll, Ma]
Subject: FW: CMS Inactivity Notification - Sent Item(s)
Attachments: EPA-SAB-18-003 .pdf; EPA Response to SAB Honeycutt letter.docx; EPA Response to SAB Turner letter.docx

Josh, Clint or Emily,

Do any of you recall see the SAB package for Bill's concurrence? It was sent to the IO for concurrence on 10/4/2018. Thanks

Sabrina Hamilton

Sabrina Hamilton
Air and Radiation Liaison Specialist
and FOIA Coordinator
Office of Air and Radiation
U.S. Environmental Protection Agency (EPA)
1200 Pennsylvania Avenue, N.W. (6101-A)
Washington, D.C. 20460
Tel: (202) 564-1083

-----Original Message-----
From: Strine, Lora
Sent: Thursday, October 4, 2018 8:27 AM
To: Hamilton, Sabrina <Hamilton.Sabrina@epa.gov>
Cc: Carroll, Maria <carroll.maria@epa.gov>; Terry, Sara <Terry.Sara@epa.gov>
Subject: FW: CMS Inactivity Notification - Sent Item(s)

Hi Sabrina

Can you please go in and take over this control? I can't see it in my box and I keep getting weird notices about it - see below. It is ready for your step in the process. I entered the response doc into the CMS control today. Please note: the incoming is in the wrong location in this control so you will have to look at both of the docs in the response section to find the incoming letter.

The response has been reviewed by OAQPS and is ready to move to you and then to the OEX.

Lora
202 564 1521

-----Original Message-----
From: cmsadmin@epa.gov [mailto:cmsadmin@epa.gov]
Sent: Tuesday, October 02, 2018 11:03 PM
To: Strine, Lora <Strine.Lora@epa.gov>
Subject: CMS Inactivity Notification - Sent Item(s)

Lora Strine:

The following item(s) sent by you have not been acted upon for more than 5 days. Please contact the responsible CMS user(s) for proper action or reassign the control.

Control Number: SAB-18-001-0787
Control Subject: Review of EPA?s draft technical report entitled Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis
From: Honeycutt, Michael
Task Name: New Assignment
Sent By: Lora Strine
Sent To: OAR-OAQPS-HEID

Date Sent: Sep 17 2018
Days Inactive: 14

Control Number: SAB-18-001-0787
Control Subject: Review of EPA?s draft technical report entitled Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis
From: Honeycutt, Michael
Task Name: Supporting Assignment
Sent By: Lora Strine
Sent To: OAR-OAQPS-HEID
Date Sent: Sep 13 2018
Days Inactive: 18

Note: This Email was automatically generated. Please do not attempt to respond to it. You can access this control at https://cms.epa.gov/cms. Questions or comments concerning CMS should be directed to CMS Support at 202-564-4985 or CMS Information@epa.gov.

Message

From: Harlow, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B5A9A34E31FC4FE6B2BEADDDA2AFFA44-HARLOW, DAV]
Sent: 12/3/2018 1:00:40 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: RE: The American Citizen's Guide to Clean Air - The New York Times

Clint,

Personal Matters / Ex. 6

David S. Harlow
Senior Counsel
Immediate Office of the Assistant Administrator
Office of Air and Radiation, USEPA
WJC-N Room 5409K
1200 Pennsylvania Avenue NW
Washington, DC 20460
202-564-1233
Harlow.David@epa.gov

From: Woods, Clint
Sent: Friday, November 30, 2018 4:08 PM
To: Wehrum, Bill <Wehrum.Bill@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Harlow, David <harlow.david@epa.gov>; Dominguez, Alexander <dominguez.alexander@epa.gov>
Subject: The American Citizen's Guide to Clean Air - The New York Times

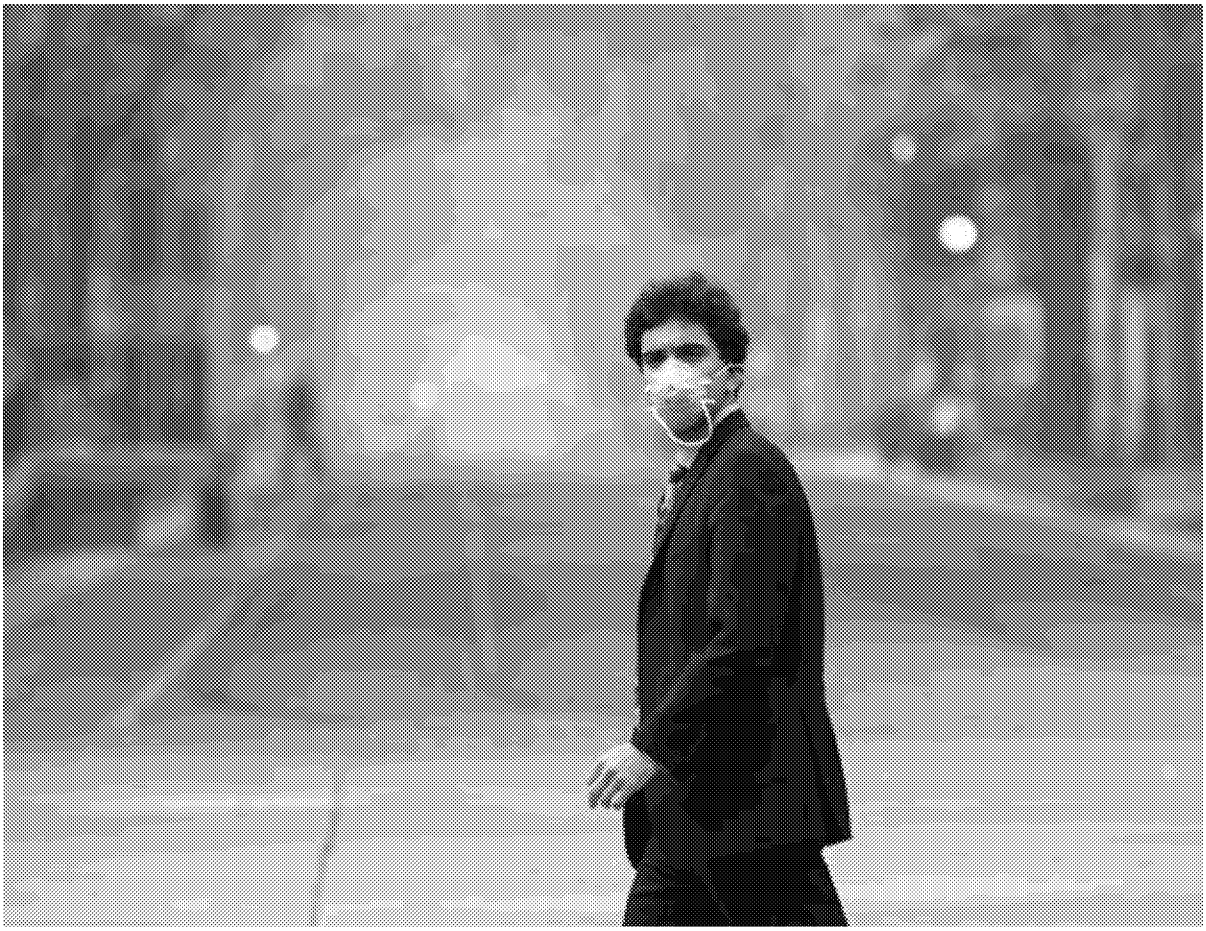
https://www.nytimes.com/2018/11/30/style/air-quality-pollution-monitors.html

The American Citizen's Guide to Clean Air

Unsure if the government is looking out for them, a guerrilla network of "breathers" has turned to personal pollution monitors.

Nov. 30, 2018

A man on the streets of Sacramento in November.Rich Pedroncelli/Associated Press



A man on the streets of Sacramento in November.Rich Pedroncelli/Associated Press

The hottest new apocalypse preparation choice for 2019 is not a bunker or a gun or a lifeboat. And it's not moving to New Zealand. It's a small gadget that measures the air pollution around you.

As climate change reports become increasingly dire, and as wildfires tear across the American West, and as trust in the federal government's air quality oversight fades, thousands of people around the country are taking air measurements into their own hands.

Installed on a porch, a console table or hooked to a backpack, these small, sleek and increasingly inexpensive devices measure hyper-local air quality. They are marketed to the discerning and alarmed consumer. Some have begun to self-identify as "breathers."

The Atmotube and PlumeLab's Flow are small and meant to be carried around, testing the air as a person walks or bikes, helping people plan routes that avoid bad air. The Awair looks like an old-timey radio and sits on a counter to test indoor air. Aeroqual's particulate monitor, one of the most advanced, looks like an enormous old-fashioned cellphone.

A Flow personal air pollution monitor from Plume Labs.Masaki Okumura/Plume Labs

A Flow personal air pollution monitor from Plume Labs.Masaki Okumura/Plume Labs

But the monitor most intriguing local government environmental protection agencies and civilians alike is PurpleAir. It hooks up outside, connects to Wi-Fi, feeds into a global network and creates something like a guerrilla air quality monitoring network.

Adrian Dybwad, 49, the founder of PurpleAir, would watch the dust from a nearby gravel pit blow near his house in Draper, Utah, where he lives with his wife. When the miners working there tried to expand it even closer, he decided he had to do something. First he had to prove there was something wrong with the air.

"I said to myself, it's 2015, surely there must be a sensor that can tell me how much dust is in there," Mr. Dybwad said.

But nothing he could find was both cheap and accurate. So he made his own.

Neighbors got interested. Mr. Dybwad, who has a background in computer networking and surface-mount electronics, asked for donations and raised a few thousand dollars, and the community installed 80 sensors. The amount of floating particles in the air (called particulate matter) was high, especially on windy days. The closest government-run sensor was more than 10 miles away, and not picking up any of this.

As the community gathered with sensors, plans for the mine expansion vaporized.

In the last year, interest in the project has spiked. Now he has more than 3,000 monitors reporting data every day. He has built a map to show what every PurpleAir around the world is reporting (green is good, red is bad). Local government air quality monitoring groups are using the devices.

The Awair air pollution monitor.Getawair.com

The Awair air pollution monitor.Getawair.com

Since the California wildfires in November, Mr. Dybwad said, traffic has been up 10,000 percent. In November, he moved production out of his backyard and into a new 2,200-square-foot workshop.

"You can't give the government control over monitoring and enforcement because then you can just monitor to the extent that you want to enforce," he said. "Having this type of power in the public's hands, it gives a check on the government."

Vera Kozyr, the chief executive of Atmotube, said her company sold 8,000 of its first version and is introducing a new tube in December.

"We've seen a huge increase of interest in the last few months, especially from the U.S.," Ms. Kozyr said. "Awareness is just starting."

Fans of the new pollution monitors tend to also be skeptical of government efforts to keep air clean and say they are wary of the air quality data that the government provides. "At some points," Ms. Kozyr said, "you can't trust the government."

The Trump administration has urged the Environmental Protection Agency to ease air quality rules. New E.P.A. leadership seems to be on board with this plan. The administration is working to overhaul restrictions on coal, which by its own estimates could lead to as many as 1,400 more premature deaths annually by 2030 from an increase in the airborne particulate matter.

President Trump claimed in October that the United States has the cleanest air in the world, which is inaccurate. The administration in August unveiled plans to freeze antipollution and fuel-efficiency standards for cars. Outlining the effort, the E.P.A. acting administrator, Andrew Wheeler, and the secretary of transportation, Elaine L. Chao, published an opinion piece in The Wall Street Journal called "Make Cars Great Again."

Mr. Wheeler announced in October that next year the E.P.A. would be disbanding a key scientific review panel on clean air and pollution.

An Atmotube Plus personal air pollution detector.

An Atmotube Plus personal air pollution detector.

Tony Cox, who sits on the E.P.A. committee on clean air, has said that the benefits of clean air are exaggerated and, in a paper sponsored by the American Petroleum Institute, that it cannot be shown that particulate matter in the air leads to deaths; this is contradicted by information provided by the E.P.A. Robert Phalen, a researcher who joined the E.P.A.'s board of science advisers to work on air quality issues, has said that air has gotten too clean.

"Do we have sufficient monitors? No. There's not enough of them," said Janice E. Nolen, the vice president of the American Lung Association, citing both lack of funding and industry interests. "People don't necessarily want to know where air quality is bad in some cases."

"Of about 3,000 counties" in the United States, Ms. Nolen said, "only eight or nine hundred have air quality monitors at all."

Having so few monitors means that something like the downwind effects of a wildfire can be hard to detect.

"It can be frustrating to residents when they see the air is bad, and then they look at a map and it's showing green or good because none of the monitors happen to be downwind of the smoke," said Sam Atwood, who works for the air quality management district that oversees much of Southern California. He installed a PurpleAir in his backyard.

The monitors his district operates can cost over $100,000, Mr. Atwood said. A PurpleAir monitor goes for $180 to $260. So Mr. Atwood's district, with funding from a 2016 E.P.A. grant, is now running a pilot program to test low cost monitors with community groups across the state.

An Aeroqual personal air pollution detector.

An Aeroqual personal air pollution detector.

Jim Leach, a retired information technology professional in Lafayette, Calif., realized that the closest government air quality sensor to him was six miles away in a quiet residential neighborhood. But he lives in a narrow valley with eight lanes of freeway running through it. For car pollution in particular, small distances can make a big difference in how much pollution is in the air.

"What that sensor picks up is just not accurate for us," Mr. Leach said.

He put a PurpleAir outside his house. The reading alarmed him. "I realized we had a much bigger problem than I'd thought," Mr. Leach said.

Neighbors joined in. Now about a dozen houses nearby are also monitoring.

"One thing I get asked quite a bit is, 'Why don't we know about this already? Why don't we know?'" Mr. Leach said. "People are starting to wake up and ask what is this stuff and how do I need to be protected."

Now he is working with a local nonprofit to finish installing PurpleAir monitors in all the public schools in his city.

Miles Keogh, the executive director of the National Association of Clean Air Agencies, bikes around his home in Alexandria, Va., and worries a lot about what he breathes.

"What is it citizens — breathers — can do?" he said.

About two weeks ago, he strapped an air quality sensor called the Plume Labs Flow to his backpack to see how much he was exposed to along his bike rides. His fellow bike commuters are doing the same.

"My fellow bike commuters and I like to run around and say I ran into an orange spot," Mr. Keogh said.

Many early adopters of private air quality monitors are people who are deeply familiar with the government's pollution monitoring systems.

"I tell my friends, 'You don't want to know what I know,'" said Joe Lyou, who sits on the South Coast Air Quality Management District Governing Board. "There's a lot of pollution."

He installed a PurpleAir two years ago and is now gathering neighbors together to do the same.

Mr. Lyou said he is concerned the Trump administration will try to hide air quality data after it has been collected.

"I'm worried that they'll distort or spin the data in a way so that people are confused or misled. They'll bury it or make it confusing to understand," Mr. Lyou said. "It's already happening."

And so for now, Mr. Lyou trusts the monitor in his backyard.

"I'm downwind of two power plants, a refinery and next to a freeway," he said. "And I have a kid who's asthmatic."

The sensor helps Mr. Lyou decide when it's safe for his son to play outside.

Mark Dixon, a filmmaker in Pittsburgh, started a local PurpleAir movement after feeling sick on jogs.

"I knew the air was bad because it stinks," Mr. Dixon said. "A foul industrial stench."

He used an app called Smell PGH that tracks industrial odors. When he started reading about air quality enforcement, he realized that some factories around the town were still polluting above the legal limit.

"I felt betrayed as a citizen," he said. "They're polluting at our doorsteps and we know it and we can see it and we can smell it, and now we can measure it."

He has been building the network out this fall and hopes to use the data to push the government to crack down. Poor and minority communities are disproportionately affected by air pollution, and a revived environmental justice movement is rising.

One home that Mr. Dixon outfitted with a PurpleAir this summer is across the river from Edgar Thomson Steelworks and near a coke refinery that emits a rotted sulfur smell. That's where Robin Kornides, 63, lives with her husband and makes her living selling sewn and knitted goods.

One recent November afternoon, she stood on her front porch in a sweatshirt and gloves, taking a break from caring for a troupe of pet pigeons to talk about the gadget.

But other days, she is not so lucky.

"A third of the time it's bad enough that I don't want to go outside, but it mostly depends how the wind is blowing," Ms. Kornides said. On the worst days, she added, "It's like trying to breath Jell-O."

That day there was a cool crisp east wind — she thinks of it as the good wind.

"It makes me feel justified to complain at least, and I'm a visual person, so I like seeing the color on the app," Ms. Kornides said. "But I can always smell it first, that coke smell."

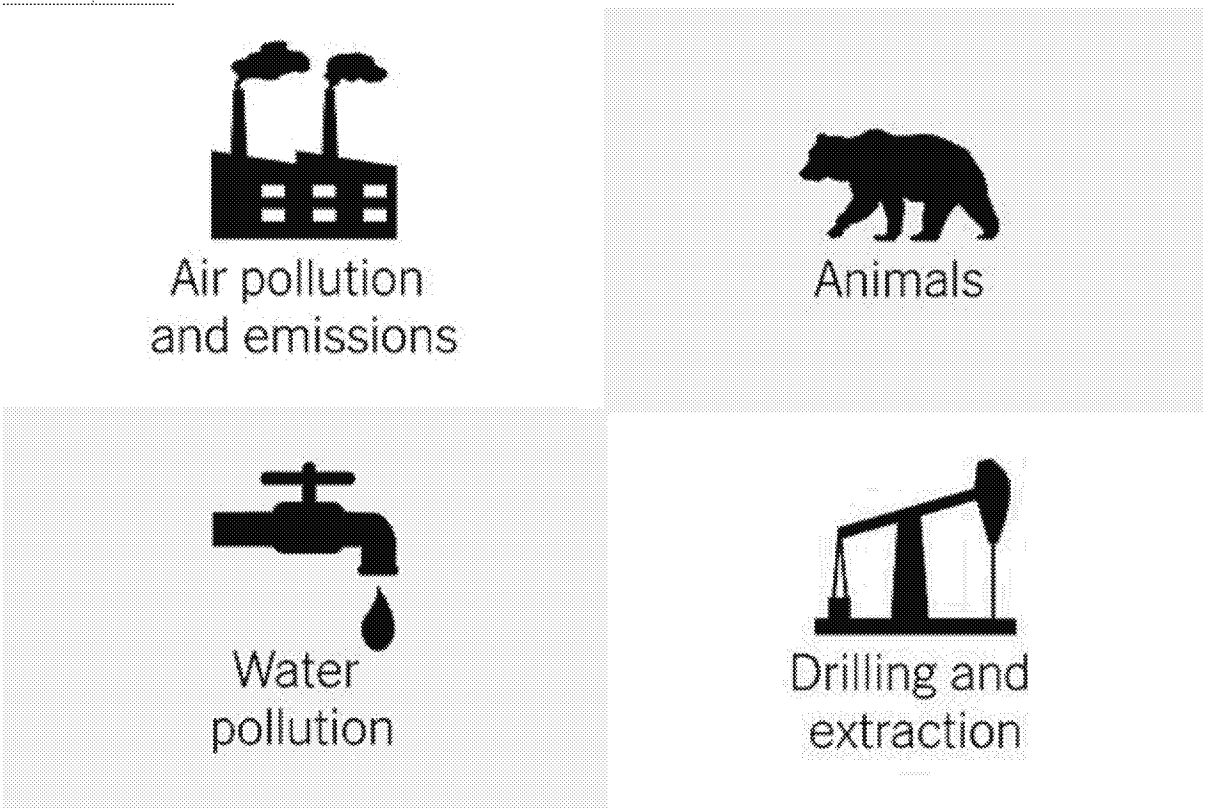
Breathing Well

More on the conditions affecting consumer choices

76 Environmental Rules on the Way Out Under Trump

The list shows dozens of environmental policies that the Trump administration has targeted, often in an effort to ease burdens on the fossil fuel industry.

Oct. 5, 2017



Trump Administration's Strategy on Climate: Try to Bury Its Own Scientific Report

Friday's government report, detailing in stark terms the economic cost of climate change, is likely to be played down by the administration, even as opponents use it to attack Trump policies.

Nov. 25, 2018

How's the Air in London? 'We Should Be Worried'

Our reporter visited an artist's "pollution pods" to sample the smog and haze he recreated from some of the world's most contaminated cities.

April 22, 2018

Scott Pruitt's Environmental Rollbacks Stumbled in Court. His Successor Is More Thorough.

President Trump's current choice to run the E.P.A., Andrew Wheeler, could emerge as an effective and efficient driver of the administration's environmental and climate deregulation agenda.

Nov. 21, 2018

Nellie Bowles covers tech and internet culture. Follow her on Twitter: @nelliebowles

Subscribe to The New York Times.

Sent from my iPhone

Message

From: Dunlap, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591EB15A268249DDA0C05A7451F765C3-DUNLAP, DAV]
Sent: 10/25/2018 2:00:47 AM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: FW: Charge to CASAC for review of the draft PM ISA
Attachments: ISA_PREAMBLE_FINAL2015 (1).pdf; Charge to CASAC_PM ISA 10-23-18.docx

Importance: High
Flag: Flag for follow up

Clint,

Are you good with these changes to the charge questions? Do the changes align with the input you provided?

DDD

From: Vandenberg, John
Sent: Tuesday, October 23, 2018 4:18 PM
To: Yeow, Aaron <Yeow.Aaron@epa.gov>
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Subject: Charge to CASAC for review of the draft PM ISA
Importance: High

Aaron,

Attached please find the charge for the CASAC review of the draft PM ISA, and the Preamble for the ISAs. (I will send you a signed version when I return to my office on Thursday).
We reviewed and considered comments from Dr. Cox and from ORD and OAR management while developing this final Charge.
Please let me know if you have any questions.
Thank you
John

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United States
Environmental Protection
Agency

Preamble to the Integrated Science Assessments

Office of Research and Development
National Center for Environmental Assessment, RTP Division

EPA/600/R-15/067
November 2015
www.epa.gov/isa

United States Environmental Protection Agency

Preamble to the Integrated Science Assessments

November 2015

National Center for Environmental Assessment—RTP Division
Office of Research and Development
U.S. Environmental Protection Agency
Research Triangle Park, NC

DISCLAIMER

This Preamble serves as a companion document to the Integrated Science Assessments prepared by the U.S. Environmental Protection Agency's National Center for Environmental Assessment in support of reviews of the national ambient air quality standards (NAAQS). It is available on the NCEA website at: www.epa.gov/isa. This document and the approach described herein may be refined in consideration of advice and comments received from the Clean Air Scientific Advisory Committee and the public during subsequent NAAQS reviews. This document has been reviewed in accordance with U.S. Environmental Protection Agency policy and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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ACRONYMS AND ABBREVIATIONS

Acronym/Abbreviation	Meaning
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CDC	Centers for Disease Control and Prevention
CO	carbon monoxide
HERO	Health and Environmental Research Online
IARC	International Agency for Research on Cancer
IOM	Institute of Medicine
IRP	Integrated Review Plan
ISA	Integrated Science Assessment
NAAQS	National Ambient Air Quality Standards
NAS	National Academy of Sciences
NO_X	oxides of nitrogen; the sum of nitric oxide and nitrogen dioxide
O_3	ozone
Pb	lead
PM	particulate matter
SES	socioeconomic status
U.S. EPA	U.S. Environmental Protection Agency

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PREAMBLE

1. Process of Integrated Science Assessment Development

This Preamble outlines the general process used by the U.S. Environmental Protection Agency (U.S. EPA) for developing an Integrated Science Assessment (ISA) including the framework for evaluating weight of evidence and drawing scientific conclusions and causal judgments. It is available on the U.S. EPA website at: www.epa.gov/isa. The ISA provides a concise review, synthesis, and evaluation of the most policy-relevant science to serve as a scientific foundation for the review of the National Ambient Air Quality Standards (NAAQS).[1] The NAAQS are established based on consideration of the air quality criteria (represented by the ISA) for the pollutants identified by the Administrator using Section 108 of the Clean Air Act (CAA). The pollutants currently identified are carbon monoxide (CO), lead (Pb), oxides of nitrogen, ozone and related photochemical oxidants, particulate matter (PM), and sulfur oxides (CAA, 1990a, b). Figure I depicts the general NAAQS review process. Information for individual NAAQS reviews is available online.[2]

[1] The general process for NAAQS reviews is described at http://www.epa.gov/ttn/naaqs/review.html.
[2] Information for individual NAAQS reviews is available at www.epa.gov/ttn/naaqs.

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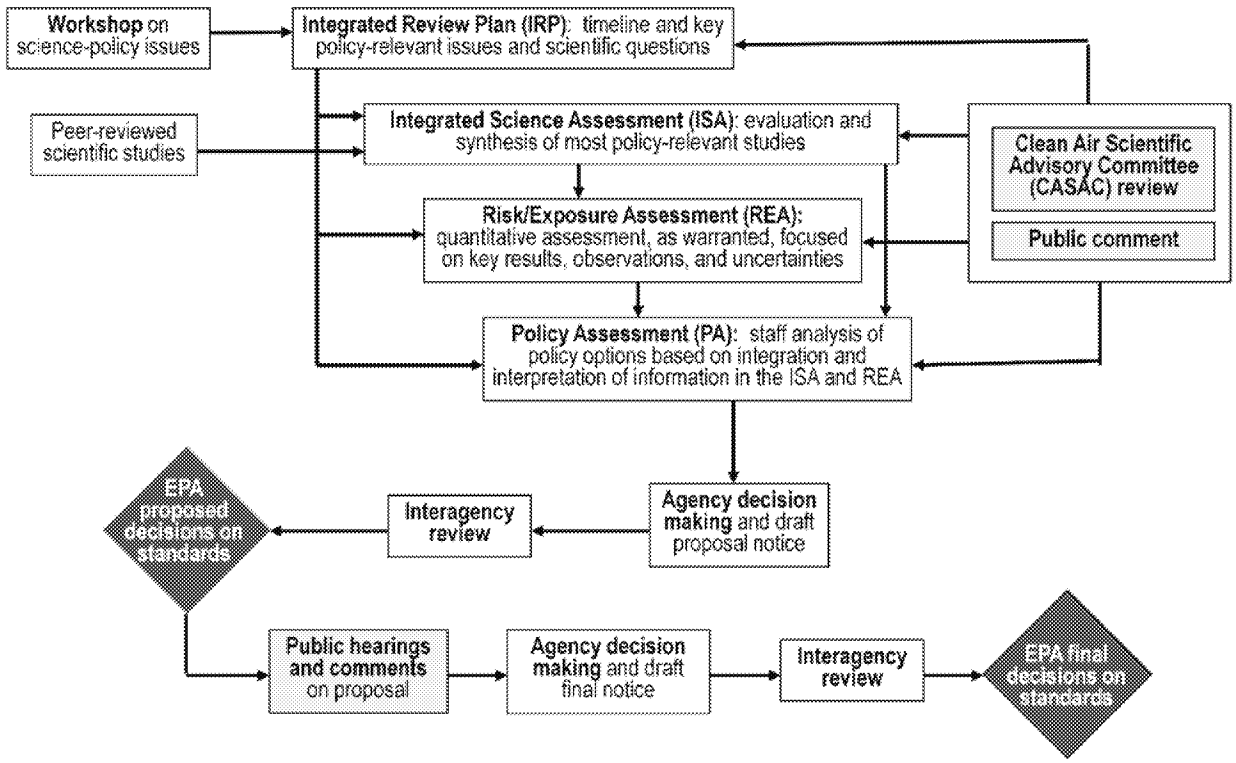

Figure I **Schematic of the key steps in review of the National Ambient Air Quality Standards.**

The development of the ISA is preceded by the release of an Integrated Review Plan (IRP) that discusses the planned scope of the NAAQS review; the planned approaches for developing the key assessment documents [e.g., ISA, Risk and Exposure Assessment (if warranted), Policy Assessment]; and the schedule for release and review of the documents and subsequent rulemaking notices. The key policy-relevant questions included in the IRP serve to clarify and focus the NAAQS review on the critical scientific and policy issues, including addressing uncertainties discussed during the previous review and newly emerging literature. The IRP is informed by a U.S. EPA-hosted public science and policy issue workshop that kicks off review of the NAAQS for each criteria pollutant by seeking input on the current state of the science and engaging stakeholders and experts in discussion of the policy-relevant questions that will frame the review.

This Preamble is a general discussion of the basic steps and criteria used in developing an ISA. Details and considerations specific to an individual ISA are included in the IRP, Preface, and introductory material for that assessment. The general process for ISA development is illustrated in Figure II. An initial step (not shown) is publication of a call

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for information in the *Federal Register* that invites the public to provide information relevant to the assessment, such as new or recent publications on health or welfare effects of the pollutant or data from the fields of atmospheric and exposure science.

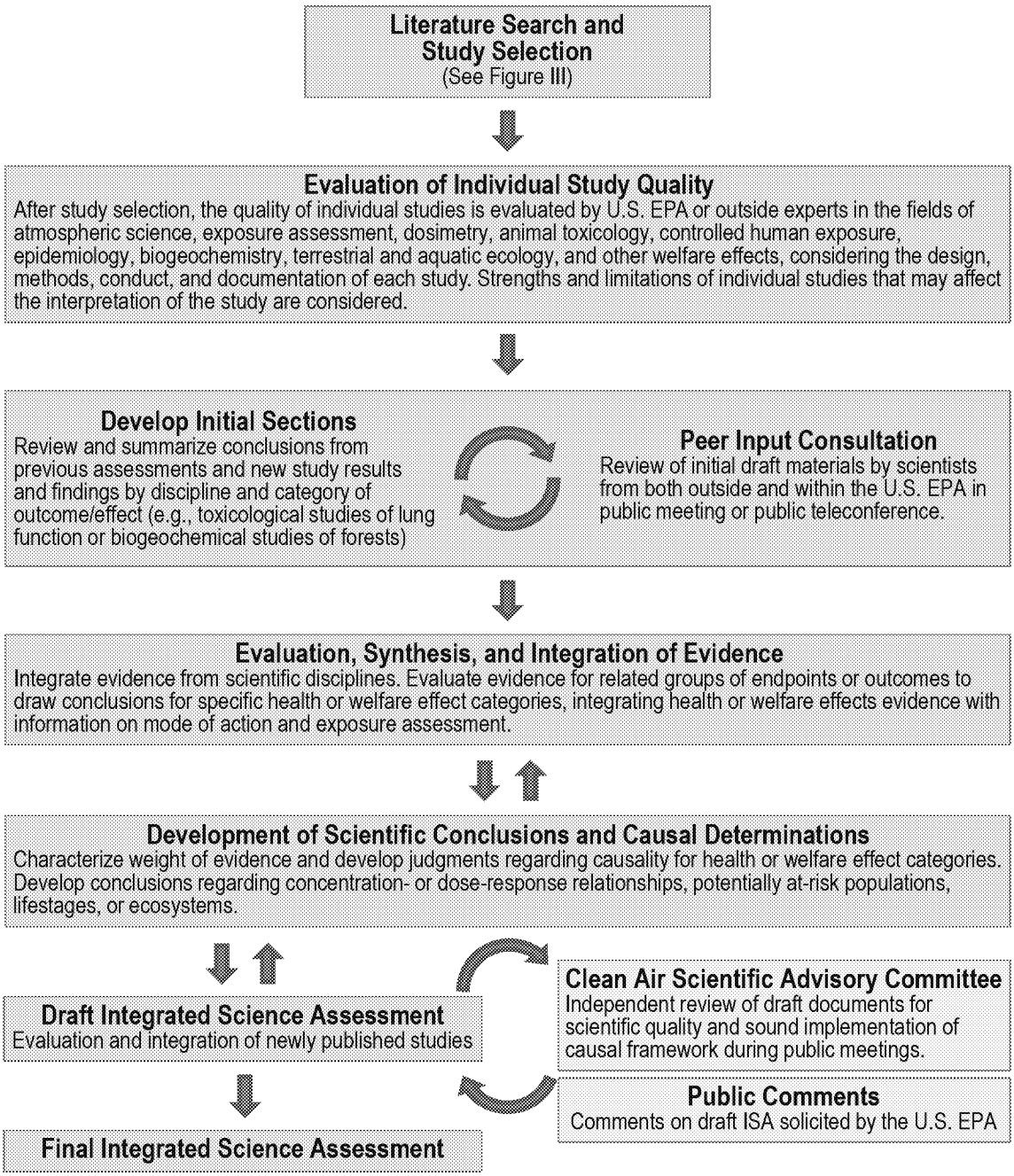

Figure II **Characterization of the general process for Integrated Science Assessment development.**

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The fundamental process for developing an ISA includes:

- Literature searches;
- Study selection;
- Evaluation of individual study quality;
- Evaluation, synthesis, and integration of the evidence; and
- Development of scientific conclusions and causal determinations.

In developing an ISA, the U.S. EPA reviews and summarizes the evidence from studies on atmospheric sciences, dosimetry, human exposure, animal toxicology, mode of action, controlled human exposure, epidemiology, biogeochemistry, and/or terrestrial and aquatic ecology and other welfare[1] effects. In the process of developing the first draft ISA, the U.S. EPA may convene a peer input meeting in which the scientific content of preliminary draft materials is reviewed by subject-matter experts to ensure that the ISA is up-to-date and is focused on the most policy-relevant findings. This review also assists the U.S. EPA with integration of evidence within and across disciplines.

The U.S. EPA integrates the evidence from across scientific disciplines or study types and characterizes the weight of evidence for relationships between the pollutant and various outcomes. Integrating evidence on human health or welfare effects involves collaboration between scientists from various disciplines. For example, an evaluation of human health effects evidence would generally include integrating the results from epidemiologic, controlled human exposure, and toxicological studies; consideration of exposure assessment, dosimetry and mode of action; and the application of the causal framework (described below) to draw conclusions.

Integration of results on human health or welfare effects that are logically or mechanistically connected (e.g., respiratory symptoms, asthma exacerbations) informs judgments of causality on the broader health or welfare effect category (e.g., effects on the respiratory system). Using the causal framework described in this Preamble, U.S. EPA scientists consider aspects, such as strength, consistency, coherence, and biological plausibility of the evidence, and develop causality determinations on the nature of the relationships. Causality determinations often entail an iterative process of review and evaluation of the evidence. One or more drafts of the ISA are released for review by the Clean Air Scientific Advisory Committee (CASAC) and the public, and comments

[1] Under CAA Section 302(h) [42 U.S.C. 7602(h)], language referring to "effects on welfare" includes, but is not limited to, "effects on soils, water, crops, vegetation, man-made 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."

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received on the characterization of the science as well as the implementation of the causal framework are carefully considered in revising and completing the ISA.

2. Literature Search

In addition to the call for information in the *Federal Register* referenced above, the U.S. EPA maintains an ongoing literature search process to identify relevant scientific studies published since the last ISA for a given criteria pollutant. Search strategies are designed a priori for pollutants and scientific disciplines and iteratively modified to optimize identification of pertinent publications. In addition, papers are identified for inclusion in several additional ways: specialized searches on specific topics, identification of new publications by relational searches conducted using citations from previous assessments, review of tables of contents for journals in which relevant papers may be published, identification of relevant literature by expert scientists, review of citations in previous assessments, and recommendations by the public and CASAC during the call for information and external review processes. References identified through the multipronged search strategy are then "screened" by title and abstract. Those references that are potentially relevant after reading the title are "considered" for inclusion in the ISA and are added to the Health and Environmental Research Online (HERO) database developed by the U.S. EPA.[1] Additional review steps (described in Section 3 below) precede a decision to "include" a study in the ISA. The references cited in the ISA contain a hyperlink to the HERO database. This literature search and study selection process including the "screened", "considered", and "included" references, is depicted in Figure III.

[1] The list of considered references and bibliographic information is accessible to the public through HERO (http://hero.epa.gov/).

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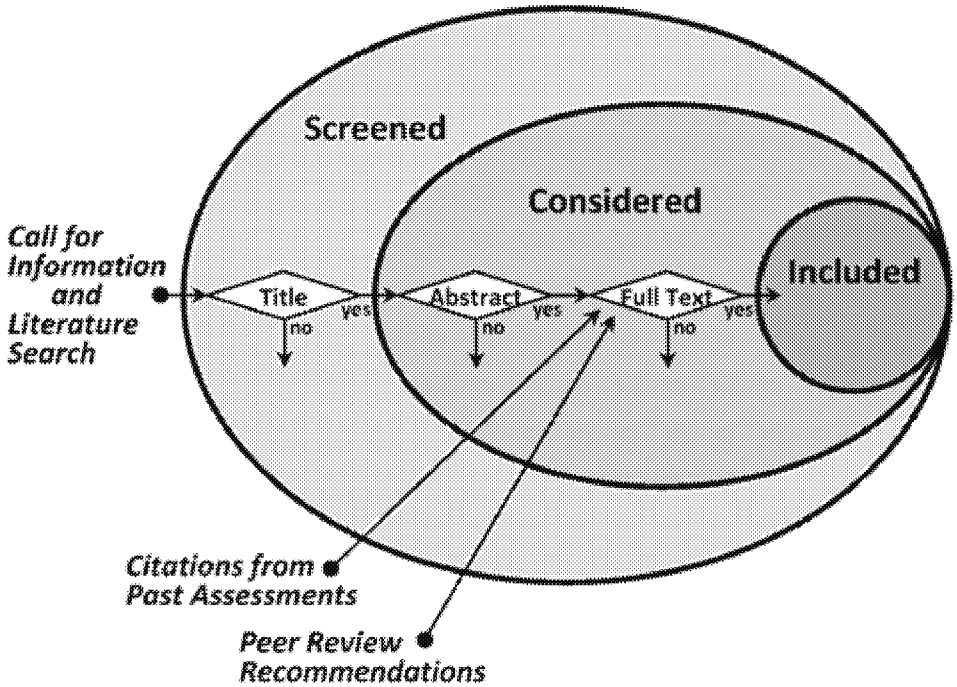

Figure III **Illustration of processes for literature search and study selection process used for development of Integrated Science Assessments.**

Studies and reports that have undergone scientific peer review and have been published (or accepted for publication) are considered for inclusion in the ISA. This includes only studies that have been ethically conducted (e.g., with approval by an Institutional Review Board or Institutional Animal Care and Use Committee). All relevant epidemiologic, controlled human exposure, toxicological, and ecological and other welfare effects studies published since the last review are considered, including those related to exposure-response relationships, mode(s) of action, and populations, lifestages, or ecosystems at increased risk of air pollution-related effects. Studies and data analyses on atmospheric chemistry, air quality and emissions, environmental fate and transport, dosimetry, toxicokinetics, and exposure are also considered for inclusion in the ISA. References considered for inclusion in a specific ISA can be found using the HERO website (http://hero.epa.gov).

Each ISA builds upon the conclusions of previous assessments for the pollutant under review. The U.S. EPA focuses on peer-reviewed literature published following the completion of the previous review and on any new interpretations of previous literature, integrating the results of recent scientific studies with previous findings. Important earlier studies may be discussed in detail to reinforce key concepts and conclusions or for

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reinterpretation in light of newer data. Earlier studies also are the primary focus in some areas of the document where research efforts have subsided, or if these earlier studies remain the definitive works available in the literature.

3. Study Selection

References considered for inclusion in the ISA undergo abstract and full-text review to determine whether they will be included in the ISA. The selection process is based on the extent to which the study is informative, pertinent, and policy relevant. Informative, pertinent, and policy-relevant studies include those that describe or provide a basis for the relationship between the criteria pollutant and effects, including studies that offer innovation in method or design and studies that reduce uncertainty on critical issues. Emphasis is placed on studies that examine effects associated with pollutant concentrations and exposure conditions relevant to current human population and ecosystem exposures, and particularly those pertaining to concentrations currently found in ambient air. Other studies are included if they contain unique data, such as a previously unreported effect or mode of action for an observed effect, or examine multiple concentrations to elucidate exposure-response relationships.

4. Evaluation of Individual Study Quality

After selecting studies for inclusion, the individual study quality is evaluated by considering the design, methods, conduct, and documentation of each study, but not the study results. This uniform approach aims to consider the strengths, limitations, and possible roles of chance, confounding, and other biases that may affect the interpretation of individual studies and the strength of inference from the results of the study. Particular study quality aspects, relevance, or limitations of some of these features do not necessarily define a less informative study or exclude a study from consideration in an ISA. As stated initially, the intent of the ISA is to provide a concise review, synthesis, and evaluation of the most policy-relevant science to serve as a scientific foundation for the review of the NAAQS, not extensive summaries of all human health and welfare effects studies for a pollutant. Of most importance for inclusion of a study is whether it provides useful qualitative or quantitative information on exposure-response relationships for effects associated with pollutant exposures at doses or concentrations relevant to ambient conditions that can inform decisions on whether to retain or revise the NAAQS.

In general, in assessing the scientific quality of studies on health and welfare effects, the following considerations are taken into account.

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- Were study design, study groups, methods, data, and results clearly presented in relation to the study objectives to allow for study evaluation? Were limitations and any underlying assumptions of the design and other aspects of the study stated?
- Were the ecosystems, study site(s), study populations, subjects, or organism models adequately selected, and are they sufficiently well defined to allow for meaningful comparisons between study or exposure groups?
- Are the air quality, exposure, or dose metrics of adequate quality and are they sufficiently representative of or pertinent to ambient conditions?
- Are the health, ecological, or other welfare effect measurements meaningful, valid, and reliable?
- Were likely covariates or modifying factors adequately controlled or taken into account in the study design and statistical analysis?
- Do the analytical methods provide adequate sensitivity and precision to support conclusions?
- Were the statistical analyses appropriate, properly performed, and properly interpreted?

Additional study quality considerations specific to particular disciplines are discussed below.

a. Atmospheric Science and Exposure Assessment

Atmospheric science and exposure assessment studies that are considered for inclusion in the ISA focus on measurement of, behavior of, and exposure to ambient air pollution using quality-assured field, experimental, and/or modeling techniques. The most informative measurement-based studies will include detailed descriptive statistics for measurements taken at varying spatial and temporal scales. These studies will also include a clear and comprehensive description of measurement techniques and quality-control procedures used. Quality-control metrics (e.g., method detection limits) and quantitative relationships between and within pollutant measurements (e.g., regression slopes, intercepts, and fit statistics) should be provided when appropriate. Measurements that include contrasting conditions for various time periods (e.g., weekday/weekend, season), populations, regions, and categories (e.g., urban/rural) are particularly useful. The most informative modeling-based studies will incorporate appropriate chemistry, transport, dispersion, and/or exposure modeling techniques with a clear and comprehensive description of model evaluation procedures, metrics, and technique strengths and limitations. The ISA also may include analyses of data pertinent to characterizing air quality or exposure, such as emissions sources and ambient air pollutant concentrations. Sources of monitoring and modeling data should be clearly referenced and described to foster transparency and reproducibility of any analysis. In

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general, atmospheric science studies and data analyses focusing on locations pertinent to the U.S. will have maximum value in informing review of the NAAQS.

Exposure measurement error, which refers to inaccuracies in the characterization of the exposures of study participants, can be an important contributor to uncertainty in air pollution epidemiologic study results. Exposure measurement error can influence observed epidemiologic associations between ambient pollutant concentrations and health outcomes by biasing effect estimates toward or away from the null and widening confidence intervals around those estimates (Zeger et al., 2000). Factors that could influence exposure estimates include, but are not limited to: choice of exposure metric, spatial variability of the pollutant concentration, nonambient sources of exposure, topography of the natural and built environment, meteorology, instrument errors, time-activity patterns, and differential infiltration of air pollutants into indoor environments. The influence of these factors on effect estimates also depends on epidemiologic study design. For example, when longitudinal studies depend on spatial contrasts in exposure estimates, it is important that the exposure estimates correspond in space to the population of interest. Likewise for time-series studies, the temporal variability of the exposure estimate must correspond temporally to the true exposures of the study population.

b. Epidemiology

In evaluating individual study quality for inference about health effects in epidemiologic studies, the U.S. EPA considers, in addition to the general quality considerations discussed previously, whether a given study: (1) presents information on associations with short- or long-term pollutant exposures at or near conditions relevant to ambient exposures; (2) addresses potential confounding, particularly by other pollutants; (3) assesses potential effect modifiers; (4) evaluates health endpoints and populations, groups, or lifestages not previously extensively researched; and (5) evaluates important methodological issues related to interpretation of the health evidence (e.g., lag or time period between exposure and effects, model specifications, thresholds).

In evaluating epidemiologic evidence, one important consideration is potential confounding. Confounding is "…a confusion of effects. Specifically, the apparent effect of the exposure of interest is distorted because the effect of an extraneous factor is mistaken for or mixed with the actual exposure effect (which may be null)" (Rothman and Greenland, 1998). A confounder is associated with both the exposure and the effect; for example, confounding can occur between correlated pollutants that are associated with the same effect. One approach to remove spurious associations due to possible confounders is to control for characteristics that may differ between exposed and

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unexposed persons; this is frequently termed "adjustment." Scientific judgment is needed to evaluate likely sources and extent of confounding, together with consideration of how well the existing constellation of study designs, results, and analyses address the potential for erroneous inferences.

Several statistical methods are available to detect and control for potential confounders; however, none of these methods is completely satisfactory. Multivariable regression models constitute one tool for estimating the association between exposure and outcome after adjusting for characteristics of participants that might confound the results. Because much of the uncertainty in inferring causality may be due to potential confounding by copollutants, evaluation of copollutant confounding in individual studies is of particular importance. The use of copollutant regression models has been the prevailing approach for controlling for potential confounding by copollutants in air pollution health effects studies. Trying to determine whether an individual pollutant is independently associated with the health outcome of interest from copollutant regression models is made difficult by the possibility that one or more air pollutants is acting as a surrogate for an unmeasured or poorly measured pollutant or for a particular mixture of pollutants. In addition, pollutants may independently exert effects on the same system; for example, several pollutants may be associated with a respiratory effect through either the same or different modes of action. Despite these limitations, the use of copollutant models is still the prevailing approach employed in most air pollution epidemiologic studies and provides some insight into the potential for confounding or interaction among pollutants.

Confidence that unmeasured confounders are not producing the findings is increased when multiple studies are conducted in various settings using different subjects or exposures, each of which might eliminate another source of confounding from consideration. For example, multicity studies can provide insight on potential confounding through the use of a consistent method to analyze data from across locations with different concentrations of copollutants and other covariates. Intervention studies, because of their quasi-experimental nature, can be particularly useful in characterizing causation.

Another important consideration in the evaluation of epidemiologic studies is effect-measure modification, which occurs when the effect differs between subgroups or strata; for example, effect estimates that vary by age group or a potential risk factor. As stated by Rothman and Greenland (1998):

> "Effect-measure modification differs from confounding in several ways. The main difference is that, whereas confounding is a bias that the investigator hopes to prevent or remove from the effect estimate, effect-measure modification is a property of the effect under study …In

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epidemiologic analysis one tries to eliminate confounding but one tries to detect and estimate effect-measure modification."

When a risk factor is a confounder, it is the true cause of the association observed between the exposure and the outcome; when a risk factor is an effect modifier, it changes the magnitude of the association between the exposure and the outcome in stratified analyses. For example, the presence of a pre-existing disease or indicator of low socioeconomic status (SES) (e.g., educational attainment, household income) may act as effect modifiers if they are associated with increased risk of effects related to air pollution exposure. It is often possible to stratify the relationship between health outcome and exposure by one or more of these potential effect modifiers. For variables that modify the association, effect estimates in each stratum will be different from one another and different from the overall estimate, indicating a different exposure-response relationship may exist in populations represented by these variables.

c. Controlled Human Exposure and Animal Toxicology

Controlled human exposure and animal toxicological studies experimentally evaluate the health effects of administered exposures in human volunteers and animal models under highly controlled laboratory conditions. Controlled human exposure studies are also referred to as human clinical studies. In controlled human exposure and animal toxicological experiments, investigators expose subjects or animals to known concentrations of air pollutants under carefully regulated environmental conditions and activity levels. In addition to the general quality considerations discussed previously, evaluation of controlled human exposure and animal toxicological studies includes assessing the design and methodology of each study with focus on (1) characterization of the intake dose, dosing regimen, and exposure route; (2) characterization of the pollutant(s); (3) sample size and statistical power to detect differences; and (4) control of other variables that could influence the occurrence of effects. The evaluation of study design generally includes consideration of factors that minimize bias in results, such as randomization, blinding, and allocation concealment of study subjects, investigators, and research staff, and unexplained loss of animals or withdrawal/exclusion of subjects. Additionally, studies must include appropriate control groups to allow for accurate interpretation of results relative to exposure. Emphasis is placed on studies that address concentration-dependent responses or time-course of responses and studies that investigate potentially at-risk lifestages or populations (e.g., older adults, groups with pre-existing disease).

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Controlled human exposure or animal toxicological studies that approximate expected human exposures in terms of concentration, duration, and route of exposure are of particular interest. Relevant pollutant exposures are considered to be those generally within two orders of magnitude of recent ambient concentrations. This range in relevant exposures is to account for differences in dosimetry, toxicokinetics, and biological sensitivity of various species, strains, or potentially at-risk populations. Studies using higher concentration exposures or doses will be considered to the extent that they provide information relevant to understanding mode of action or mechanisms, inter-species variation, or at-risk human populations. In vitro studies may provide mechanistic insight for effects examined in vivo or in epidemiologic studies.

d. Ecological and Other Welfare Effects

Ecological effects considered in the ISAs typically include several of the topics given as examples by the Clean Air Act definition in Section 302(h) related to effects on welfare including soils, water, vegetation, animals, and wildlife. Additional topic areas that may be evaluated by an ISA include visibility, weather, and climate, as well as materials damage, economic values, and impacts to personal comfort and well-being. In evaluating studies that consider ecological and other welfare effects, in addition to assessing the general quality considerations discussed previously, emphasis is placed on studies that evaluate effects at or near ambient concentrations. Studies conducted in any country that contribute significantly to the general understanding of air pollutant effects may be evaluated for relevance to U.S. air quality considerations and inclusion in the ISA.

For ecological effects, studies at higher concentrations are used to evaluate ecological effects only when they are part of a range of concentrations that also included more ambient-relevant concentrations, or when they inform understanding of modes of action and illustrate the wide range of sensitivity to air pollutants across taxa or across biomes and ecoregions. In evaluating quantitative exposure-response relationships, emphasis is placed on findings from studies conducted in the U.S. and Canada as having ecological and climatic conditions most relevant for review of the NAAQS. The type of experimental approach used in the study (e.g., controlled laboratory exposure, growth chamber, open-top chamber, mesocosm, gradient, field study, etc.) is also evaluated when considering the applicability of the results to the review of criteria air pollutant effects.

In evaluating studies on climate and visibility, emphasis is placed on studies that use well-established measurement and modeling techniques, especially those that report uncertainty or compare results from an ensemble of techniques. Novel methods may also be informative in addressing knowledge gaps not well characterized by existing techniques. Relevant climate studies include those evaluating direct and indirect climate

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impacts of criteria air pollutants at a global scale, while for visibility, studies conducted in the U.S. and Canada provide information more applicable for review of the NAAQS. In both cases, studies that evaluate effects by source sector or region, such as regional climate modeling studies, are particularly informative. Studies that report impacts of multiple PM components for visibility, and, for climate, multiple criteria pollutants are useful in evaluating interactions and the relative contributions of atmospheric constituents. For example, in evaluating the climate forcing effects of ozone (O_3), it is useful to understand the atmospheric chemistry involving CO and NO_X (the sum of nitric oxide and nitrogen dioxide) that affects atmospheric concentrations of O_3. Visibility preference and valuation studies that explicitly separate preferences for visibility from concerns about health risks of air pollution are particularly relevant in considering a welfare-based secondary NAAQS for pollutants that affect visibility.

5. Evaluation, Synthesis, and Integration of Evidence across Disciplines and Development of Scientific Conclusions and Causal Determinations

The U.S. EPA has developed an approach for integrating the scientific evidence gained from the array of studies discussed above in order to draw conclusions regarding the causal nature of ambient air pollutant-related health or welfare effects. Evidence from all disciplines is integrated to evaluate consistency and inconsistency in the pattern of effects as well as strengths and limitations of the evidence across disciplines. Part of this approach includes a framework for making determinations with regard to the existence of a causal relationship between the pollutant in ambient air and health or welfare effects (described in Section 5.b). This framework establishes uniform language concerning causality and brings specificity to the conclusions.

a. Evaluation, Synthesis, and Integration of Evidence across Disciplines

The ISA focuses on evaluation of the findings from the body of evidence across disciplines, drawing upon the results of all studies judged of adequate quality and relevance per the criteria described previously. Evidence from across scientific disciplines for related and similar health or welfare effects is evaluated, synthesized, and integrated to develop conclusions and causality determinations. This process includes evaluating strengths and weaknesses in the overall collection of studies across disciplines. Confidence in the collective body of evidence is based on evaluation of study design and quality. The roles of different types of evidence in drawing the conclusions varies by

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pollutant or assessment, as does the availability of different types of evidence for causality determination. Consideration of human health effects are informed by controlled human exposure, epidemiologic, and toxicological studies. Evidence on ecological and other welfare effects may be drawn from a variety of experimental approaches (e.g., greenhouse, laboratory, field) and numerous disciplines (e.g., community ecology, biogeochemistry, paleontological/historical reconstructions). Other evidence, including mechanistic, toxicokinetics, and exposure assessment, may be highlighted if it is relevant to the evaluation of health and welfare effects and is of sufficient importance to affect the overall evaluation. Causal inference can be strengthened by integrating evidence across disciplines. A weak inference from one line of evidence can be addressed by other lines of evidence, and coherence of these lines of evidence can add support to a cause-effect interpretation of the association. Interpretation of the body of epidemiologic associations as evidence of causal relationships involves assessing the full evidence base with regard to elimination of alternative explanations for the association.

Evaluation and integration of evidence must also include consideration of uncertainty, which is inherent in scientific findings. "Uncertainty" can be defined as a deficit of knowledge to describe the existing state or future outcome with accuracy and precision (e.g., the lack of knowledge about the correct value for a specific measure or estimate). Uncertainty analysis may be qualitative or quantitative in nature. In many cases, the analysis is qualitative and can include professional judgment or inferences based on analogy with similar situations. Quantitative uncertainty analysis may include use of simple measures (e.g., ranges) and analytical techniques. Quantitative uncertainty analysis might progress to more complex measures and techniques, if needed for decision support. Various approaches to evaluating uncertainty include classical statistical methods, sensitivity analysis, or probabilistic uncertainty analysis, in order of increasing complexity and data requirements. However, data may not be available for all aspects of an assessment, and those data that are available may be of questionable or unknown quality. Ultimately, the assessment is based on a number of assumptions with varying degrees of uncertainty. While the ISA may include quantitative analysis approaches such as meta-regression in some situations, generally qualitative evaluation of uncertainties is used to assess the evidence from across studies.

Publication bias is another source of uncertainty that can impact the magnitude of health or welfare risk estimates. It is well understood that studies reporting non-null findings are more likely to be published than reports of null findings. Publication bias can result in overestimation of effect estimate sizes (Ioannidis, 2008). For example, effect estimates from single-city epidemiologic studies have been found to be generally larger than those from multicity studies. This is an indication of publication bias because null or negative

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single-city results may be reported in multicity analyses but might not be published independently (Bell et al., 2005).

Health-specific considerations

Potential strengths and limitations of the body of studies can vary across disciplines and are evaluated during data synthesis and integration. Direct evidence of a relationship between pollutant exposures and human health effects may come from controlled human exposure studies. These studies can also provide important information on the biological plausibility of associations observed in epidemiologic studies and inform determinations of factors that may increase or decrease the risk of health effects in certain populations. In some instances, controlled human exposure studies can be used to characterize concentration-response relationships at pollutant concentrations relevant to ambient conditions. Controlled human exposures are typically conducted using a randomized crossover design, with subjects exposed both to the pollutant and a clean air control. In this way, subjects serve as their own experimental controls, effectively limiting the variance associated with potential inter-individual confounders. Limitations that must be considered in evaluating controlled human study findings include the generally small sample size and short exposure time used in experimental studies, and that severe health outcomes are not assessed. By experimental design, controlled human exposure studies are structured to evaluate physiological or biomolecular outcomes in response to exposure to a specific air pollutant and/or combination of pollutants. In addition, the study design generally precludes inclusion of subjects with serious health conditions or heightened risks of exposure, and therefore, the results often cannot be generalized to an entire population, which includes populations or lifestages at potentially increased risk of air pollutant-induced effects. Although some controlled human exposure studies have included health-compromised individuals, such as those with mild or moderate respiratory or cardiovascular disease, these individuals may also be relatively healthy and may not represent the most sensitive individuals in the population. Thus, observed effects in these studies may underestimate the response in certain populations. In addition, the study design is limited to exposures and endpoints that are not expected to result in severe health outcomes.

Epidemiologic studies provide important information on the associations between health effects and exposure of human populations to ambient air pollution. In epidemiologic or observational studies of humans, the investigator tends not to control exposures or intervene with the study population. Broadly, observational studies can describe associations between exposures and effects. These studies fall into several categories and include, for example, cross-sectional, prospective cohort, time-series, and panel studies. Each type of study has various strengths and limitations. Cross-sectional ecologic studies

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use health outcome, exposure, and covariate data available at the community level (e.g., annual mortality rates and pollutant concentrations), but do not have individual-level data. Cross-sectional studies may have limited power to evaluate an extensive set of confounding factors because these studies examine between-subject or between-location comparisons. Prospective cohort studies include some data collected at the individual level, typically health outcome data, and in some cases, individual-level data on exposure and covariates are collected. Time-series and case-crossover studies are often used to evaluate the relationship between day-to-day changes in air pollution exposures and a specific health outcome at the population-level (i.e., mortality, hospital admissions, or emergency department visits). Panel studies include repeated measurements of health outcomes, such as respiratory symptoms or heart rate variability, at the individual level. "Natural experiments" offer the opportunity to investigate changes in health related to a change in exposure, such as closure of a pollution source.

When evaluating the collective body of epidemiologic studies, consideration of many study design factors and limitations must be taken into account to properly inform their interpretation. One key consideration is the evaluation of the potential independent contribution of the pollutant to a health outcome when it is a component of a complex air pollutant mixture. Reported effect estimates in epidemiologic studies may reflect (1) independent effects on health outcomes, (2) effects of the pollutant acting as an indicator of a copollutant or a complex ambient air pollution mixture, and (3) effects resulting from interactions between that pollutant and copollutants.

The third main type of health effects evidence, animal toxicological studies, provides information on the pollutant's biological action under controlled and monitored exposure circumstances. Taking into account biological differences among species, these studies contribute to our understanding of potential health effects, exposure-response relationships, and modes of action. Further, animal models can inform determinations of factors that may increase or decrease the risk of health effects in certain populations. These studies evaluate the effects of exposures to a variety of pollutants in a highly controlled laboratory setting and allow exploration of toxicological pathways or mechanisms by which a pollutant may cause effects. Understanding the biological mechanisms underlying various health outcomes can be crucial in establishing or negating causality. In the absence of human studies data, extensive, well-conducted animal toxicological studies can support determinations of causality, if the evidence base indicates that similar responses are expected in humans under ambient exposure conditions.

Interpretations of animal toxicological studies are affected by limitations associated with extrapolation between animal and human responses. The differences between humans

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and other species have to be taken into consideration, including metabolism, hormonal regulation, breathing pattern, and differences in lung structure and anatomy. Also, in spite of a high degree of homology and the existence of a high percentage of orthologous genes across humans and rodents (particularly mice), extrapolation of molecular alterations at the gene or protein level is complicated by species-specific differences in transcriptional regulation and/or signaling. Given these differences, uncertainties are associated with quantitative extrapolations of observed pollutant-induced pathophysiological alterations between laboratory animals and humans, as those alterations are under the control of widely varying biochemical, endocrine, and neuronal factors.

Ecological- and welfare-specific considerations

For ecological effects assessment, both laboratory and field studies (including field experiments and observational studies) can provide useful data for causal determination. Because conditions can be controlled in laboratory studies, responses may be less variable and smaller effects may be easier to detect. However, the control conditions may limit the range of responses (e.g., animals may not be able to seek alternative food sources) or incompletely reflect pollutant bioavailability, so the responses under controlled conditions may not reflect responses that would occur in the natural environment. In addition, larger scale processes are difficult to reproduce in the laboratory.

Field observational studies measure biological changes in uncontrolled situations with high natural variability (in organismal genetics or in abiotic seasonal, climatic, or soil-related factors) and describe an association between a disturbance and an ecological effect. Field data can provide important information to assess multiple stressors or circumstances where site-specific factors significantly influence exposure. Field data are also often useful for analyzing pollutant effects at larger geographic scales and higher levels of biological organization. However, because conditions are not controlled, variability of the response is expected to be higher and may mask effects. Field surveys are most useful for linking stressors with effects when stressor and effect levels are measured concurrently. The presence of confounding factors can make it difficult to attribute observed effects to specific stressors.

Ecological impacts of pollutants are also evaluated in studies "intermediate" between the lower variability typically associated with laboratory exposures and high natural variability usually found in field studies. Some studies use environmental media collected from the field to examine the biological responses under controlled laboratory conditions. Other studies are experiments performed in the natural environment that control for some, but not all, of the environmental or genetic variability (e.g., mesocosm studies).

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This type of study in manipulated natural environments can be considered a hybrid between a field experiment and laboratory study because some sources of response variation are removed through use of control conditions, while others are included to mimic natural variation. Such studies make it possible to observe community and/or ecosystem dynamics and provide strong evidence for causality when combined with findings of studies that have been made under more controlled conditions.

b. Considerations in Developing Scientific Conclusions and Causal Determinations

In its evaluation and integration of the scientific evidence on health or welfare effects of criteria pollutants, the U.S. EPA determines the weight of evidence in support of causation and characterizes the strength of any resulting causal classification. The U.S. EPA also evaluates the quantitative evidence and draws scientific conclusions, to the extent possible, regarding the concentration-response relationships and the loads to ecosystems, exposures, doses or concentrations, exposure duration, and pattern of exposures at which effects are observed.

Approaches to assessing the separate and combined lines of human health evidence (e.g., epidemiologic, controlled human exposure, and animal toxicological studies) have been formulated by a number of regulatory and science agencies, including the National Academy of Sciences (NAS) Institute of Medicine (IOM, 2008), the International Agency for Research on Cancer (IARC, 2006), the U.S. EPA (2005), and the Centers for Disease Control and Prevention (CDC, 2004)]. Causal inference criteria have also been described for ecological effects evidence (U.S. EPA, 1998; Fox, 1991). These formalized approaches offer guidance for assessing causality. The frameworks of each are similar in nature, although adapted to different purposes, and have proven effective in providing a uniform structure and language for causal determinations.

The 1964 Surgeon General's report on tobacco smoking defined "cause" as a "significant, effectual relationship between an agent and an associated disorder or disease in the host" (HEW, 1964). More generally, a cause is defined as an agent that brings about an effect or a result. An association is the statistical relationship among variables, but alone, it is insufficient proof of a causal relationship between an exposure and a health outcome. Unlike an association, a causal claim supports the creation of counterfactual claims; that is, a claim about what the world would have been like under different or changed circumstances (IOM, 2008).

Many of the health and welfare outcomes reported in studies have complex etiologies. Diseases such as asthma, coronary heart disease, or cancer are typically initiated by

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multiple agents. Outcomes depend on a variety of factors, such as age, genetic background, nutritional status, immune competence, and social factors (IOM, 2008; Gee and Payne-Sturges, 2004). Effects on ecosystems are also often multifactorial with a complex web of causation. Further, exposure to a combination of agents could cause synergistic or antagonistic effects. Thus, the observed risk may represent the net effect of many actions and counteractions.

To aid judgment, various "aspects"[1] of causality have been discussed by many philosophers and scientists. The 1964 Surgeon General's report on tobacco smoking discussed criteria for the evaluation of epidemiologic studies, focusing on consistency, strength, specificity, temporal relationship, and coherence (HEW, 1964). Sir Austin Bradford Hill (Hill, 1965) articulated aspects of causality in epidemiology and public health that have been widely used (IOM, 2008; IARC, 2006; U.S. EPA, 2005; CDC, 2004). These aspects (Hill, 1965) have been modified (Table I) for use in causal determinations specific to health and welfare effects for pollutant exposures (U.S. EPA, 2009).[2] Although these aspects provide a framework for assessing the evidence, they do not lend themselves to being considered in terms of simple formulas or fixed rules of evidence leading to conclusions about causality (Hill, 1965). For example, one cannot simply count the number of studies reporting statistically significant results or statistically nonsignificant results and reach credible conclusions about the relative weight of evidence and the likelihood of causality. Rather, these aspects provide a framework for systematic appraisal of the body of evidence, informed by peer and public comment and advice, which includes weighing alternative views on controversial issues. In addition, it is important to note that the aspects in Table I cannot be used as a strict checklist, but rather to determine the weight of evidence for inferring causality. In particular, not meeting one or more of the principles does not automatically preclude a determination of causality [see discussion in (CDC, 2004)].

[1] The "aspects" described by Sir Austin Bradford Hill (Hill, 1965) have become, in the subsequent literature, more commonly described as "criteria." The original term "aspects" is used here to avoid confusion with "criteria" as it is used, with different meaning, in the Clean Air Act.

[2] The Hill aspects were developed for interpretation of epidemiologic results. They have been modified here for use with a broader array of data (i.e., epidemiologic, controlled human exposure, ecological, and animal toxicological studies as well as in vitro data) and to be more consistent with the EPA Guidelines for Carcinogen Risk Assessment.

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Table I Aspects to aid in judging causality.

Aspect	Description
Consistency	An inference of causality is strengthened when a pattern of elevated risks is observed across several independent studies. The reproducibility of findings constitutes one of the strongest arguments for causality. Statistical significance is not the sole criterion by which the presence or absence of an effect is determined. If there are discordant results among investigations, possible reasons such as differences in exposure, confounding factors, and the power of the study are considered.
Coherence	An inference of causality from one line of evidence (e.g., epidemiologic, controlled human exposure, animal, or ecological studies) may be strengthened by other lines of evidence that support a cause-and-effect interpretation of the association. There may be coherence in demonstrating effects from evidence across various fields and/or across multiple study designs or related health endpoints within one scientific line of evidence. For example, evidence on welfare effects may be drawn from a variety of experimental approaches (e.g., greenhouse, laboratory, and field) and subdisciplines of ecology (e.g., community ecology, biogeochemistry, and paleontological/historical reconstructions).
Biological plausibility	An inference of causality is strengthened by results from experimental studies or other sources demonstrating biologically plausible mechanisms. A proposed mechanism, which is based on experimental evidence and which links exposure to an agent to a given effect, is an important source of support for causality.
Biological gradient (exposure-response relationship)	A well-characterized exposure-response relationship (e.g., increasing effects associated with greater exposure) strongly suggests cause and effect, especially when such relationships are also observed for duration of exposure (e.g., increasing effects observed following longer exposure times).
Strength of the observed association	The finding of large, precise risks increases confidence that the association is not likely due to chance, bias, or other factors. However, it is noted that a small magnitude in an effect estimate may or may not represent a substantial effect in a population.
Experimental evidence	Strong evidence for causality can be provided through “natural experiments” when a change in exposure is found to result in a change in occurrence or frequency of health or welfare effects.
Temporality of the observed association	Evidence of a temporal sequence between the introduction of an agent and appearance of the effect constitutes another argument in favor of causality.
Specificity of the observed association	Evidence linking a specific outcome to an exposure can provide a strong argument for causation. However, it must be recognized that rarely, if ever, does exposure to a pollutant invariably predict the occurrence of an outcome, and that a given outcome may have multiple causes.
Analogy	Structure activity relationships and information on the agent’s structural analogs can provide insight into whether an association is causal. Similarly, information on mode of action for a chemical, as one of many structural analogs, can inform decisions regarding likely causality.

Consistency of findings across studies is informed by the repeated observation of effects or associations across multiple independent studies. Further strength is provided by reproducibility of findings in different populations under different circumstances.

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However, discordant results among independent investigations may be explained by differences in study methods, random errors, exposure, confounding factors, or study power, and thus may not be used to rule out a causal connection.

In evaluating the consistency of findings across studies, the U.S. EPA emphasizes the importance of examining the pattern of results across various studies and does not focus solely on statistical significance or the magnitude of the direction of the association as criteria of study reliability. Statistical significance is influenced by a variety of factors including, but not limited to, the size of the study, exposure and outcome measurement error, and statistical model specifications. Statistical significance may be informative; however, it is just one of the means of evaluating confidence in the observed relationship and assessing the probability of chance as an explanation. Other indicators of reliability such as the consistency and coherence of a body of studies as well as other confirming data may be used to justify reliance on the results of a body of epidemiologic studies, even if results in individual studies lack statistical significance. Traditionally, statistical significance is used to a larger extent to evaluate the findings of controlled human exposure and animal toxicology studies. Understanding that statistical inferences may result in both false positives and false negatives, consideration is given to both trends in data and reproducibility of results. Thus, in drawing judgments regarding causality, the U.S. EPA emphasizes statistically significant findings from experimental studies, but does not limit its focus or consideration to statistically significant results in epidemiologic studies.

In evaluating the strength of the observed association, the U.S. EPA considers both the magnitude and statistical precision (i.e., width of confidence interval) of the association in epidemiologic studies. In a large study that accounts for several potential confounding factors, a strong association can serve to increase confidence that a finding is not due to a weak unmeasured confounder, chance, or other biases. However, in a study that accounts for several potential confounding factors and other sources of bias, a weak association does not rule out a causal connection. The health effects evaluated in the ISAs tend to have multiple risk factors that likely vary in strength of effect, and the magnitude of effect of air pollution exposure will depend on the prevalence of other risk factors in the study population. Further, a small effect size can be important from a public health impact perspective. The air pollution-related change in a health effect observed in a study can represent a shift in the distribution of responses in the study population and potentially an increase in the proportion of individuals with clinically important effects.

In making judgments regarding causality, the biological plausibility of effects resulting from air pollutant exposure is considered. Experimental results from in vivo studies involving animal models and humans, as well as from in vitro studies when appropriate,

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may be used to establish biological plausibility and to interpret other lines of evidence (e.g., health effects from epidemiologic studies). Biological plausibility is often provided from understanding the mode of action by which exposure to a pollutant leads to health effects. This understanding may encompass several different levels of biological organization including, but not limited to, molecular and cellular events in the pathways leading to disease. While a complete understanding of the mode of action is not considered necessary for making causal determinations within the ISA, biological plausibility plays a key role.

c. Framework for Causal Determinations

In the ISA, the U.S. EPA assesses the body of relevant literature, building upon evidence available during previous NAAQS reviews, to draw conclusions on the causal relationships between relevant pollutant exposures and health or environmental effects. ISAs use a five-level hierarchy that classifies the weight of evidence for causation.[1] This weight-of-evidence evaluation is based on the integration of findings from various lines of evidence from across health and environmental effect disciplines that are integrated into a qualitative statement about the overall weight of the evidence and causality. The five descriptors for causal determination are described in Table II.

Table II Weight of evidence for causal determination.

	Health Effects	Ecological and Other Welfare Effects
Causal relationship	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures (e.g., doses or exposures generally within one to two orders of magnitude of recent concentrations). That is, the pollutant has been shown to result in health effects in studies in which chance, confounding, and other biases could be ruled out with reasonable confidence. For example: (1) controlled human exposure studies that demonstrate consistent effects, or (2) observational studies that cannot be explained by plausible alternatives or that are supported by other lines of evidence (e.g., animal studies or mode of action information). Generally, the determination is based on multiple high-quality studies conducted by multiple research groups.	Evidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures. That is, the pollutant has been shown to result in effects in studies in which chance, confounding, and other biases could be ruled out with reasonable confidence. Controlled exposure studies (laboratory or small- to medium-scale field studies) provide the strongest evidence for causality, but the scope of inference may be limited. Generally, the determination is based on multiple studies conducted by multiple research groups, and evidence that is considered sufficient to infer a causal relationship is usually obtained from the joint consideration of many lines of evidence that reinforce each other.

[1] The CDC and IOM frameworks use a four-level hierarchy for the strength of the evidence. A five-level hierarchy is used here to be consistent with the five-level hierarchy used in the U.S. *EPA Guidelines for Carcinogen Risk Assessment* and to provide a more nuanced set of categories.

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Table II (Continued): Weight of evidence for causal determination.

	Health Effects	Ecological and Other Welfare Effects
Likely to be a causal relationship	Evidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures. That is, the pollutant has been shown to result in health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the evidence overall. For example: (1) observational studies show an association, but copollutant exposures are difficult to address and/or other lines of evidence (controlled human exposure, animal, or mode of action information) are limited or inconsistent, or (2) animal toxicological evidence from multiple studies from different laboratories demonstrate effects, but limited or no human data are available. Generally, the determination is based on multiple high-quality studies.	Evidence is sufficient to conclude that there is a likely causal association with relevant pollutant exposures. That is, an association has been observed between the pollutant and the outcome in studies in which chance, confounding, and other biases are minimized but uncertainties remain. For example, field studies show a relationship, but suspected interacting factors cannot be controlled, and other lines of evidence are limited or inconsistent. Generally, the determination is based on multiple studies by multiple research groups.
Suggestive of, but not sufficient to infer, a causal relationship	Evidence is suggestive of a causal relationship with relevant pollutant exposures but is limited, and chance, confounding, and other biases cannot be ruled out. For example: (1) when the body of evidence is relatively small, at least one high-quality epidemiologic study shows an association with a given health outcome and/or at least one high-quality toxicological study shows effects relevant to humans in animal species, or (2) when the body of evidence is relatively large, evidence from studies of varying quality is generally supportive but not entirely consistent, and there may be coherence across lines of evidence (e.g., animal studies or mode of action information) to support the determination.	Evidence is suggestive of a causal relationship with relevant pollutant exposures, but chance, confounding, and other biases cannot be ruled out. For example, at least one high-quality study shows an effect, but the results of other studies are inconsistent.
Inadequate to infer a causal relationship	Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quantity, quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.	Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect.
Not likely to be a causal relationship	Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies, covering the full range of levels of exposure that human beings are known to encounter and considering at-risk populations and lifestages, are mutually consistent in not showing an effect at any level of exposure.	Evidence indicates there is no causal relationship with relevant pollutant exposures. Several adequate studies examining relationships with relevant exposures are consistent in failing to show an effect at any level of exposure.

This standardized language was drawn from sources across the federal government and wider scientific community, especially the U.S. EPA *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005), U.S. Surgeon General's report, *The Health Consequences of Smoking* (CDC, 2004), and NAS IOM document, *Improving the Presumptive Disability Decision-Making Process for Veterans* (IOM, 2008), a comprehensive report on evaluating causality.

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This framework:

- describes the kinds of scientific evidence used in making determinations on causal relationships between exposure and health or welfare effects,
- summarizes the key aspects of the evaluation of evidence necessary to reach a conclusion about the existence of a causal relationship,
- identifies issues and approaches related to uncertainty, and
- classifies and characterizes the weight of evidence in support of a general causal determination.

Determination of causality involves evaluating and integrating evidence for different types of health or welfare effects associated with short- and long-term exposure periods. In drawing conclusions regarding causality, evidence is evaluated for major outcome categories or groups of related endpoints (e.g., respiratory effects, vegetation growth), integrating evidence from across disciplines, and evaluating the coherence of evidence across a spectrum of related endpoints. In discussing the causal determination, the U.S. EPA characterizes the evidence on which the judgment is based, including strength of evidence for individual endpoints within the outcome category or group of related endpoints.

In drawing judgments regarding causality for the criteria air pollutants, the ISA focuses on evidence of effects in the range of relevant pollutant exposures or doses and not on determination of causality at any dose. Emphasis is placed on evidence of effects at doses (e.g., blood Pb concentration) or exposures (e.g., air concentrations) that are relevant to, or somewhat above, those currently experienced by the population. The extent to which studies of higher concentrations are considered varies by pollutant and major outcome category, but generally includes those with doses or exposures in the range of one to two orders of magnitude above current or ambient conditions to account for intra-species variability and toxicokinetic or toxicodynamic differences between experimental animals and humans. Studies that use higher doses or exposures may also be considered to the extent that they provide useful information to inform understanding of mode of action, inter-species differences, or factors that may increase risk of effects for a population and if biological mechanisms have not been demonstrated to differ based on exposure concentration. Thus, a causality determination is based on weight-of-evidence evaluation for health or welfare effects, focusing on the evidence from exposures or doses generally ranging from recent ambient concentrations to one or two orders of magnitude above recent ambient concentrations.

In addition, the U.S. EPA evaluates evidence relevant to understanding the quantitative relationships between pollutant exposures and health or welfare effects. This includes evaluating the form of concentration-response or dose-response relationships and, to the

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extent possible, drawing conclusions on the concentrations at which effects are observed. The ISA also draws scientific conclusions regarding important exposure conditions for effects and populations and lifestages that may be at greater risk for effects, as described in the following two sections on public health and public welfare impacts.

6. Public Health Impact

Once a determination is made regarding the causality of relationship between the pollutant and outcome category, the public health impact of exposure to the pollutant is evaluated. Important questions regarding the public health impact include:

- What populations and lifestages appear to be differentially affected (i.e., at greater or less risk of experiencing effects)?
- What exposure conditions (dose or exposure, duration, and pattern) are important?
- What is the severity of the effect (e.g., clinical relevance)?
- What is the concentration-response, exposure-response, or dose-response relationship in the human population?
- What is the interrelationship between incidence and severity of effect?

To address these questions, the entirety of quantitative evidence is evaluated to characterize pollutant concentrations and exposure durations at which effects were observed for exposed populations, including populations and lifestages potentially at increased risk. To accomplish this, evidence is considered from multiple and diverse types of studies, and a study or set of studies that best approximates the concentration-response relationships between health outcomes and the pollutant may be identified. Controlled human exposure studies provide the most direct and quantifiable exposure-response data on the human health effects of pollutant exposures, although they tend to examine potential at-risk populations and lifestages to a limited extent and tend to have small sample sizes for between-group comparisons. To the extent available, the ISA evaluates results from epidemiologic studies that characterize the shape of the relationship between a pollutant and a health outcome. Animal data may also inform evaluation of concentration-response relationships, particularly relative to modes of action and characteristics of at-risk populations.

a. Approach to Identifying, Evaluating, and Characterizing At-Risk Factors

A critical part of assessing the public health impact of an air pollutant is the identification, evaluation, and characterization of populations potentially at greater risk of

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an air pollutant-related health effect. Under the Clean Air Act, the primary NAAQS are intended to protect public health with an adequate margin of safety. In doing so, protection is provided for both the population as a whole and those groups potentially at increased risk for health effects from exposure to a criteria air pollutant. To inform decisions on the NAAQS, the ISA evaluates the currently available information regarding those factors (e.g., lifestage, pre-existing disease) that contribute to portions of the population being at greater risk for an air pollutant-related health effect.

Studies often use a variety of terms to classify factors and subsequently populations that may be at increased risk of an air pollutant-related health effect, including "susceptible," "vulnerable," "sensitive," and "at-risk," with recent literature introducing the term "response-modifying factor" (Vinikoor-Imler et al., 2014; Sacks et al., 2011; U.S. EPA, 2010, 2009). The inconsistency in the definitions for each of these terms across the scientific literature has shifted the focus away from answering the key questions: Which populations are at increased risk and what evidence forms the basis of this conclusion (Vinikoor-Imler et al., 2014)? Due to the lack of a consensus on terminology in the scientific community, the term "susceptible populations" was used in previous reviews and ISAs (Sacks et al., 2011; U.S. EPA, 2010, 2009) to encompass these various factors. However, it was recognized that even using the term "susceptible populations" was problematic because it often refers to populations at increased risk specifically due to biological or intrinsic factors such as pre-existing disease or lifestage. As such, starting with the ISA for Ozone and Related Photochemical Oxidants (U.S. EPA, 2013), the terminology "at-risk" was introduced to define populations and lifestages potentially at increased risk of an air pollutant-related health effect. In assessing the overall public health impact of an air pollutant, the ISA focuses on identifying, evaluating, and characterizing "at-risk" factors to address the main question of what populations and lifestages are at increased risk of an air pollutant-related health effect. Each "at-risk" factor is evaluated with a focus on identifying whether the factor contributes to a population at increased risk of an air pollutant-related health effect. Some factors may lead to a reduction in risk, and these are acknowledged during the evaluation process. However, for the purposes of identifying those populations or lifestages at increased risk to inform decisions on the NAAQS, the focus of this ISA is on characterizing those factors that may increase risk.

A population or lifestage may be at increased risk for various reasons, which can generally be divided into four broad categories. The first category of factors often is referred to as intrinsic. Intrinsic factors can increase risk for an effect through a biological mechanism and include genetic or developmental factors, race, sex, lifestage, or the presence of pre-existing diseases. For example, people in this category would have a steeper concentration-risk relationship and a greater or more severe effect at a given

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pollutant concentration compared to those not in the category. The second category often is referred to as extrinsic or nonbiological. These factors include SES (e.g., educational attainment, income, access to healthcare), activity pattern, and exercise level. The third category includes factors that can increase risk by increasing internal dose at a given exposure concentration. Individuals in this category could have a greater dose of delivered pollutant because of breathing patterns and could include children who are typically more active outdoors. In addition, some groups could have greater exposure (concentration × time) regardless of the delivered dose, such as outdoor workers. The final category encompasses factors that may increase risk for experiencing a greater exposure based on exposure to a higher concentration. For example, populations that live near roadways could be exposed to higher pollutant concentrations. Some factors described above are multifaceted and may influence the risk of an air pollutant-related health effect through a combination of ways (e.g., SES). Additionally, it is recognized that some portions of the population or lifestages may be at increased risk of an air pollutant-related health effect because they experience insults from a combination of factors. The emphasis is to identify and understand the factors that potentially increase the risk of air pollutant-related health effects, regardless of whether the increased risk is due to intrinsic factors, extrinsic factors, increased dose/exposure, or a combination due to the often interconnectedness of factors.

To identify at-risk factors that potentially lead to some portions of the population being at increased risk of air pollution-related health effects, the evidence is systematically evaluated across relevant scientific disciplines (i.e., exposure sciences, dosimetry, toxicology, epidemiology). The evaluation process consists of evaluating studies that conduct stratified analyses (i.e., epidemiologic, controlled human exposure) to compare populations or lifestages exposed to similar air pollutant concentrations within the same study design. Experimental studies also provide an important line of evidence in evaluating factors that can lead to increased risk of an air pollutant-related health effect. Specifically, toxicological studies conducted using animal models of disease and controlled human exposure studies that examine individuals with underlying disease or genetic polymorphisms can provide coherence with the health effects observed in epidemiologic studies as well as an understanding of biological plausibility. The potential increased risk of an air pollutant-related health effect may also be determined from studies that examine factors that result in differential air pollutant exposures. The characterization of each at-risk factor consists of evaluating the evidence across scientific disciplines and assessing the overall confidence that a specific factor may result in a population or lifestage being at increased risk of an air pollutant-related health effect. The categories considered for evaluating the potential increased risk of an air pollutant-related health effect are "adequate evidence," "suggestive evidence," "inadequate evidence," and "evidence of no effect." They are described in more detail in Table III.

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Table III Characterization of evidence for potential at-risk factors.

Classification	Health Effects
Adequate evidence	There is substantial, consistent evidence within a discipline to conclude that a factor results in a population or lifestage being at increased risk of air pollutant-related health effect(s) relative to some reference population or lifestage. Where applicable, this evidence includes coherence across disciplines. Evidence includes multiple high-quality studies.
Suggestive evidence	The collective evidence suggests that a factor results in a population or lifestage being at increased risk of air pollutant-related health effect(s) relative to some reference population or lifestage, but the evidence is limited due to some inconsistency within a discipline or, where applicable, a lack of coherence across disciplines.
Inadequate evidence	The collective evidence is inadequate to determine whether a factor results in a population or lifestage being at increased risk of air pollutant-related health effect(s) relative to some reference population or lifestage. The available studies are of insufficient quantity, quality, consistency, and/or statistical power to permit a conclusion to be drawn.
Evidence of no effect	There is substantial, consistent evidence within a discipline to conclude that a factor does not result in a population or lifestage being at increased risk of air pollutant-related health effect(s) relative to some reference population or lifestage. Where applicable, the evidence includes coherence across disciplines. Evidence includes multiple high-quality studies.

b. Evaluating Adversity of Human Health Effects

In evaluating health evidence, a number of factors can be considered in delineating between adverse and nonadverse health effects resulting from exposure to air pollution. Some health outcomes, such as hospitalization for respiratory or cardiovascular diseases, are clearly adverse. It is more difficult to determine the extent of change that constitutes adversity in more subtle health measures. These more subtle health effects include a wide variety of responses, such as alterations in markers of inflammation or oxidative stress, changes in pulmonary function or heart rate variability, or alterations in neurocognitive function measures. The challenge is to determine the magnitude of change in these measures when there is no clear point at which a change becomes adverse. The extent to which a change in health measure constitutes an adverse health effect may vary between populations and lifestages. Some changes that may not be considered adverse in healthy individuals would be potentially adverse in more at-risk individuals.

Professional scientific societies may evaluate the magnitude of change in an outcome or event that is considered adverse. For example, in an official statement titled *What Constitutes an Adverse Health Effect of Air Pollution?* (ATS, 2000), the American Thoracic Society described transient decrements in lung function as adverse when accompanied by clinical symptoms. Additionally, an air pollution-induced shift in the

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population distribution of a given risk factor for a health outcome was viewed as adverse, even though it may not increase the risk of any one individual to an unacceptable level. For example, a population with asthma could have a distribution of lung function such that no identifiable individual has a level associated with significant impairment. Exposure to air pollution could shift the distribution such that no identifiable individual experiences clinically relevant effects. This shift toward decreased lung function, however, could be considered adverse because individuals within the population would have diminished reserve function and therefore would be at increased risk to further environmental insult. The committee also observed that elevations of biomarkers, such as cell number and types, cytokines, and reactive oxygen species, may signal risk for ongoing injury and clinical effects or may simply indicate transient responses that can provide insights into mechanisms of injury, thus illustrating the lack of clear boundaries that separate adverse from nonadverse effects.

The more subtle health outcomes may be connected mechanistically to health events that are clearly adverse. For example, air pollution may affect markers of transient myocardial ischemia such as ST-segment abnormalities or onset of exertional angina. These effects may not be apparent to the individual, yet may still increase the risk of a number of cardiac events, including myocardial infarction and sudden death. Thus, small changes in physiological measures may not appear to be clearly adverse when considered alone, but may be a part of a coherent and biologically plausible chain of related health outcomes that range up to responses that are very clearly adverse, such as hospitalization or mortality.

c. Concentration-Response Relationships

An important consideration in characterizing the public health impacts associated with exposure to a pollutant is whether the concentration-response relationship is linear across the range of concentrations or if nonlinear relationships exist along any part of this range. The shape of the concentration-response curve at and below the level of the current standards is of particular interest. Various sources of variability and uncertainty, such as low data density in the lower concentration range, possible influence of exposure measurement error, and variability among individuals with respect to air pollution health effects, tend to smooth and "linearize" the concentration-response function and thus can obscure the existence of a threshold or nonlinear relationship. Because individual thresholds vary from person-to-person due to individual differences such as genetic differences or pre-existing disease conditions (and even can vary from one time to another for a given person), it can be difficult to demonstrate that a threshold exists in a population study. These sources of variability and uncertainty may explain why the

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available human data at ambient concentrations for some environmental pollutants (e.g., PM, O_3, Pb, environmental tobacco smoke, radiation) do not exhibit population-level thresholds for cancer or noncancer health effects, even though likely mechanisms include nonlinear processes for some key events.

7. Public Welfare Impact

Once a determination is made regarding the causality of relationships between the pollutant and outcome category, important questions regarding the public welfare impact include:

- What endpoints or services appear to be differentially affected (i.e., at greater or less risk of experiencing effects)? What elements of the ecosystem (e.g., types, regions, taxonomic groups, populations, functions, etc.) appear to be affected, or are more sensitive to effects? Are there differences between locations or materials in welfare effects responses, such as impaired visibility or materials damage?
- What is concluded from the evidence with regard to other types of welfare effects?
- Under what exposure conditions (amount deposited or concentration, duration, and pattern) are effects seen?
- What is the shape of the concentration-response, exposure-response, or dose-response relationship?

To address these questions, the entirety of quantitative evidence is evaluated to characterize pollutant concentrations and exposure durations at which effects were observed. To accomplish this, evidence is considered from multiple and diverse types of studies, and a study or set of studies that best approximates the concentration-response relationships between welfare outcomes and the pollutant may be identified. Controlled experimental studies provide the most direct and quantifiable exposure-response data on the effects of pollutant exposures. To the extent available, the ISA also evaluates results from less controlled field studies that characterize the shape of the relationship between a pollutant and an outcome. Other types of data may also inform evaluation of concentration-response relationships, particularly relative to modes of action and characteristics of at-risk ecosystems.

a. Evaluating Adversity of Ecological and Other Welfare Effects

The final step in assessing the public welfare impact of an air pollutant is the evaluation of the level considered to be adverse. A secondary standard, as defined in Section 109(b)(2) of the CAA must "specify a level of air quality the attainment and

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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." In setting standards that are "requisite" to protect public health and welfare, as provided in Section 109(b), the U.S. EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes.

Adversity of ecological effects can be understood in terms ranging in biological level of organization from the cellular level to the individual organism and to the population, community, and ecosystem levels. In the context of ecology, a population is a group of individuals of the same species, and a community is an assemblage of populations of different species that inhabit an area and interact with one another. An ecosystem is the interactive system formed from all living organisms and their abiotic (physical and chemical) environment within a given area (IPCC, 2007). The boundaries of what could be called an ecosystem are somewhat arbitrary, depending on the focus of interest or study. Thus, the extent of an ecosystem may range from very small spatial scales to, ultimately, the entire Earth (IPCC, 2007).

Effects on an individual organism are generally not considered to be adverse to public welfare. However if effects occur to enough individuals within a population, then communities and ecosystems may be disrupted. Changes to populations, communities, and ecosystems can in turn result in an alteration of ecosystem processes. Ecosystem processes are defined as the metabolic functions of ecosystems, including energy flow, elemental cycling, and the production, consumption, and decomposition of organic matter (U.S. EPA, 2002). Growth, reproduction, and mortality are species-level endpoints that may be clearly linked to community and ecosystem effects and are considered to be adverse when negatively affected. Other endpoints, such as changes in behavior and physiological stress, can decrease ecological fitness of an organism but are harder to link unequivocally to effects at the population, community, and ecosystem level. Support for consideration of adversity beyond the species level by making explicit the linkages between stress-related effects at the species and effects at the ecosystem level is found in *A Framework for Assessing and Reporting on Ecological Condition: an SAB report* (U.S. EPA, 2002). Additionally, the National Acid Precipitation Assessment Program (NAPAP, 1991) uses the following working definition of "adverse ecological effects" in the preparation of reports to Congress mandated by the Clean Air Act: "any injury (i.e., loss of chemical or physical quality or viability) to any ecological or ecosystem component, up to and including the regional level, over both long and short terms."

Beyond species-level impacts, consideration of ecosystem services allows for evaluation of how pollutant exposure may adversely impact species or processes of particular

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economic or cultural importance to humans. On a broader scale, ecosystem services may provide indicators for ecological impacts. Ecosystem services are the benefits that people obtain from ecosystems (UNEP, 2003). According to the *Millennium Ecosystem Assessment*, ecosystem services include "provisioning services such as food and water; regulating services such as regulation of floods, drought, land degradation, and disease; supporting services such as soil formation and nutrient cycling; and cultural services such as recreational, spiritual, religious, and other nonmaterial benefits" (UNEP, 2003). For example, a more subtle ecological effect of pollution exposure may result in a clearly adverse impact on ecosystem services if it results in a population decline in a species that is recreationally or culturally important.

A consideration in evaluating adversity of climate-related effects is that criteria air pollutants have both direct and indirect effects on radiative forcing. For example, CO has a relatively small direct forcing effect, but it influences the concentrations of other atmospheric species, such as O_3 and methane, which are important contributors to climate forcing. PM has both direct and indirect effects. For example, black carbon and sulfate contribute directly to warming and cooling, respectively, while aerosols are involved in cloud formation which affects climate indirectly. Thus, it is crucial to consider the role of multiple pollutants together in evaluating the climate impact of criteria pollutants. Although climate effects of criteria air pollutants impact terrestrial and aquatic environments in diverse ways over multiple time scales, their effect on temperature is the main metric of adversity, with some consideration of proximate effects such as precipitation and relatively rapid feedbacks impacting the composition of the troposphere. Downstream effects such as land use changes are more difficult to link back to changes in concentrations of individual pollutants regulated under the NAAQS. The relative adversity of U.S. versus global emissions and concentrations is informed by regional climate modeling studies, including consideration of uncertainty and spatial and temporal variability.

The adversity of visibility impacts may be expressed in terms of psychological stress, such as impairment of aesthetic quality or enjoyment of the environment, or in monetary terms, such as willingness to pay to improve air quality. Understanding the relationship between pollutant concentration and perception of visibility, including distinguishing between concerns about health risks due to air pollution and perceived visibility impairment, can be crucial in evaluating the level of protection provided by a welfare-based secondary NAAQS when impacts on visibility are among the welfare effects that are potentially relevant for a pollutant.

Adversity of materials damage is evaluated considering the impact to human and economic well-being. Physical damage and soiling impair aesthetic qualities and function

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of materials. Additionally, damage to property and cultural heritage sites due to pollutant deposition may be considered adverse.

b. Quantitative Relationships: Effects on Welfare

Evaluations of causality generally consider the probability of quantitative changes in welfare effects in response to exposure. A challenge to the quantification of exposure-response relationships for ecological effects is the great regional and local spatial variability, as well as temporal variability, in ecosystems. Thus, exposure-response relationships are often determined for a specific ecological system and scale, rather than at the national or even regional scale. Quantitative relationships, therefore, are estimated site by site and may differ greatly between ecosystems.

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References

ATS (American Thoracic Society). (2000). What constitutes an adverse health effect of air pollution? Am J Respir Crit Care Med 161: 665-673. http://dx.doi.org/10.1164/ajrccm.161.2.ats4-00

Bell, ML; Dominici, F; Samet, JM. (2005). A meta-analysis of time-series studies of ozone and mortality with comparison to the national morbidity, mortality, and air pollution study. Epidemiology 16: 436-445. http://dx.doi.org/10.1097/01.ede.0000165817.40152.85

CAA (Clean Air Act). (1990a). Clean Air Act, as amended by Pub. L. No. 101-549, section 108: Air quality criteria and control techniques, 42 USC 7408. http://www.law.cornell.edu/uscode/text/42/7408

CAA (Clean Air Act). (1990b). Clean Air Act, as amended by Pub. L. No. 101-549, section 109: National primary and secondary ambient air quality standards, 42 USC 7409. http://www.epa.gov/air/caa/title1.html#ia

CDC (Centers for Disease Control and Prevention). (2004). The health consequences of smoking: A report of the Surgeon General. Washington, DC: U.S. Department of Health and Human Services. http://www.surgeongeneral.gov/library/smokingconsequences/

Fox, GA. (1991). Practical causal inference for ecoepidemiologists. J Toxicol Environ Health A 33: 359-373. http://dx.doi.org/10.1080/15287399109531535

Gee, GC; Payne-Sturges, DC. (2004). Environmental health disparities: A framework integrating psychosocial and environmental concepts [Review]. Environ Health Perspect 112: 1645-1653. http://dx.doi.org/10.1289/ehp.7074

HEW (U.S. Department of Health, Education and Welfare). (1964). Smoking and health: Report of the advisory committee to the surgeon general of the public health service. Washington, DC: U.S. Department of Health, Education, and Welfare. http://profiles.nlm.nih.gov/ps/retrieve/ResourceMetadata/NNBBMQ

Hill, AB. (1965). The environment and disease: Association or causation? Proc R Soc Med 58: 295-300.

IARC (International Agency for Research on Cancer). (2006). IARC monographs on the evaluation of carcinogenic risks to humans: Preamble. Lyon, France: World Health Organization. http://monographs.iarc.fr/ENG/Preamble/

Ioannidis, JPA. (2008). Why most discovered true associations are inflated [Review]. Epidemiology 19: 640-648. http://dx.doi.org/10.1097/EDE.0b013e31818131e7

IOM (Institute of Medicine). (2008). Improving the presumptive disability decision-making process for veterans. In JM Samet; CC Bodurow (Eds.), Improving the Presumptive Disability Decision-making Process for Veterans. Washington, DC: National Academies Press. http://www.nap.edu/openbook.php?record_id=11908

IPCC (Intergovernmental Panel on Climate Change). (2007). Climate change 2007: Impacts, adaptation and vulnerability. Cambridge, UK: Cambridge University Press. http://www.ipcc.ch/ipccreports/ar4-wg2.htm

NAPAP (National Acid Precipitation Assessment Program). (1991). The experience and legacy of NAPAP: Report of the Oversight Review Board of the National Acid Precipitation Assessment Program. Washington, DC.

Rothman, KJ; Greenland, S. (1998). Modern epidemiology. In Modern Epidemiology (2nd ed.). Philadelphia, PA: Lippincott, Williams, & Wilkins.

Sacks, JD; Stanek, LW; Luben, TJ; Johns, DO; Buckley, BJ; Brown, JS; Ross, M. (2011). Particulate-matter induced health effects: Who is susceptible? [Review]. Environ Health Perspect 119: 446-454. http://dx.doi.org/10.1289/ehp.1002255

U.S. EPA (U.S. Environmental Protection Agency). (1998). Guidelines for ecological risk assessment [EPA Report]. (EPA/630/R-95/002F). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. http://www.epa.gov/raf/publications/guidelines-ecological-risk-assessment.htm

ED_002496_00001428-00039

U.S. EPA (U.S. Environmental Protection Agency). (2002). A framework for assessing and reporting on ecological condition: An SAB report [EPA Report]. (EPA-SAB-EPEC-02-009). Washington, DC. http://yosemite.epa.gov/sab%5CSABPRODUCT.NSF/7700D7673673CE83852570CA0075458A/$File/epec02009.pdf

U.S. EPA (U.S. Environmental Protection Agency). (2005). Guidelines for carcinogen risk assessment. (EPA/630/P-03/001F). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. http://www2.epa.gov/osa/guidelines-carcinogen-risk-assessment

U.S. EPA (U.S. Environmental Protection Agency). (2009). Integrated science assessment for particulate matter [EPA Report]. (EPA/600/R-08/139F). Research Triangle Park, NC: U.S. Environmental Protection Agency, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546

U.S. EPA (U.S. Environmental Protection Agency). (2010). Integrated science assessment for carbon monoxide [EPA Report]. (EPA/600/R-09/019F). Research Triangle Park, NC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=218686

U.S. EPA (U.S. Environmental Protection Agency). (2013). Integrated science assessment for ozone and related photochemical oxidants. (EPA/600/R-10/076F). Research Triangle Park, NC: U.S. Environmental Protection Agency, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=247492

UNEP (United Nations Environment Programme). (2003). Ecosystems and human well-being: A framework for assessment. Washington, DC: Island Press.

Vinikoor-Imler, LC; Owens, EO; Nichols, JL; Ross, M; Brown, JS; Sacks, JD. (2014). Evaluating potential response-modifying factors for associations between ozone and health outcomes: a weight-of-evidence approach [Review]. Environ Health Perspect 122: 1166-1176. http://dx.doi.org/10.1289/ehp.1307541

Zeger, SL; Thomas, D; Dominici, F; Samet, JM; Schwartz, J; Dockery, D; Cohen, A. (2000). Exposure measurement error in time-series studies of air pollution: Concepts and consequences. Environ Health Perspect 108: 419-426.

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Message

From: Dunlap, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591EB15A268249DDA0C05A7451F765C3-DUNLAP, DAV]
Sent: 3/25/2019 2:54:51 PM
To: Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
CC: Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Schiermeyer, Corry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0332276a9784253a5a78f39eccf1f29-Schiermeyer]; McFaul, Jessica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51b00479cd7446e4aa7743028c0d8d91-McFaul, Jes]
Subject: RE: deadline query

I am fine with this response. See highlight below - Deliberative Process / Ex. 5

DDD

David D. Dunlap
O Personal Email / Ex. 6

From: Abboud, Michael
Sent: Monday, March 25, 2019 10:52 AM
To: Woods, Clint <woods.clint@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Konkus, John <konkus.john@epa.gov>; Schiermeyer, Corry <schiermeyer.corry@epa.gov>; McFaul, Jessica <mcfaul.jessica@epa.gov>
Subject: RE: deadline query

I like this, Dave do you have any issues?

From: Woods, Clint
Sent: Monday, March 25, 2019 10:10 AM
To: Abboud, Michael <abboud.michael@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Konkus, John <konkus.john@epa.gov>; Schiermeyer, Corry <schiermeyer.corry@epa.gov>; McFaul, Jessica <mcfaul.jessica@epa.gov>
Subject: Re: deadline query

Suggestion:

Deliberative Process / Ex. 5

On Mar 25, 2019, at 9:49 AM, Abboud, Michael <abboud.michael@epa.gov> wrote:

> Clint and Dave -
>
> Is there anything we would like to say in regard to the process of this review?

Sent from my iPhone

Begin forwarded message:

Resent-From: <Press@epa.gov>
From: Jeff Tollefson <J.Tollefson@us.nature.com>
Date: March 25, 2019 at 8:26:27 AM EDT
To: Press <Press@epa.gov>
Subject: deadline query

Hello,

We're going to be posting a story this afternoon about the EPA's PM review, which discusses both the expedited timeline and CASAC's review - including the cancelled review panel, questions about the lack of scientific expertise on the existing CASAC, and alleged efforts by the chairman, Tony Cox, to undermine mainstream pollution and health science. A former CASAC chair says that it seems to be an effort to undermine the link between air pollution and mortality, by gaming the system and stacking the deck.

I would like to get a response from Wheeler/the agency. I would also like to know how the EPA will proceed. Will there be a second draft of the initial PM assessment? Will there be a separate risk and exposure assessment? Or will that be combined with the policy proposal? The normal process, I'm told, is to do two drafts of both the main science assessment and the risk and policy assessment - the former first, and then the latter - before moving on to the policy proposal, but there's no way to get all of that done by December 2020...

Deadline is early afternoon - 2 p.m.

Thanks,

Jeff

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Message

From: Hamilton, Sabrina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=68D3167C798743848AAFCDFB73BB74F1-SHAMILTN]
Sent: 11/28/2018 3:00:45 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
CC: Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]; Strine, Lora [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7adebb3d4944d0f985aadae46031f48-LSTRINE]; Terry, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5f08a9bf1324b05bc02a7dd2ea695e4-STERRY]; Meekins, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7f46e8a314b46d190b600593fcf4ad3-tmeekins]; Lubetsky, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e125d09a658e48119789ccae5712b4a5-JLUBETSK]; Mroz, Jessica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64b0c7f807df436a9b40ce52f7dec34c-Mroz, Jessi]; Carroll, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e868254d9da47e1ab5831814a7ff2fb-Carroll, Ma]; Weaver, Marilyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3fb70847cd9b4d7fbe7d6007179aceda-Weaver, Mar]
Subject: SAB Assignments
Attachments: EPA-SAB-18-001 -- SAB-18-000-8586.pdf; EPA-SAB-18-002 -- SAB-18-000-8594 .pdf

Clint,

We received two more SAB controls which are attached for your information. I'll hold the assignments in my inbox until you are ready to move forward with the consolidated response. Thanks

Sabrina Hamilton

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and FOIA Coordinator
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

June 21, 2018

EPA-SAB-18-001

The Honorable E. Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Subject: Science Advisory Board (SAB) Consideration of EPA Planned Actions in the Spring 2017 Unified Agenda of Regulatory and Deregulatory Actions and their Supporting Science

Dear Administrator Pruitt:

As part of its statutory duties, the EPA's Science Advisory Board recently concluded discussions about possible review of the science supporting major EPA planned actions associated with the Spring 2017 Unified Agenda of Regulatory and Deregulatory Actions. The EPA Office of Policy provided notice of the release of this information on July 20, 2017. The SAB discussed whether to review the science supporting any of the planned regulatory actions in that agenda in order to provide advice and comment on the adequacy of the science, as authorized by section (c) of the Environmental Research, Development and Demonstration Authorization Act, during a public meeting held on May 31, 2018.

The SAB focused its attention on 12 major planned actions identified by the EPA Office of Policy and published in the *Federal Register*. The SAB convened a Work Group to review the planned actions, conduct fact-finding, and develop recommendations for further consideration by the chartered SAB[1]. At the public meeting, the SAB discussed the Work Group's findings and decided to undertake review of the science supporting three of the actions in the semi-annual regulatory agenda at this time. The SAB also identified two actions for which insufficient information was available and deferred a determination until such information is available. The list of actions considered is enclosed.

[1] Memorandum: Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2017 Regulatory Agenda https://yosemite.epa.gov/sab/sabproduct.nsf/A4070377D540D61B8525827F0075E673/$File/SABWkGrpSpring2017Att+ABC.pdf

The SAB notes that nine of the planned actions were listed as long-term actions. The Office of Management and Budget defines long term actions as planned actions "under development but for which the Agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda" and notes that some long-term actions may only have abbreviated information. The SAB considered the stage of rulemaking of the planned actions and notes that the Board has the option to defer a decision on whether the planned action merits further review until sufficient information is available.

EPA Planned Actions that Merit SAB Review

Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed, and Modified Sources (RIN 2060-AT54): This planned action merits review by the SAB. The SAB has considered two previous actions regarding Oil and Gas New Source Performance Standards: 1) *Oil and Natural Gas Sector: Reconsideration of Remaining Provisions of New Source Performance Standards (RIN 2060-AS30);* and 2) *Guidelines for the Existing Oil and Natural Gas Sector (RIN 2060–AT29).* The SAB found that the EPA sought out expert review and public input and determined that the *Remaining Provisions to the NSPS (RIN 2060-AS30)* did not merit further review[2] stating that further SAB input was likely to provide marginal benefits to the Agency's expert input processes. The SAB deferred consideration of a related rule, the *Emission Guidelines for the Existing Oil and Natural Gas Sector (RIN 2060–AT29)* noting there was insufficient information to review the planned action and the SAB requested the agency provide more information about the scientific and technical basis. The Agency informed the SAB that the Guideline rule (2060-AT29) withdraws the 2016 Information Collection Request (ICR) from the oil and gas industry and no further activity is anticipated. Thus, this action is currently listed as completed in the Spring 2017 Regulatory agenda.

The EPA has made a broad commitment to reviewing the information in the original rule setting the NSPS promulgated in 2016[3] and evaluating the information submitted by commenters on the current action (RIN 2060-AT54). The EPA states that, at this time, they do not anticipate using new Influential Scientific Information (ISI) during the reconsideration of additional requirements. However, the scientific and technical basis for identifying and evaluating measures being reconsidered for methods to reduce emissions of greenhouse gases, including methane, and volatile organic compounds (VOCs) in the oil and natural gas industry was not provided. Given that some time has elapsed since the rule-making processes for the 2016 Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources was finalized, information regarding the scientific and technical basis for identifying alternative measures applicable to individual power plants may have changed. Therefore, the SAB recommends a review of any new ISI that would change the prior justification for the rule.

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[2] Preparations for Chartered SAB Discussions of EPA Planned Actions and Their Supporting Science in the Fall 2014 Regulatory Agenda (Attachment B and C) available at: https://yosemite.epa.gov/sab/sabproduct.nsf/8D67738EFAF3C69385257E3500532AF6/$File/Work+Group+Memorandum+Fall+2014+Reg+Rev+posted.pdf

[3] Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources (Federal Register 81 35824-35942) 40 CFR part 60, subpart OOOOa

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Review of the Clean Power Plan (RIN 2060-AT55): This action also merits review by the SAB. The review of the Clean Power Plan (CPP) pertains to a scope of scientific and technical issues that should be considered and subjected to peer review. Limited information was available to the SAB about this planned action. The scientific and technical basis for identifying and evaluating measures including heat rate improvement, and other options that are applicable to individual plants, is not specified in the announcements of the planned action. The identification and use of ISI or Highly Influential Scientific Information (HISI) is not explained or defined. In the SAB Work Group's fact-finding, the EPA was asked to provide further details regarding what specific sources of new information will be used and how ISI or HISI will be properly vetted through a rigorous peer review process (See Attachment C of the Work Group memorandum[4]). The Agency replied that public comments were being solicited on "whether there are additional control measures and information beyond what was included in the original Clean Power Plan." The response did not address whether the EPA would seek updated information on measures that were included in the original CPP, or whether such information would be considered ISI or HISI, or, the nature of peer review procedures planned for any ISI or HISI.

In the absence of information from the EPA, a presumption could be made that there have been updates to scientific and technical information for control measures that were included in the original CPP. Given the potential significance of the CPP with regard to addressing GHG emissions that endanger public health and welfare, and the myriad of potential best systems of emissions reductions, further SAB review of this matter is warranted to ensure the soundness of the scientific and technical basis for the action.

Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units (RIN 2060-AT56): This planned action merits review by the SAB. In its *Federal Register* notice the EPA stated that the Agency "will review whether this Rule or alternative approaches appropriately maintain the diversity of reliable energy resources and encourage the production of domestic energy sources to achieve energy independence and security." This statement implies that scientific questions and new analyses may arise regarding diversity of energy sources, reliability of energy sources, or capabilities to recover or utilize energy resources domestically. These analyses may be novel and require review or development of methodology and collection and evaluation of data. The specific scope of technical issues to be addressed is not provided, such as regarding what fuels, co-firing, firing, gasification, control, steam cycle, sequestration, and other options might form the basis of determination of best systems of emissions reduction. There is further complexity since this rule covers new, modified, and reconstructed facilities. The applicable range of options may differ depending on these stages of the plant life cycle. Based on a fact-finding query, the EPA indicated that it "plans to issue a proposed revision to the final NSPS and will consider comments it receives on that proposal." However, no further details were provided. (See Attachment C of the Work Group Memorandum[5]).

Given the potential significance of the Rule with regard to addressing GHG emissions that endanger public health and welfare, and the myriad of potential best systems of emissions

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[4] Ibid.
[5] Ibid.

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reductions, further SAB review of this matter is warranted to ensure the soundness of the scientific and technical basis for the action.

The full SAB overwhelmingly voted to categorize these three activities as meriting further review, rather than deferring them until additional information is available, in part for expediency. If the EPA ultimately provides the SAB with supporting scientific and technical information demonstrating that the activities do not use new ISI or HISI, the SAB will not review them.

EPA Planned Actions Awaiting Further Information for SAB Review

Two separate planned actions consider the recodification of the Waters of the United States. *Definition of "Waters of the United States" – Recodification of Preexisting Rules (RIN 2040-AF74)*: This planned action does not merit further SAB consideration. It redefines WOTUS from the current 2015 rule to the definition in place before 2015. The goal of this first step is to provide stability in the regulation of the Clean Water Act pursuant to a decision issued by the U.S. Court of Appeals for the Sixth Circuit staying the 2015 WOTUS definition, a decision that is under review by the Supreme Court.

Second Action: Definition of "Waters of the U.S." (RIN 2040-AF75): The SAB will defer a decision on reviewing this planned action until reviewable supporting documents or draft rule language are available. A significant amount of time and effort has gone into determining the connectivity of different water bodies to downstream navigable waters. The science related to that connectivity has been well documented by well over hundreds of journal articles and technical reports. The SAB has reviewed EPA's September 2013 scientific report and synthesis that documented this extensive literature.

In 2014, the SAB provided a report to the EPA Administrator and recommended that the interpretation of connectivity be revised from a binary, categorical distinction (connected versus not connected) to a gradient that is a function of the frequency, duration, magnitude, predictability, and consequences of physical, chemical, and biological connections. The SAB also commented on approaches to measuring or otherwise quantifying connectivity.

The SAB reviewed the proposed rule "Definition of 'Waters of the United States' Under the Clean Water Act[6]" and provided advice and comments[7] related to that proposal. The SAB found that the available science provides an adequate scientific basis for the key components of the proposed rule.

EPA's Office of Water stated it does not intend to develop any new work products to support *Definition of "Waters of the U.S." (RIN 2040-AF75*), yet it is unclear how any development of new boundaries can be justified without new scientific analysis and further review by the SAB.

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[6] Definition of ''Waters of the United States'' Under the Clean Water Act RIN 2040–AF30 (FR 79 22188-22274)
[7] Science Advisory Board (SAB) Consideration of the Adequacy of the Scientific and Technical Basis of the EPA's Proposed Rule titled "Definition of Waters of the United States under the Clean Water Act" available at: https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/518D4909D94CB6E585257D6300767DD6/$File/EPA-SAB-14-007+unsigned.pdf

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The SAB should evaluate the science that would support any decision about bright-line boundaries for WOTUS jurisdiction. The SAB requests that the EPA provide briefings on the science that would underlie the Agency's selection of these boundaries and justify what is and is not jurisdictional under the revised WOTUS rule.

The SAB found that at present there is insufficient information to make a determination as to whether a review of *Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK34)* will be warranted. At this time, it is not known what information base is available for the five chemical compounds, the particulars of the peer review process, or whether the individual chemical assessments will be brought back to the SAB or the Scientific Advisory Committee on Chemicals. The EPA is developing a plan and has indicated that letter peer review will be used. Due to the timeframes established by the statute, and the need to determine the likelihood of exposure, the EPA plans to use reasonably available information to complete exposure and use assessments. Depending on the available information base, these assessments may be qualitative or quantitative. The assessments are intended to support rulemaking under TSCA section 6(h) in order to reduce exposure to the extent practicable. The SAB has previously reviewed planned actions for specific TSCA chemical assessments and urged the EPA to continue this level of robust transparent peer review. A final recommendation on further SAB review will await the provision of updated information about these scientific and technical issues.

EPA Planned Actions Not Meriting Further SAB Review

National Primary Drinking Water Regulations: Finished Water Storage Facility Inspection Requirements Addendum to the Revised Total Coliform Rule (RIN2040-AF37): This action does not merit further SAB consideration. The SAB notes that the Safe Drinking Water Act requires EPA to request comments from the Board prior to proposal of a maximum contaminant level goal and national primary drinking water regulation. Thus, EPA may bring this action to the SAB in the future.

Clean Water Act Hazardous Substances Spill Prevention (RIN2050-AG87): This action does not merit further SAB consideration. EPA states that no scientific work products are being developed and standard methods for regulatory impact and economic analyses are being used. Data from the National Response Center will be surveyed from 2007 through 2016, and impacts will be assessed with information from National Toxic Substance Incident Program. While the environmental risks are high and uncertainties growing, especially given the recent decision to open more off shore drilling across the US Coasts, there is no scientific work to be analyzed and evaluated by SAB.

Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide (RIN2060-AR57): This action does not merit further SAB consideration. This action will undergo a multi-year detailed review process by the EPA Clean Air Scientific Advisory Committee and its Nitrogen Oxides Review Panel. CASAC is a FACA committee. The NOx Review Panel will be specifically constituted, in terms of independent scientific expertise, to review this proposed action. CASAC has a statutory mandate under the Clean Air Act to advise the Administrator regarding National Ambient Air Quality Standards (NAAQS).

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The SAB finds that two actions regarding the eight-year review of National Emissions Standards for Hazardous Air Pollutants (NESHAPs) do not merit further SAB consideration. They are the risk and technology review (RTR) for the *National Emission Standards for Hazardous Air Pollutants for Iron and Steel Foundries (RIN 2060-AT30)* and *National Emission Standards for Hazardous Air Pollutants: Asphalt Processing and Asphalt Roofing Manufacturing Residual Risk and Technology Review (RIN 2060-AT34*) While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, have been employed in numerous previous RTRs, and have been subject to multiple peer reviews over the past 17 years. As EPA's RTR methodologies are refined and revised over time, there is a need for periodic peer reviews of the changing methods. In addition, the SAB just completed the review of recent revisions to the screening methodologies used to support RTR reviews. Given the extensive past and currently ongoing peer reviews that have been conducted on RTR methodologies, the SAB finds that review is not warranted for these specific RTRs at this time.

Review of Pesticides; Certification of Pesticide Applicators (RIN 2070-AK37) In the current context this action does not merit further SAB consideration. If EPA identifies a need for changes to the certification rule, SAB review may be warranted. In a related planned action (RIN 2070-AJ20), EPA's FIFRA Science Advisory Panel considered whether to review certification for pesticide applicators and waived its review of the proposed rule on September 4, 2014, and the final rule on August 15, 2016, because the proposed revisions were administrative in nature and did not contain scientific issues that required the SAP's consideration.

SAB Requests Improvements in the Descriptions of EPA Planned Actions

The SAB thanks the EPA for providing information for consideration but emphasizes that more complete and timely information is required from the Agency to make recommendations and decisions regarding the science supporting planned actions. To improve the process for future review of the semi-annual regulatory agenda, the SAB strongly recommends that the EPA enhance descriptions of future planned actions by providing specific information on the peer review associated with the science basis for actions and more robust descriptions of the scientific and technical bases for the actions. In reviewing the Spring 2017 Regulatory Agenda, there were several cases where key information about the planned action, its supporting science and peer review were provided only after specific SAB Work Group requests. The SAB finds that the EPA's written responses to fact finding questions were not comprehensive and participation in the fact-finding teleconference was limited.

Effective SAB evaluation of planned actions requires the Agency to characterize the following elements in the initial descriptions provided to the work group:

- All relevant key information associated with the planned action.
- The science supporting the regulatory action. If there is new science to be used, provide a description of what is being developed. If the EPA is relying on existing science, provide a short description.

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- The nature of planned or completed peer review. To the extent possible, provide information about the type of peer review, the charge questions provided to the reviewers, how relevant peer review comments were integrated into the planned action, and information about the qualifications of the reviewer(s).

Despite the SAB making several of these recommendations in previous reviews, less information is being provided. We request that the Agency provide more complete information to support future SAB decisions about the adequacy of the science supporting actions in future regulatory agendas.

On behalf of the SAB, I thank you for the opportunity to support EPA through consideration of the science supporting actions in the Agency's regulatory agenda.

Sincerely,

/S/

Dr. Michael Honeycutt, Chair
Science Advisory Board

Enclosure
(1) Summary of Proposed Actions Considered
(2) Roster of SAB Members

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NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to 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 Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA Web site at http://www.epa.gov/sab.

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Summary of Proposed Actions Considered

Proposed actions in the Spring 2017 Unified (Regulatory) Agenda and Regulatory Plan considered by the Science Advisory Board and whether to provide advice and comment on the adequacy of the science supporting the action		
RIN[1]	**Planned Action Title**	**Recommendation**
2060-AT54	Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed, and Modified Sources	Merits review by the SAB.
2060-AT55	Review of the Clean Power Plan	Merits review by the SAB
2060-AT56	Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units	Merits review by the SAB
2040-AF75	Second Action: Definition of "Waters of the U.S."	Defer a determination until sufficient information is available
2070-AK34	Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)	Defer a determination until sufficient information is available
2040-AF37	National Primary Drinking Water Regulations: Finished Water Storage Facility Inspection Requirements Addendum to the Revised Total Coliform Rule	No further SAB consideration is merited.
2040-AF74	Definition of "Waters of the United States" – Recodification of Preexisting Rules	No further SAB consideration is merited.
2050-AG87	Clean Water Act Hazardous Substances Spill Prevention	No further SAB consideration is merited.
2060-AR57	Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide	No further SAB consideration is merited.

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Proposed actions in the Spring 2017 Unified (Regulatory) Agenda and Regulatory Plan considered by the Science Advisory Board and whether to provide advice and comment on the adequacy of the science supporting the action		
RIN[1]	**Planned Action Title**	**Recommendation**
2060-AT30	National Emission Standards for Hazardous Air Pollutants for Iron and Steel Foundries	No further SAB consideration is merited.
2060-AT34	National Emission Standards for Hazardous Air Pollutants: Asphalt Processing and Asphalt Roofing Manufacturing Residual Risk and Technology Review	No further SAB consideration is merited.
2070-AK37	Review of Pesticides; Certification of Pesticide Applicators	No further SAB consideration is merited.

[1]The Regulatory Identification Number provides a hyperlink to the Office of Management and Budget's webpage and information on the planned action provided in the Unified Regulatory Agenda on the OMB website http://www.reginfo.gov/

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U.S. Environmental Protection Agency
Science Advisory Board

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

June 21, 2018

EPA-SAB-18-002

The Honorable E. Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Subject: Science Advisory Board (SAB) Consideration of EPA Planned Actions in the Fall 2017 Unified Agenda of Regulatory and Deregulatory Actions and their Supporting Science

Dear Administrator Pruitt:

As part of its statutory duties, the EPA's Science Advisory Board recently concluded discussions about possible review of the science supporting major EPA planned actions associated with the Fall 2017 Unified Agenda of Regulatory and Deregulatory Actions. The EPA Office of Policy provided notice of the release of this information on December 14, 2017. During its public meeting on May 31, 2018, the SAB discussed whether to review any of the planned regulatory and deregulatory actions in order to provide advice and comment on the adequacy of the scientific and technical basis underlying each, as authorized by section (c) of the Environmental Research, Development and Demonstration Authorization Act.

The SAB focused its attention on nine major planned actions identified by the EPA Office of Policy and published in the *Federal Register*. The SAB convened a Work Group to review the planned actions, conduct fact-finding, and develop recommendations for further consideration by the chartered SAB[1]. At the public meeting, the SAB discussed the Work Group's findings and decided to undertake review of the science supporting two of the actions in the semi-annual Regulatory and Deregulatory Agenda at this time. The SAB also identified one action for which insufficient information was available and deferred a determination until such information is available.

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[1] Memorandum: Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Fall 2017 Regulatory Agenda https://yosemite.epa.gov/sab/sabproduct.nsf//9263940BB05B89A885258291006AC017/$File/WG_Memo_Fall17_RegRevAttsABC.pdf

The SAB notes that three of the nine major planned actions are listed as long-term actions and another three are listed as Pre-Rule Stage actions. The Office of Management and Budget defines long-term actions as planned actions "under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda" and notes that some long-term actions may only have abbreviated information. OMB defines the Pre-Rule Stage as "actions agencies will undertake to determine whether or how to initiate rulemaking. Such actions occur prior to a Notice of Proposed Rulemaking (NPRM) and may include Advance Notices of Proposed Rulemaking (ANPRMs) and reviews of existing regulations." The SAB considered these early stages of rulemaking for the planned actions to facilitate planning and interaction with the Agency and notes that the Board has the option to defer a decision on whether planned actions merit further review until sufficient information is available.

EPA Planned Actions that Merit SAB Review

Reconsideration of Final Determination: Mid Term Evaluation of Greenhouse Gas Emissions Standards for Model Year 2022-2025 Light Duty Vehicles (RIN 2060-AT77): The SAB finds this action merits further review. The SAB Work Group submitted fact-finding questions regarding the types of analyses that may be used to support the action. The EPA responded that the analyses "could be considered to inform the forthcoming NPRM" and that they would assess these issues as they develop the proposed rule. The EPA also responded that the schedule for the rulemaking addressing model years 2022-2025 light-duty vehicle greenhouse gas (GHG) standards has not yet been announced. The SAB notes that EPA, in collaboration with the National Highway Traffic Safety Administration (NHTSA) and the California Air Resources Board (CARB), developed extensive documentation for the mid-term evaluation (MTE), including a technical assessment report and several supporting studies. NHTSA is conducting an MTE and Regulatory Impact Analysis (RIA) regarding fuel economy standards to inform a companion rule to the EPA standards. Key questions that merit an SAB review could include but need not be limited to the following:

- What are the barriers (e.g., price, foregone power or safety) to consumer acceptance of redesigned or advanced technology vehicles, and how might such barriers be overcome?
- Would or could there be a significant "rebound" effect from the deployment of new fuel efficient (and lower GHG-emitting) vehicles, and how might such an effect be mitigated?
- Would requirements for more fuel efficient new vehicles lead to longer retention of older less fuel-efficient vehicles and, if so, would this significantly affect projected emission reductions and have effects on crash-related safety?
- What proportion of vehicle electrification, particularly for plug-in vehicles including plug-in hybrid electric vehicle (PHEV) and battery electric vehicles (BEVs), would be needed to achieve fleet average GHG emission reductions?
- What are the effects, co-benefits or harms in terms of emissions reductions or increases for other pollutants, and costs benefits of technology options?
- What are the projected fleet level GHG emissions and co-pollutant emission changes associated with various scenarios?

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Such a review might begin with existing documents developed by EPA, NHTSA and CARB during the MTE process, such as the Draft Technical Assessment Report. To the extent that the agencies have appropriately addressed key issues such as those above with adequate peer review, the scope of SAB review could be narrowed or redirected. A detailed rationale is provided in the Work Group Memorandum [2] and the fact-finding is summarized in Attachment C of that document.

Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits (RIN 2060-AT79): The SAB finds that this action merits review regarding the adequacy of the supporting science. In response to fact-finding questions submitted by the SAB Work Group, the EPA stated that there is "uncertainty about what scientific work, if any, would support" this action, did not describe the approach being taken to develop the needed science, and did not identify any peer review plans. The SAB finds issues, such as: i) determining whether glider vehicles have operational and life cycle emissions less than, comparable to, or greater than new vehicles; ii) answering technical questions regarding the impact of emissions from glider vehicles; and iii) identifying and applying suitable methodologies for assessing the effect of the proposed rule on emissions, air quality and public health, are scientific and technical in nature.

Key questions that merit SAB review could include but need not be limited to the following:

- What are the emission rates of glider trucks for GHGs, nitrogen oxides, particulate matter, and other pollutants of concern? What are the key sources of variability and uncertainty in these rates?
- How do these emission rates compare to those of conventionally manufactured trucks that are: (a) new; and (b) used at prices comparable to the purchase price of a "new" glider truck? What are key sources of variability and uncertainty in the comparisons?
- What is the range of possible market penetration of glider trucks into the on road heavy duty vehicle stock? What is the effect of glider truck penetration into the market on fleet level emissions at national, regional, and local scales in the near-term and long-term, compared to the status quo?
- What are implications of changes in emissions in the near-term and long-term from the penetration of glider trucks regarding GHG emissions, air quality, air quality attainment, and human health, compared to the status quo?

Such a review might begin with existing documents developed by EPA, such as the November 20, 2017 test report in which emissions of gliders and conventionally manufactured trucks were compared, and focus on areas where updates are needed. To the extent that EPA appropriately addresses key issues such as those outlined above with adequate peer review, the scope of SAB review could be narrowed or redirected. A detailed rationale is provided in the Work Group Memorandum[3] and the fact-finding effort is summarized in Attachment C of that document.

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[2] Ibid.
[3] Ibid.

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EPA Planned Actions Awaiting Further Information for SAB Review

Increasing Consistency, Reliability, and Transparency in the Rulemaking Process (RIN 2010-AA12): The SAB finds that a review of the scientific and technical basis for this planned action should be deferred until more information is available and, at that time, determine if it is appropriate to provide advice and comment. From the information provided by EPA staff and the pre-rule stage status of the action, the SAB finds that there is not enough information to recommend a review of the underlying science at this time. The EPA indicated that this action would not involve basic economic methodology changes. However, given the concern for consistency, such changes may well have to be considered. Depending upon how the action proceeds and the comments on the ANPRM, it may ultimately involve precedential issues and become an influential scientific or technical work product. The SAB also notes that some of the issues presented by the Work Group regarding RIAs may be appropriate for inclusion in this planned action and review by the SAB (see RIN 2060-AT67).

EPA Planned Actions Not Meriting Further SAB Review

State Guidelines for Greenhouse Gas Emissions From Existing Electric Utility Generating Units (RIN 2060-AT67): This planned action does not merit review by the SAB. While the SAB does not wish to provide advice on this planned action, it does find several aspects of the underlying "Regulatory Impact Analysis for the Review of the Clean Power Plan: Proposal" (RIA) dated October 2017 to be appropriate for an advisory activity by the Board. Specifically, the RIA makes assumptions that warrant further review, as follows: i) sensitivity analysis assumptions about mortality associated with particulate matter at concentrations below the current NAAQS; ii) calculations of climate change benefits on a US-only basis rather than a global scale; and iii) application of a 7% discount rate to estimate foregone GHG mitigation benefits which extend across multiple generations. These aspects may be appropriately considered under the planned action, *Increasing Consistency, Reliability, and Transparency in the Rulemaking Process* (RIN 2010-AA12) as noted above.

Review of the Primary National Ambient Air Quality Standards for Sulfur Oxides (RIN 2060-AT68) and *Review of the Secondary National Ambient Air Quality Standards for Ecological Effects of Oxides of Nitrogen, Oxides of Sulfur and Particulate Matter. (RIN 2060-AS35)*: These actions do not merit further SAB consideration. These actions undergo a multi-year detailed review process by the EPA Clean Air Scientific Advisory Committee (CASAC) and its panels. CASAC is a federal advisory committee and has a statutory mandate under the Clean Air Act to advise the Administrator regarding the National Ambient Air Quality Standards (NAAQS). The Sulfur Oxides Review Panel and the Secondary NAAQS Review Panel for Oxides of Nitrogen and Sulfur were specifically constituted, in terms of independent scientific expertise, to review the proposed actions, respectively. CASAC completed its review of the Sulfur Oxides NAAQS on April 30, 2018.

National Emission Standards for Hazardous Air Pollutants for Hydrochloric Acid Production Residual Risk and Technology Review (RIN 2060-AT74): This action does not merit further SAB consideration. While the details of each Residual Risk and Technology Review (RTR) are unique to the sources and pollutants being evaluated, the general approaches and methodologies

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employed in EPA RTRs have become standardized, have been employed in numerous previous RTRs, and have been subject to multiple peer reviews over the past 17 years, most recently in 2009. As EPA's RTR methodologies are refined and revised over time, there is a need for periodic peer reviews of the changing methods. The SAB is completing a review of recent revisions to the screening methodologies used to support RTR reviews. Given the extensive past and ongoing peer reviews no additional SAB review is warranted.

Pesticides; Agricultural Worker Protection Standard; Reconsideration of Several Requirements (RIN 2070-AK43): This action does not merit further SAB consideration. Per Executive Order 13777, the EPA solicited suggestions about regulations that may be appropriate for repeal, replacement or modification as part of the Regulatory Reform Agenda. Specific changes to the 2015 Worker Protection Standard (WPS) regulations at 40 CFR 170 were suggested and EPA is soliciting public input on these specific revisions. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) contains the requirement that EPA must provide copies of draft proposed and final rules to the FIFRA Science Advisory Panel (SAP) for review of any related scientific issues.

Fuels Regulation Modernization - Phase 1 (RIN 2060-AT31): The planned action does not merit further review by the SAB. This long-term action to "streamline and modernize EPA's existing fuels regulations under 40 CFR part 80" is described as "an administrative action to add clarity to the regulations to help improve compliance, and will not change any currently applicable fuel standards or propose new fuel ones." No new scientific techniques or analysis are contemplated under this planned action, as currently described. Also, the process for this action is in an early stage, with publication of proposed and final regulations planned for 2019. As such, consideration by the SAB is not recommended at this stage in the process.

SAB Requests Improvements in the Descriptions of EPA Planned Actions

The SAB thanks the EPA for providing information for consideration but emphasizes that more complete and timely information is required from the Agency to make recommendations and decisions regarding the science supporting planned actions. To improve the process for future reviews of the semi-annual regulatory agenda, the SAB strongly recommends that EPA enhance descriptions of future planned actions by providing specific information on the peer review associated with the science basis for actions and more description of the scientific and technological bases for the actions. In reviewing the Spring 2017 and Fall 2017 Regulatory Agendas, there were several cases where key information about the planned action, its supporting science and peer review were provided only after specific Work Group requests. The SAB finds that the written responses to fact-finding questions were not comprehensive and participation in the fact-finding teleconference was limited. EPA should provide such information in the initial descriptions provided to the Work Group.

Effective SAB evaluation of planned actions requires the EPA to characterize:

- All relevant key information associated with the planned action;

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- The science supporting the regulatory action. If there is new science to be used, provide a description of what is being developed. If the Agency is relying on existing science, provide a short description.
- The nature of planned or completed peer review. To the extent possible, provide information about the type of peer review, the charge questions provided to the reviewers, how relevant peer review comments were integrated into the planned action, and information about the qualifications of the reviewer(s).

The SAB urges the Agency to provide more complete information to support future SAB decisions about the adequacy of the science supporting actions in future regulatory agendas.

On behalf of the SAB, I thank you for the opportunity to support EPA through consideration of the science supporting actions in the Agency's regulatory agenda.

Sincerely,

/S/

Dr. Michael Honeycutt, Chair
Science Advisory Board

Enclosure
(1) Summary of Proposed Actions Considered
(2) Roster of SAB Members

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NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to 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 Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA Web site at http://www.epa.gov/sab.

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Summary of Proposed Actions Considered

Proposed actions in the Spring 2017 Unified (Regulatory) Agenda and Regulatory Plan considered by the Science Advisory Board and whether to provide advice and comment on the adequacy of the science supporting the action		
RIN[1]	**Planned Action Title**	**Recommendation**
2060-AT77	Reconsideration of Final Determination: Mid Term Evaluation of Greenhouse Gas Emissions Standards for Model Year 2022-2025 Light Duty Vehicles	Merits SAB Review
2060-AT79	Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits	Merits SAB Review
2010-AA12	Increasing Consistency, Reliability, and Transparency in the Rulemaking Process	Defer SAB consideration of the planned action until more information is available
2060-AT67	State Guidelines for Greenhouse Gas Emissions From Existing Electric Utility Generating Units	Does not merit further SAB review
2060-AT68	Review of the Primary National Ambient Air Quality Standards for Sulfur Oxides	Does not merit further SAB review
2060-AT74	National Emission Standards for Hazardous Air Pollutants for Hydrochloric Acid Production Residual Risk and Technology Review	Does not merit further SAB review
2070-AK43	Pesticides; Agricultural Worker Protection Standard; Reconsideration of Several Requirements	Does not merit further SAB review
2060-AS35	Review of the Secondary National Ambient Air Quality Standards for Ecological Effects of Oxides of Nitrogen, Oxides of Sulfur and Particulate Matter.	Does not merit further SAB review
2060-AT31	Fuels Regulation Modernization - Phase 1	Does not merit further SAB review

[1]The Regulatory Identification Number provides a hyperlink to the Office of Management and Budget's webpage and information on the planned action provided in the Unified Regulatory Agenda on the OMB website http://www.reginfo.gov/

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U.S. Environmental Protection Agency
Science Advisory Board

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Also Member: CASAC

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Dr. Susan P. Felter, Research Fellow, Global Product Stewardship, Procter & Gamble, Mason, OH

Dr. R. William Field, Professor, Department of Occupational and Environmental Health and Department of Epidemiology, College of Public Health, University of Iowa, Iowa City, IA

Dr. H. Christopher Frey, Glenn E. Futrell Distinguished University Professor, Department of Civil, Construction and Environmental Engineering, College of Engineering, North Carolina State University, Raleigh, NC

Dr. Joseph A. Gardella, SUNY Distinguished Professor and John and Frances Larkin Professor of Chemistry, Department of Chemistry, College of Arts and Sciences, University at Buffalo, Buffalo, NY

Dr. John D. Graham, Dean, School of Public and Environmental Affairs, Indiana University, Bloomington, IN

Dr. Steven P. Hamburg, Chief Scientist, Environmental Defense Fund, Boston, MA

Dr. Cynthia M. Harris, Director and Professor, Institute of Public Health, Florida A&M University, Tallahassee, FL

Dr. Merlin R. Lindstrom, Vice President Technology, Phillips 66 Research Center, Bartlesville, OK

Dr. Robert E. Mace, The Meadows Center for Water and the Environment, Texas State University, San Marcos, TX

Dr. Clyde F. Martin, Horn Professor of Mathematics, Emeritus, Department of Mathematics and Statistics, Texas Tech University, Crofton, MD

Dr. Sue Marty, Senior Toxicology Leader, Toxicology & Environmental Research, The Dow Chemical Company, Midland, MI

Dr. Kristina D. Mena, Associate Professor, Epidemiology, Human Genetics and Environmental Sciences, School of Public Health, University of Texas Health Science Center at Houston, El Paso, TX

Dr. Surabi Menon, Director of Research, ClimateWorks Foundation, San Francisco, CA

Mr. Robert W. Merritt, Independent Consultant, Houston, TX

Dr. Larry Monroe, Independent Consultant, Braselton, GA

Dr. Thomas F. Parkerton, Senior Environmental Associate, Toxicology & Environmental Science Division, ExxonMobil Biomedical Science, Houston, TX

Dr. Robert Phalen, Professor, Air Pollution Health Effects Laboratory, Medicine, Department of

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Medicine, University of California-Irvine, Irvine, CA

Mr. Richard L. Poirot, Independent Consultant, Burlington, VT

Dr. Kenneth M. Portier, Independent Consultant, Athens, GA

Dr. Robert Puls, Owner/Principal, Robert Puls Environmental Consulting, Hilton Head Island, SC

Dr. Kenneth Ramos, Associate Vice-President of Precision Health Sciences and Professor of Medicine, Arizona Health Sciences Center, University of Arizona, Tucson, AZ

Dr. Tara L. Sabo-Attwood, Associate Professor and Chair, Department of Environmental and Global Health, College of Public Health and Health Professionals, University of Florida, Gainesville, FL

Dr. William Schlesinger, President Emeritus, Cary Institute of Ecosystem Studies, Millbrook, NY

Dr. Anne Smith, Managing Director, NERA Economic Consulting, Washington, DC

Dr. Richard Smith, Professor, Department of Statistics and Operations Research, University of North Carolina, Chapel Hill, NC

Dr. Jay Turner, Associate Professor and Vice Dean for Education, Department of Energy, Environmental and Chemical Engineering, School of Engineering & Applied Science, Washington University, St. Louis, MO

Dr. Jeanne M. VanBriesen, Duquesne Light Company Professor of Civil and Environmental Engineering, and Director, Center for Water Quality in Urban Environmental Systems (Water-QUEST), Department of Civil and Environmental Engineering, Carnegie Mellon University, Pittsburgh, PA

Dr. Donald vanderVaart, Independent Consultant, Raleigh, NC

Dr. Kimberly White, Senior Director, Chemical Products and Technology Division, American Chemistry Council, Washington, DC

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Mr. Thomas Carpenter, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board Washington, DC

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Message

From: Clint Woods [clintwoods@gmail.com]
Sent: 9/14/2018 8:01:43 AM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Miscommunicating Risk, Uncertainty, and Causation: Fine Particulate Air Pollution and Mortality Risk as an Example - Anthony (Tony) Cox - 2012 - Risk Analysis - Wiley Online Library

https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1539-6924.2012.01806.x

Message

From: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
Sent: 12/11/2018 11:35:26 PM
To: Grantham, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12a3c2ed7158417fb0bb1b1b72a8cfb0-Grantham, Nancy]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Brennan, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78caa4c8d91743c887c1bb5dc8cdb369-Thomas Brennan]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Sauerhage, Maggie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b13c7152d704546b40a91220914d3cc-Sauerhage,]
Subject: CASAC Packet
Attachments: CASAC Packet 12.11.18.docx

The attached packet will include information Maggie will hand to the press at the door when they check in. It includes our reasoning for the new committee members, as well as bios of the members to highlight their qualifications.

Maggie will let us know who checks in from the press and we will send them our quote along with quotes from former CASAC chairs via email. We will see how the turnout is looking, and send someone down if needed before the end of the public comment period to provide comms support to Tom and Tony during the transition as Tom stated this may be the most likely time that reporters will want to ask questions of us.

Michael Abboud
U.S. Environmental Protection Agency
Office of Public Affairs
M: 202-564-6461

New CASAC Membership

In October, EPA announced the appointment of five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). This seven-member panel, required under Section 109 of the Clean Air Act, provides critical advice related to National Ambient Air Quality Standards (NAAQS). EPA also tasked this panel with leading the review any necessary changes to the NAAQS for ozone or particulate matter.

1. The new chartered CASAC is filled with [HYPERLINK "https://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalCommitteeRosters?OpenView&committee=CASAC&secondname=Clean%20Air%20Scientific%20Advisory%20Committee%20"] who are have decades of experience working on ozone and particulate matter issues. This includes several individuals who have served or actively participated in previous NAAQS reviews for ozone and particulate matter. The full line up: [HYPERLINK \l "_Dr._Louis_Anthony"], Cox Associates (Chair); [HYPERLINK \l "_Dr._James_Boylan"], Georgia Department of Natural Resources; [HYPERLINK \l "_Mark_W._Frampton"], University of Rochester Medical Center; [HYPERLINK \l "_Dr._Sabine_Lange"], Texas Commission on Environmental Quality; [HYPERLINK \l "_Dr._Timothy_Lewis"], U.S. Army Corps of Engineers; [HYPERLINK \l "_Dr._Corey_Masuca"], Jefferson County (AL) Department of Health; [HYPERLINK \l "_Steven_C._Packham"], Utah Department of Environmental Quality

2. Tasking the chartered CASAC with overseeing these reviews ensures the early engagement of the advisors who ultimately provide advice to the Administrator and is consistent with the clear requirements of the Clean Air Act*, regulations implementing the Federal Advisory Committee Act**, and CASAC's charter***. Under all of these authorities, any subcommittee or individual pollutant panel would need to provide their advice through the chartered CASAC.

3. As outlined in the May 2018 "Back-to-Basics Process for Reviewing NAAQS" memorandum, any changes to the particulate matter and ozone NAAQS would be finalized by late 2020. In order to meet these deadlines, which reflect Congress' intent for a five-year review cycle, relying on the expertise of these seven PM and ozone experts ensures robust advice. Administrator Wheeler can add more expert consultants to provide relevant expertise to the CASAC if deemed necessary.

4. EPA did not disrupt any scientific advice process. A stand-alone ozone review panel was never formed and the particulate matter review panel was established to operate from 2015 to 2018. The latter panel was engaged by EPA over an "integrated review plan" but it did not provide scientific advice for any of the key assessments for the NAAQS review process. Several members of the new chartered CASAC served on that panel and will continue providing advice. EPA welcomes feedback on these science assessments from any and all members of the scientific community and public.

*Section 109(d)(2)(A) of the Clean Air Act: "The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies."

** "Unless otherwise provided by statute, Presidential directive, or other establishment authority, advisory committee members serve at the pleasure of the appointing or inviting authority. Membership terms are at the sole discretion of the appointing or inviting authority." (41 CFR § 102–3.130)

"From this reasoning, it is not permissible for parent advisory committees simply to 'rubber-stamp' the advice or recommendations of their subcommittees, thereby depriving the public of its opportunity to know about, and participate contemporaneously in, an advisory committee's deliberations." (66 FR 37729)

***[HYPERLINK "https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2017casaccharter/$File/CASAC%202017%20Renewal%20Charter%20Filed%206-5-17.pdf"], last updated May 2017: "EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter. Such 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."

Dr. Louis Anthony (Tony) Cox, Jr.

Dr. Tony Cox is President of Cox Associates, a Denver-based applied research company specializing in quantitative health risk analysis, epidemiology, causal analytics, and operations research. Since 1986, Cox Associates' mathematicians and scientists have applied epidemiological and biomathematical models, biostatistical and computational risk analyses, causal data mining, machine learning, artificial intelligence, bioinformatics, and operations research models to measurably improve health risk assessment and decision-making for public and private sector clients. In 2006, Cox Associates was inducted into the Edelman Academy of the Institute for Operations Research and Management Science (INFORMS), recognizing outstanding real-world achievements in the practice of operations research and the management sciences. In 2012, Dr. Cox was inducted into the National Academy of Engineering (NAE), "For applications of operations research and risk analysis to significant national problems." He has served as a member of the National Academies' Board on Mathematical Sciences and their Applications (BMSA) (2012-2016) and has served on many National Academies and National Research Council committees dealing with health and safety risk analysis. In 2013, he co-founded NextHealth Technologies, a Denver-based company offering advanced data analytics solutions to healthcare plans to reduce health, financial, and member attrition risks. Since 2015, Dr. Cox and Cox Associates have received funding from the George Washington University Regulatory Studies Center to develop statistical software for causal analysis of epidemiological data; the American Chemistry Council to develop predictive analytics software and research lung diseases caused by crystalline silica and other poorly soluble particles; the American Petroleum Institute and its members for research on methods of causal analysis applied to epidemiological data on asthma, coronary heart disease, all-cause mortality, and other adverse health effects associated with exposure to fine particulate matter (PM2.5) and ozone (O3); the U.S. EPA for expert review of research proposals; the National Stone, Sand, and Gravel Association for research on the statistical reliability and variability of laboratory measurements of crystalline silica in air filters; the European petroleum consortium CONCAWE for research on low-dose metabolism of benzene among Chinese workers; plaintiff's attorneys for expert opinions on the use of statistical methods and models in construction defect litigation; and telecommunications companies for research and software on high-reliability optical networks.

Dr. Cox holds a Ph.D. in Risk Analysis (1986) and an S.M. in Operations Research (1985), both from MIT; an AB from Harvard University (1978); and is a graduate of the Stanford Executive Program (1993). He is Clinical Professor of Biostatistics and Informatics at the University of Colorado Health Sciences Center and has served at the University of Colorado, Denver as Honorary Full Professor of Mathematics, lecturing on decision and risk analysis, biomathematics, health risk modeling, computational statistics and causality; and on the Faculties of the Center for Computational Mathematics and the Center for Computational Biology. He has taught many graduate and professional courses in decision and risk analysis, causal analytics, computational statistics, and biomathematical modeling. Dr. Cox is Editor-in-Chief of Risk Analysis: An International Journal. He is Area Editor for Real World Applications for the Journal of Heuristics and is on the Editorial Board of the International Journal of Operations Research and Information Systems. He is an Edelman Laureate of INFORMS, a member of the American Statistical Association (ASA), and a lifetime Fellow of the Society for Risk Analysis (SRA). He has authored and co-authored over 200 journal articles and book chapters on these fields. His most recent books are Breakthroughs in Decision Science and Risk Analysis (Wiley, 2015), Improving Risk Analysis (Springer, 2013), Risk Analysis of Complex and Uncertain Systems (Springer, 2009) and the Wiley Encyclopedia of Operations Research and Management Science (Wiley, 2011), which Dr. Cox co-edited. He has over a dozen U.S. patents on applications of artificial intelligence, signal processing, statistics and operations research in telecommunications. His current research interests include computational statistical methods for causal inference in public health risk analysis, data-mining, and advanced analytics for risk analysis and public policy applications.

Dr. James Boylan

Dr. James Boylan is currently the Manager of the Planning & Support Program in the Air Protection Branch of the Georgia Environmental Protection Division. His modeling team consists of eight Ph.D. engineers/scientists, his emission inventory team consists of four environmental engineers/scientists, and his regulatory development team consists of seven environmental engineers/scientists. Dr. Boylan is responsible for air dispersion modeling with AERMOD and CALPUFF required for PSD permit applications (SO2, NO2, CO, PM2.5, and lead); photochemical grid modeling with CMAQ and CAMx required for Georgia's ozone, PM2.5, and regional haze State Implementation Plans (SIPs); meteorological modeling with MM5 and WRF; emissions modeling with SMOKE and MOVES; the development of annual state-wide emission inventories for criteria pollutants; and the technical analyses for nonattainment area designation recommendations (ozone, PM2.5, lead, SO2, NO2). In addition, he is responsible for updating Georgia's Rules for Air Quality Control and developing and submitting all attainment demonstration SIPs, infrastructure SIPs, and rule revision SIPs to EPA. Previously, he worked at the Florida Department of Environmental Protection performing regulatory audits of stationary sources. He has a B.S. in Chemical Engineering from the University of Notre Dame, a M.S. in Chemical Engineering from Auburn University, and a M.S. and Ph.D. in Environmental Engineering from the Georgia Institute of Technology (under the direction of Dr. Armistead "Ted" Russell). Dr. Boylan's Ph.D. research included the development of the first comprehensive three-dimensional Eulerian photochemical grid model (URM-1ATM) that included full ozone chemistry, heterogeneous sulfate chemistry, aerosol thermodynamics, wet deposition and scavenging, and the decoupled direct method (DDM) for ozone and particulate matter. This model was applied as part of the Southern Appalachian Mountain Initiative (SAMI) to simulate 1-hour maximum ozone, W126 ozone, speciated PM2.5, acid deposition (ANC), and regional haze. Also, he developed and published the first model performance goals and criteria for PM2.5 which has become the benchmark for most PM2.5 modeling projects both nationally and internationally. Dr. Boylan was one of the first modelers to merge traditional air permit dispersion modeling with photochemical grid models (PGMs) when he applied a PGM to evaluate the single source impacts on ozone and secondary PM2.5 from a coal-fired power plant as part of a PSD permitting review in 2009. In addition, he developed the "Inter-Pollutant Trading Ratio Approach" for accounting for secondary PM2.5 formation from SO2 and NOx in EPA's AERMOD steady-state dispersion model. Over the past several years he has held numerous leadership positions within many regional and national workgroups. Currently, he is the chair of the Southeastern States Air Resource Managers (SESARM) Technical Analysis Workgroup, leader of the SESARM Emissions and Air Quality Modeling Workgroup, and co-chair of the Association of Air Pollution Control Agencies (AAPCA) Modeling Committee. Dr. Boylan has authored 18 peer-reviewed journal articles on ozone and PM2.5 formation, has presented research findings at over 200 national, regional, and local conferences/meetings, and was awarded "Outstanding Reviewer Status" by Atmospheric Environment in 2015. In 2001, Dr. Boylan was inducted into the Sigma Xi Scientific Research Honor Society. Currently, Dr. Boylan serves on the CASAC Sulfur Oxides Review Panel where he specializes in the analysis of ambient SO2 concentrations from measurements and modeling.

Dr. Mark W. Frampton

Dr. Mark W. Frampton is Professor Emeritus in Medicine in the Pulmonary & Critical Care division, at the University of Rochester Medical Center (URMC), Rochester, NY. Dr. Frampton holds an M.D. from New York University. During pulmonary specialty training at URMC in the late 1980s, Dr. Frampton became interested in the adverse health effects of air pollution, at a time when epidemiology studies were beginning to provide strong links between ambient particulate air pollution and mortality. Working with Dr. Mark Utell and utilizing the human clinical studies facility at URMC, he expanded the focus of human clinical air pollution studies beyond pulmonary function effects to include effects on airway inflammation, host defense against viral infection, and cardiovascular effects. Dr. Frampton's laboratory was the first to conduct human clinical studies of ultrafine particles (smaller than 100 nm), first using laboratory generated elemental carbon particles, and subsequently with concentrated ambient ultrafine particles, using the Harvard ultrafine concentrator system. Over the years his laboratory has studied healthy subjects as well as those considered to have increased susceptibility, including older subjects and people with mild asthma, chronic obstructive pulmonary disease, type 2 diabetes, and even genetic susceptibility. Dr. Frampton's laboratory is one of three centers completing a study of the cardiovascular effects of ozone exposure in healthy older subjects, funded by the Health Effects Institute. These studies have helped to understand the physiological changes and pathways to adverse effects that occur in response to pollutant exposure, and have helped to inform the EPA's promulgation of rational ambient air quality standards. Funding for these studies has come from the National Institutes of Health, the U.S. EPA, the Health Effects Institute, the New York State Energy Research and Development Authority, CONCAWE, ExxonMobil, the American Petroleum Institute, and others.

Dr. Frampton has served on numerous scientific review panels with the National Institutes of Health and other scientific funding organizations. He has been active in the Environmental and Occupational Health Assembly of the American Thoracic Society, serving as its Chair in 2001-2003. At the request of the ATS President at the time, Dr. Frampton chaired a Task Force on Bioterrorism, and helped to form a new Section on Bioterrorism, serving as its first Chair in 2003-2005. He recently served as a member of the ATS committee preparing a revision of the important and oft-cited document, "What Constitutes a Health Effect of Air Pollution?", which has now been published. Dr. Frampton has served as a consultant and reviewer for the Health Effects Institute, a health research organization jointly funded by EPA and the automobile industry. He is currently a member of the Science Review Committee for the Health Effects Institute. He participated in an HEI review panel on the health effects of traffic-related air pollution, and chaired an HEI Review Panel on ultrafine particles, which produced a recent HEI Perspectives, "Understanding the Health Effects of Ambient Ultrafine Particles". Dr. Frampton has served as a consultant to the EPA in developing and reviewing Integrated Scientific Assessments (formerly Criteria Documents) for nitrogen dioxide, ozone, and particulate matter. In addition, he has served on several EPA grant and fellowship review panels and scientific workshops, and has been invited to speak at EPA functions. He currently serves on the CASAC PM Review Panel.

Dr. Sabine Lange

Dr. Sabine Lange is the section manager for the Toxicology Division at the Texas Commission on Environmental Quality (TCEQ). Dr. Lange's responsibilities include overseeing health effects risk assessments of air permit applications, ambient air monitoring projects, and hazardous waste sites; overseeing the development of chemical toxicity factors; and conducting and overseeing systematic reviews and independent analyses of risk assessments. Dr. Lange serves as a technical resource for the State and citizens of Texas for human health and environmental risk assessment, especially related to air and water quality. Dr. Lange's research interests include the toxicology of criteria air pollutants, and risk assessment methods used for derivation of toxicity factors. In these areas she has published articles, given invited talks, presented posters, and served as a workshop panel member. On behalf of the TCEQ, she has intensively reviewed the documents released by the US EPA on the National Ambient Air Quality Standards (NAAQS) for ozone, particulate matter, sulfur dioxide, nitrogen dioxide, and lead. Dr. Lange and colleagues have provided comments to the US EPA on the assessment documents supporting these standards, particularly as they relate to principles of toxicology, risk assessment, and the State's perspective on these rules. She has also served as a peer reviewer for EPA on chemical hazard assessments for regulations under the Toxic Substances Control Act. Dr. Lange's work since joining TCEQ has been entirely funded by the State of Texas. Dr. Lange received a Bachelor's degree from the University of Western Ontario in Canada, and completed a Ph.D. and post-doctoral training in biochemistry and molecular carcinogenesis at the University of Texas at Houston and MD Anderson Cancer Center. Dr. Lange is a Diplomate of the American Board of Toxicology.

Dr. Timothy Lewis

Tim Lewis is a supervisory research ecologist with the U.S. Army Corps of Engineer, Engineer Research and Development Center, Environmental Laboratory in Vicksburg, MS. He worked for Lockheed Engineering, primary contractor for the U.S. EPA, serving as Project Leader and Principal Scientist on studies related to the National Surface Water Survey, the Direct Delayed Response Project (soil acidification), and the Environmental Monitoring and Assessment Program (EMAP). He accepted a position with the Bureau of Land Management in 1993 and served as the National Indicator Development Coordinator for the U.S. EPA's EMAP - Forest Health Monitoring program. He edited and authored a CRC Press book entitled Tree Rings as Indicators of Ecosystem Health. He went on to become Effectiveness Monitoring Coordinator for the Northwest Forest Plan. In 1996 Tim became the first Director of the Forest Science Project at Humboldt State University, where he applied his regional aquatic and terrestrial monitoring experience to private and public lands in Northern California. In 2001, Dr. Lewis accepted a position as senior ecologist with the U.S. EPA's National Center for Environmental Assessment, where he was involved in the assessment of ecological risks due to air pollutants. He served as associate editor of the premier journal Ecological Indicators during its startup. In 2007 Tim joined the Environmental Laboratory at the USACE's Engineer Research and Development Center in Vicksburg, MS as Chief for the Aquatic Ecology and Invasive Species Branch. The branch is actively engaged in ecosystem restoration and the assessment of the impact of Corps projects on habitat for threatened and endangered species and prevention and reduction of impacts of invasive plants and animals in the nation's waterways.

Education

B.A., West Chester University, West Chester, PA, 1977, Biology

M.S., Rutgers University, New Brunswick, NJ, 1980, Plant Pathology Ph.D., Rutgers University, New Brunswick, NJ, 1984, Environmental Science.

Dr. Corey Masuca

Corey Masuca, PE, PhD, JD is currently the Principal Air Pollution Control Engineer with the Jefferson County Department of Health. As the leader of the Air Pollution Control Program with the Jefferson County of Health he is responsible for overseeing a staff of approximately 35 persons who responsibilities include regulating industrial sources of emissions, area and point sources of emissions such as dry cleaners/gasoline stations and open burning, respectively. In addition, he oversees the ambient air monitoring program which is responsible for measuring air contaminant concentrations within Jefferson County, Alabama to ensure compliance with healthy clean air standards set by the United States Environmental Protection Agency (USEPA). Since he graduated from Auburn University with a Bachelor of Chemical Engineering degree, he has continued to work in the environmental arena, specifically air quality and air pollution. As a student at Auburn University, he completed a cooperative education program rotation with the Tennessee Valley Authority in Muscle Shoals, Alabama where he completed stack testing of fertilizer plant residuals including stack testing equipment preparation and calibration. After he graduated from Auburn University, he was employed as an Environmental Engineer with the State of Connecticut Department of Environmental Protection where he regulated sources of air pollutant emissions and was responsible for the implementation of a major new air regulatory USEPA program as part of the 1990 Clean Air Act Amendments. Following his tenure with the Connecticut Department of Environmental Protection, he worked as a consulting engineer with the environmental consultant firm, CH2M Hill, in the Atlanta, Georgia area. With CH2M Hill, he prepared air program applications for several industrial air-polluting facilities applying for applications to operate. This involved extensive regulatory review and complex, mathematical calculations to determine compliance and/or regulatory applicability. Next, he returned to Alabama where he worked an Environmental Engineer with the Alabama Department of Environmental Management where he continued his work as an Environmental Engineer where he was responsible for permitting, determining compliance, inspecting, and initiating enforcement actions, where applicable, of industrial sources of air pollution. Finally, he was initially employed as an Air Pollution Control Engineer with the Jefferson County Department of Health where, again, his primary duties entailed permitting, determining compliance, inspection, and initiating enforcement actions of industrial sources of air pollutant emissions. While with the Jefferson County Department of Health, he continued his professional and academic pursuits where he was promoted to the position of a Senior Air Pollution Control Engineer, became a registered/licensed Professional Engineer with the State of Alabama, and obtained a doctoral degree in Environmental Health Engineering from the University of Alabama in Birmingham. His doctoral degree research consisted of completing an epidemiology study of air pollutant concentrations and pre-term birth defects for populations within Atlanta, Georgia. After obtaining his doctoral degree and while still working full-time as a Senior Air Pollution Control Engineer with the Jefferson County Department of Health, he was also employed an adjunct professor both with the University of West Alabama (where he continues to be an advisory board member for the Environmental Sciences section of the Biology Division) and with the University of Phoenix (Birmingham campus). He taught classes in environmental science, environmental ethics, and general environmental air pollution health effects with both the University of Phoenix (Birmingham campus) and the University of West Alabama. In addition, during and subsequent to this time, he acted as a professional consultant providing air pollution data and review/analyses for three (3) epidemiological studies being performed/conducted by the University of Alabama at Birmingham, School of Public Health, Department of Epidemiology, which involved determining the relationship between ambient air pollution and emergency room visits for cardiovascular disease in Jefferson County, Alabama; ambient air pollution and emergency room visits for respiratory disease among adults in Jefferson County, Alabama; and ambient air pollution and respiratory diseases in children in Jefferson County, Alabama. During and subsequent to this time, he was promoted to his current position of Principal Air Pollution Control Engineer with responsibility for all of the various components of the Health Department's Air Pollution Control Program. Following his teaching stints with the University of West Alabama and with the University of Phoenix (Birmingham campus), all the while still being employed with the Health Department, he undertook an initiative to pursue as Juris Doctorate degree from the Miles College School of Law in Birmingham. He completed his requisite law studies and recently graduated from law school (May 2018). He is still employed as the Principal Air Pollution Control Engineer with the Jefferson County Department of Health Air Pollution Control Program and is currently planning to sit for the Alabama State Bar in July 2018, after which he will continue to work at/with the Health Department in a lead scientific and administrative capacity, and, hopefully, legal capacity subsequent to passing the Alabama State Bar.

Steven C. Packham

Dr. Steven Packham is an inhalation toxicologist with 28 years of regulatory experience with the Utah Division of Air Quality. Foremost among his responsibilities has been public education and communication of the scientific basis and intent of USC Title 42, Chapter 85 (particularly Sections 7409 and 7412): To protect human health with an ample margin of safety "requisite to protect" public health. His actual regulatory experience includes: Preparation of case-specific HAPs residual risks and leaking underground storage tank vapor intrusion risk assessments. Development of State Implementation Plans. State adoption of Federal NESHAP MACT's, and annual reviews of Utah's NATA Urban Air Toxics program. His research has focused on causal biologic mechanisms of dose-dependent health effects from breathing air pollution. He has developed a model to estimate margins of safety for mobile app users based on EPA Air Quality Index (AQI) values for sensitive and normal groups who may wish to engage in fitness improvement training and enjoy physical recreational activities outdoors under fluctuating air quality conditions.

Dr. Packham is an Adjunct Associate Professor in the University of Utah College of Health Sciences Department of Family and Preventative Medicine and a member of the Advisory Board of the Rocky Mountain Center for Occupational and Environmental Health in Salt Lake City. Past professional activities include: Editorial Board, Journal of Fire Sciences. Chairman, American Society for Testing and Materials (ASTM) Task Group E5.21.05. Member, Toxicity Advisory Committee National Fire Protection Association. Member, ASTM Committee on Toxic Hazard Assessment of Materials used in Transportation Vehicles. United States of America Member, Technical Advisory Committee, ISO/TC 92/SC 3. Convener: ISO Technical Committee 92, Subcommittee 3, Working Group 1 on Fire Model. United States of America Assigned Expert: ISO/TC 92/SC 3/Working Group on Bio-assays.

Message

From: Clint Woods [clintwoods@gmail.com]
Sent: 9/14/2018 8:00:34 AM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Attachments: ReassessingCleanAirAug22.pdf

https://cmpa.gmu.edu/wp-content/uploads/2013/10/ReassessingCleanAirAug22.pdf

Reassessing the Human Health Benefits from Cleaner Air

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ABSTRACT

Recent proposals to further reduce permitted levels of air pollution emissions are supported by high projected values of resulting public health benefits. For example, EPA recently estimated that the 1990 Clean Air Act Amendment (CAAA) will produce human health benefits in 2020, from reduced mortality rates, valued at nearly two trillion dollars per year, compared to compliance costs of $65 billion (0.065 trillion) dollars. However, while compliance costs can be measured, health benefits are unproved; they depend on a series of uncertain assumptions. Among these are that additional life expectancy gained by a beneficiary (with median age of about 80 years) should be valued at about $80,000 per month; that there is a 100% probability that a positive, linear, no-threshold, causal relation exists between $PM_{2.5}$ concentration and mortality risk; and that progress in medicine and disease prevention will not greatly diminish this relationship. We present an alternative uncertainty analysis that assigns a positive probability of error to each assumption. This discrete uncertainty analysis suggests (with probability > 90% under plausible alternative assumptions) that the costs of CAAA exceed its benefits. Thus, instead of suggesting to policy makers that CAAA benefits are almost certainly far larger than its costs, we believe that accuracy requires acknowledging that the costs purchase a relatively uncertain, possibly much smaller, benefit. The difference between these contrasting conclusions is driven by different approaches to uncertainty analysis, i.e., excluding or including discrete uncertainties about the main assumptions required for non-zero health benefits to exist at all.

KEY WORDS: Clean Air Act Amendment 1990, air pollution health effects, uncertainty analysis, risk-cost-benefit analysis, Weibull distribution

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Introduction

Media, regulatory, and advocacy reports and recommendations frequently suggest that particulate matter in outdoor air ($PM_{2.5}$) kills people and causes serious health problems. For example, an Environmental Protection Agency (EPA) web site warns that "Numerous scientific studies have linked particle pollution exposure to a variety of problems, including irregular heartbeat; nonfatal heart attacks; and premature death in people with heart or lung disease" (www.epa.gov/pm/health.html). Conversely, regulatory proposals to further decrease currently permitted levels of pollutants are increasingly supported by reference to large estimated or predicted health benefits from doing so. For example, in early 2011, the EPA released the results of its cost-benefit analysis of the 1990 Clean Air Act Amendments (CAAA). The assessment made two striking claims[1]: (1) As of 2020, the CAAA would produce estimated health benefits valued at approximately two trillion (i.e., two thousand billion) dollars per year, compared to estimated compliance costs of only about $65 billion per year; and (2) The uncertainties in the cost-benefit analysis are small enough so that, "***The extent to which estimated benefits exceed estimated costs*** and an in-depth analysis of uncertainties ***indicate that it is extremely unlikely the costs of 1990 Clean Air Act Amendment programs would exceed their benefits under any reasonable combination of alternative assumptions or methods identified during this study***" (emphasis in original).

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This paper reexamines the assumptions, methods, and numbers used in reaching these encouraging conclusions. We come to the very different conclusion that EPA's evaluation of health benefits is unrealistically high, by a factor that could well exceed 1000, and that it is therefore very likely that the costs of the 1990 CAAA exceed its benefits, plausibly by more than 50-fold. Our reasoning involves re-examining specific uncertainties (including model uncertainty, toxicological uncertainty, confounder uncertainty, and uncertainty about what actually affects the timing of death in people) that were acknowledged qualitatively, but whose discrete contributions to uncertainty in health benefits were not quantified, in EPA's cost-benefit analysis.

Of greater methodological interest than the difference in conclusions is the difference in uncertainty analyses. If EPA's assessment of uncertainties were correct, then it should be impossible, or at least very improbable, for any plausible variations in assumptions to reverse the main conclusion that CAAA benefits greatly exceed its costs. Yet, this is precisely what we will show: plausible variations in assumptions easily reverse the sign of the estimated net benefits. The principal methodological challenge that we seek to address in this paper is, therefore, to diagnose the features of the uncertainty analysis that led to such a confident – but, we think, erroneous – conclusion, and to understand how to avoid such overconfidence in future risk-cost-benefit analyses.

1. The Main Logic of EPA's Benefit Assessment

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Most of the benefit that EPA projects for 2020 is based on the estimated number and dollar value of mortalities that it expects will be prevented in that year by having cleaner air. The main calculation is simple:

Benefit = reduced number of deaths in 2020 x value per statistical life saved (1)

≈ (230,000 fewer deaths) x ($8,900,000 per life saved) ≈ $2 trillion.

The rationales for these two input values are provided in detail in EPA's report[2]. The 230,000 number for fewer deaths is given in Table 5-6, and is the estimated reduction in mortalities for all adults over 30 from reduced fine particulate matter ($PM_{2.5}$) in air. The value per statistical life saved (VSL) in 2020, of $8,900,000, is given in Table 5-4.The actual calculation is more refined, as it includes discounting and additional sources of benefits (e.g., from reduced morbidities and improved visibility, as well as reduced mortalities from lower ozone levels), but these make little difference to the final answer, which is still close to two trillion dollars worth of benefits for 2020, and even more in later years. As EPA states, "These avoided deaths are valued at 1.8 trillion ($2006), with primary low and primary high bounds on this estimate of $170 billion to $5.5 trillion."[2]. The reduction to $1.8 trillion reflects the passage of time before the estimated benefit is received. We will therefore focus on this simple calculation, and on the uncertainty analysis that led to these stated lower and upper bounds, as these calculations drive both the main quantitative results and the important qualitative conclusion that the value of health benefits almost certainly greatly exceeds the costs of compliance, which EPA estimates (Table 7-4) as $65 billion for 2020.

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2. EPA's Input Estimates and Weibull Uncertainty Analysis

The upper and lower bounds for the two trillion dollar main estimate of benefits reflect uncertainties about the number of mortalities that will not occur in 2020 because of cleaner air, as well as uncertainty about the correct VSL value to use. The reduction in mortalities is estimated by multiplying estimated reductions in $PM_{2.5}$ concentrations by an estimated concentration-response potency factor, called the C-R coefficient. As EPA explains (p. 5-10), "We based the primary C-R coefficient estimate of the Second Prospective study on a Weibull distribution with a mean of 1.06 percent decrease in annual all-cause mortality per one $\mu g/m^3$. This mean is roughly equidistant between the results of the two most well-studied PM cohorts, the ACS cohort (0.58, as derived from Pope et al., 2002) and the Six Cities cohort (1.5, as derived from Laden et al., 2006), both of whose results have been robust to continued follow-up and extensive re-analysis." Likewise, for the VSL number, EPA again used a Weibull uncertainty distribution, noting (Table 5-4) that, "[The] Mean Value of Statistical Life (VSL) [is] based on 26 wage-risk and contingent valuation studies. A Weibull distribution, with a mean of $7.4 million (in 2006$), provided the best fit to the 26 estimates." The $7.4 million value is shown for 1990 income levels, and is updated to $8.9 million for 2020 income levels. These two Weibull distributions, for the C-R coefficient and VSL, together with estimated reductions in $PM_{2.5}$ concentration levels due to CAAA, drive the 2 trillion dollar main benefit estimate and the upper and lower bounds around it.

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3. Questioning the Logic: Does the Main Calculation Make Sense?

EPA's main analysis, as just summarized, has the commendable virtues of simple, transparent logic and well documented input values and reasoning. It invites open inspection by the scientific community, so that any important deficiencies can be noted and, if necessary, repaired. To such deficiencies, we now turn.

The logic of equation (1) requires estimating the reduction in mortalities in 2020 due to cleaner air (reduced $PM_{2.5}$ concentrations) resulting from the CAAA. The total number of mortalities in 2020 *with* the CAAA is (or should be) calculated as follows: From the number of mortalities that would have occurred in 2020 without the CAAA (as estimated from population sizes and mortality rates), *subtract* the number of mortalities that are postponed until 2021 or later because of reduced mortality rates attributed to the CAAA; and *add* the number of mortalities that are postponed until 2020 from 2019 or earlier because of reduced mortality rates attributed to the CAAA. The difference between this number (i.e., the mortalities that occur in 2020 *with* the CAAA) and the original number (i.e., the mortalities that occur in 2020 *without* the CAAA) is the total change in mortalities in 2020 attributable to the CAAA. In other words,

deaths in 2020 <u>with</u> CAAA = number that would have occurred <u>without</u> CAAA – deaths postponed because of CAAA until after 2020 + deaths postponed because of CAAA until 2020 from earlier (2a)

Similarly,

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Change in deaths in 2020 attributable to CAAA = – deaths postponed because of CAAA until after 2020 + deaths postponed because of CAAA until 2020 from before 2020 (2b)

Unfortunately, EPA's calculation includes only the first term in the change (that is, the reduction – *deaths postponed because of CAAA until after 2020*), but neglects the second term (that is, the increase *deaths postponed because of CAAA until 2020 from before 2020*). EPA estimates that the average gain in life expectancy is less than a year (Table 5-8), so if mortality rates and population sizes change relatively slowly between 2019 and 2021, the deaths postponed from 2020 to 2021 or later will be approximately equal to the deaths postponed until 2020 from 2019 or earlier. Hence, *the net change in deaths in 2020 will be approximately zero,* instead of the 230,000 reduction in mortality estimated by EPA.

More generally, calculating "deaths avoided" in any year is not the correct risk analysis tool to use to estimate the health benefits from a regulation or other intervention. A correct analysis (e.g., using age-specific hazard functions and life table analysis) shows that even a regulation that successfully decreases age-specific mortality rates, thereby increasing life expectancy, may not reduce the annual number of deaths in the population.

Example: Accounting for Deaths

The following simplified numerical example illustrates why a regulation that extends lives does not necessarily reduce deaths per year. For simplicity, suppose that, before the regulation, each individual lived to age 80, and then had a 50-50 chance of either dying at age 80, or of surviving for a further decade and dying at age 90. Suppose that the regulation prevents early deaths, so that all those who would have died at age 80 now die at age 90. (Those who would have died at age 90 still do so.) Now,

how many people die each year before and after the regulation? (Assume a constant birth rate of *N* people per year, which is unaffected by the regulation.) Before the regulation, *N* people die each year (half of the cohort of *N* people born 80 years ago + half of those born 90 years ago, for a total of $N/2 + N/2 = N$.) After the regulation has fully taken effect, *N* people still die each year (all of the cohort born 90 years ago). Although half of the population lives longer, the number of deaths per year is unchanged.

Of course, even if the net deaths prevented in 2020 are zero (as will necessarily be true under steady-state conditions, and as will be approximately true if the population size is changing relatively slowly on a time scale of months to years), this would not imply that increasing life expectancy by several months has no value. But it does suggest that equation (1)'s emphasis on reduced mortalities in 2020 is the wrong way to capture this value. The problem is that the main projected health benefits are not (or should not be) deaths "prevented" or "avoided," or lives "saved," but rather life-years gained. EPA's own report[2] explains this well: "Avoided premature mortality is one of the more commonly cited results of benefits analyses for air pollution control. However, as noted in the valuation section of this chapter, *a more accurate description of the benefit of clean air is a reduction in the risk of mortality* for the exposed population over many years, which results in the extension of lives (sometimes referred to as 'lives saved'). *Other useful metrics of the benefit of cleaner air are the number of life years that are gained through the reduction of mortal risks*, and the number of years of life expectancy gained on average throughout the population." (Emphases added.)

Accordingly, we can re-do the calculation of benefits in equation (1), switching from deaths "prevented" or avoided (which, in reality, do not occur, since reducing $PM_{2.5}$ does not confer immortality) to life-years gained. EPA estimates (Table 5-8 of [2]) that, in 2020, almost two million (1,900,000) life-years will be gained because of cleaner air

caused by CAAA. No value of a statistical life-year ($VSLY) gained is explicitly identified in EPA's report, and values in the literature vary widely, depending on the elicitation techniques used and the ages of the recipients. We tentatively use a $VSLY value of $150,000 per life-year, which has previously been used for life-years gained by cancer patients through the year 2020[3]. (For comparison, if we assumed, simplistically, that the $8,900,000 VSL number used in equation (1) consists of at least 50 equally-valued life-years, then the corresponding $VSLY value would be at most $8,900,000/50 = $178,000. This ignores the important complexities of age-specific $VSLY values and discounting, but suggests that the estimated $VSLY value of $150,000/year is not grossly inconsistent with EPA's $VSL number.) Equation (1) can now be replaced with the following estimated value of health benefits based on estimated life-years gained:

Benefit = (life-years gained in 2020) x ($VSLY per life-year gained) (3)

= (1,900,000 life-years gained) x ($150,000/life-year gained) = 0.3 trillion.

Thus, simply replacing lives saved with life-years gained, and hence the $VSL value in equation (1) with the $VSLY value in equation (3), reduces the benefit estimate from about 2 trillion to about 0.3 trillion.

As it happens, a similar numerical conclusion results even if the logic of equation (1) is retained, but the ages at which projected benefits occur are taken into account. EPA estimates the median age of people whose lives are "saved" (i.e., who gain extra months of life) from cleaner air to be close to 80 years (Table 5-8 of [2]). The $VSL of $8,900,000 is appropriate for a healthy young adult of age about 25 (Aldy and Viscusi[4], Figure 1). The $VSL for people aged close to 80 has been estimated to be

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approximately one sixth of the $VSL for people aged about 25 (Murphy and Topel[5], Figure 1). Thus, using $VSL numbers that condition on the ages at which benefits are received would also reduce the estimated value of health benefits substantially, with a six-fold reduction reducing EPA's current estimate of $1.8 trillion to a revised estimate of 0.3 trillion. Despite this numerical coincidence, however, we believe that equation (3) is logically (and perhaps ethically) preferable to equation (1), since, as EPA notes, the true benefit from reduced mortality rates is gain in expected life-years.

Two other ways of framing the simple analysis in this section may help to clarify the crucial role that conditioning on age should play in health effects benefits assessments. The first is that, in very round numbers, about two million life-years gained in 2020 can create about two trillion dollars worth of benefit only if each life-year gained is valued at about a million dollars (or, equivalently, at about $80,000 per additional month of life). This is a much higher value than many octogenarians place on their own gains in life-years[4,5]. Second, applying a $VSL value appropriate for a 25-year old to people who are mostly over 75 (and a significant fraction of whom are over 100 years old, according to EPA's[2] Table 5-8, since this group contributes as much to estimated life-years gained as the 40 to 49 year olds in 2020) suggests that cleaner air is being evaluated, perhaps inadvertently, as a sort of fountain of youth, restoring the full value of youth (e.g., with at least another 50 years of healthy life expectancy) to people who, in fact, have a median age close to 80 years (*ibid*). This appears to be overly optimistic.

Health economics studies of the costs and benefits of medical interventions routinely quantify health benefits in terms of the monetized value of quality adjusted life

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years (QALYs), per the recommendation of the U.S. Panel on Cost Effectiveness[19]. QALY values of between $50k and $100k per year are common, and values up to $200k can be found, but these values are substantially less than the $1 million that EPA implicitly places on a life-year (without adjusting for quality). Thus, whether one uses monetized values of "lives saved," or life-years added, or quality-adjusted life-years added, EPA's valuation appears to be higher than others, for similarly aged (and perhaps similarly infirm) people, by approximately one order of magnitude.

4. Questioning the Major Premise: Will Reducing $PM_{2.5}$ Concentrations Further Really Reduce Mortality Rates Further?

Even more important than uncertainty about the correct value of $VSL (or of $VSLY) is uncertainty about the correct value of the C-R coefficient that converts reductions in $PM_{2.5}$ concentrations to corresponding projected reductions in mortality rates. If the C-R coefficient is zero, then the health benefit from further reducing $PM_{2.5}$ concentrations is also zero. The assumption that the C-R coefficient is positive might be wrong. EPA's qualitative discussion of key uncertainties (Table 5-11 of [2]) explicitly identifies this crucial assumption, noting that the "Analysis assumes a causal relationship between PM exposure and premature mortality based on strong epidemiological evidence of a PM/mortality association. However, epidemiological evidence alone cannot establish this causal link." The possible impact of this assumption is identified as being a "potentially major" overestimate of benefits. However, EPA rates its confidence in its causal hypothesis as "High," arguing that, "The assumption of causality is suggested by the epidemiologic and toxicological evidence

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and is consistent with current practice in the development of a best estimate of air pollution-related health benefits. At this time, we can identify no basis to support a conclusion that such an assumption results in a known or suspected overestimation bias." EPA's quantitative uncertainty analysis goes further, implicitly expressing 100% confidence that this causal hypothesis is correct. The Weibull uncertainty distribution for the C-R coefficient implicitly assigns a probability of 100% to the C-R coefficient being positive, and hence a 0% probability to it being zero (or negative). Thus, the qualitative assessment of "high" confidence is implicitly mapped to a quantitative assessment of 100% certainty. Such complete certainty is unwarranted by available data and knowledge, as discussed next.

Is There Really a Significant Positive Association Between $PM_{2.5}$ and Mortality Rates?

Being unable to identify a basis for a suspicion of an overestimation bias does not, of course, guarantee that there is no such bias. Nor, perhaps, should a (subjectively perceived) suggestion of the possibility of a causal relation in epidemiological and toxicological data, or consistency with current practices in developing best estimates, warrant a very confident conclusion – let alone 100% confidence – that a causal relation necessarily exists.

For toxicological data, both theory and empirical evidence indicate that the inflammation-mediated adverse health effects of fine particulates probably have thresholds, below which the C-R coefficient is zero[6,7]. For example, low levels of exposure induce increased antioxidant (AOX) production in the lung, but higher levels induce levels of reactive oxygen species (ROS) that overwhelm the very limited capacity

of the lung to increase AOX. Increased disease risks occur only when there is an imbalance that leads to a sustained high-ROS lung environment and other changes that disrupt homeostasis, which may not occur at or near currently permitted exposure levels[6].

For epidemiological data, the National Academy of Sciences and several expert statisticians have long questioned whether reported findings of significant positive C-R coefficients may be misinterpreting ambiguous data as showing evidence of a significant association where none actually exists[8-10]. This concern is based largely on awareness that multiple testing biases (which inflate the rate of false positives) can arise when pollution health effects investigators make numerous modeling choices (e.g., of which pollutant summaries, confounders, covariates, and interactions to include in the model; what logarithmic or other transformations to apply to them; lags in variables; model form specifications; treatment of exposure uncertainties, etc.) in arriving at the reported significant positive associations. Attempts to increase the objectivity of conclusions about PM-mortality rate associations, by considering all of the effect estimates from many (e.g., thousands of) computer-generated models that fit the available data approximately well, without applying human judgment to select or defend any particular model or conclusion, have found that the hypothesized associations may not exist. For example, some Bayesian model-averaging (BMA) analyses (averaging effects over multiple models, weighted by their likelihoods in light of the data) of time series studies have reported, contrary to findings based on subjective selection of modeling assumptions, that available time series data sets give no overall indication of a positive relation between $PM_{2.5}$ and mortality rates[8, 9]. The probability that current or

lagged $PM_{2.5}$ values help to predict mortality rates (compared to predictions based solely on non-pollutant variables such as temperature and pressure) ranges from about 2% to 7% in some BMA studies[9], and associations between pollutants (including particulate matter and ozone) and mortality rates have been reported as not significantly different from zero in some Canadian and U.S. investigations[8-10]. However, the BMA analyses were conducted for time-series data, and thus are not directly comparable to the long-term cohort studies used by EPA. We do not know whether the conclusion that only a small fraction of models show any association of PM with mortality rates would hold in the two main studies (the Harvard Six Cities and American Cancer Society cohort study data) used in EPA's assessment[2].

Against such reports of apparently non-existent associations, some investigators whose methods and models have informed EPA's benefits assessment have argued that "Bayesian approaches in general and BMA in particular are not panaceas for model selection." (This is certainly true, as they are not model selection methods at all.) They further note that Bayesian approaches may be mistakenly applied, and therefore urge that "model selection should be informed by substantive knowledge about the environmental health processes influencing the outcome."[11] This response appears to reject the BMA principle that model selection should not be used at all (since even the "best" single model is almost certain to be wrong); but to advocate instead the continued use of judgment, "informed by substantive knowledge," as a basis for selecting models (which, in turn, may drive conclusions that are more consonant with the modelers' judgments about what should be found) – thus reopening the possibility that confirmation bias (selecting modeling assumptions that are favored by prior

expectations or expert opinions) and multiple selection bias might explain some reported positive associations. For example, imposing an *a priori* modeling assumption that mortality rates increase approximately in direct proportion to pollutant levels at low concentrations (e.g., in a Cox proportional hazards model), or that the C-R function is linear at low concentrations (and piecewise linear overall), makes it possible to conclude that the C-R curve "is linear, clearly continuing below the current U.S. standard of 15 $\mu g/m^3$"[12]. In this way, substantive knowledge or *a priori* assumptions and model selection constraints can still be used to produce low-dose linear results and a positive C-R coefficient. EPA (2011, Table 5-11, p. 5-42) identifies the "Assumption of a linear, no-threshold model for PM and ozone mortality" as a "Key uncertainty," but assesses as "High" its subjective confidence that this choice of model is correct, and as "Probably minor" the potential impact on overestimation of benefits of considering other model forms. This contrasts with time series studies that conclude that considering other models removes all significant positive associations between $PM_{2.5}$ and mortality rates[8-10]. A possible explanation is that the one cohort study that EPA's table cites in support of these crucial conclusions (an EPA- (Health Effects Institute)-funded study of the ACS data[24]) focused on models (random effects Cox proportional hazards and Poisson regression models) that imply low-dose linearity, rather than considering other (e.g., J-shaped or threshold) models that could have revealed absence of a positive C-R relationship at low exposure levels.

Even without further discussing, or seeking to resolve, how best to use computationally intensive statistical methods such as BMA to more fully characterize uncertainty about the C-R coefficient, it seems clear that there is significant uncertainty

about whether a true association exists between ambient $PM_{2.5}$ concentrations and mortality rates; it is still being investigated. This crucial uncertainty should not be lightly dismissed. EPA's qualitative caveat deserves emphasis, that the "Analysis assumes a causal relationship between PM exposure and premature mortality based on strong epidemiological evidence of a PM/mortality association, [but] epidemiological evidence alone cannot establish this causal link." Even this caveat should perhaps be tempered further, by acknowledging that calling the epidemiological evidence favoring a PM/mortality rate association "strong" may largely reflect unvalidated modeling assumptions (e.g., of a linear, no-threshold C-R relation at ambient levels). Frequent minority reports of statistically significant *negative* C-R coefficients, in models that allow this possibility, raise further questions about the coherence and reality of claimed statistical associations. For example, a recent review of associations between $PM_{2.5}$ and all-cause and cause-specific mortality in 27 U.S. communities indicated *reduced* all-cause mortality rates at increased levels of $PM_{2.5}$ for one third of the communities, including Birmingham, Dallas, Houston, Las Vegas, and Riverside[11].

To understand the sensitivities of EPA's cost-benefit assessment to plausible alternative assumptions, it suffices to note that the question of whether a real (data-driven, rather than model selection-driven) association exists between $PM_{2.5}$ concentrations and mortality rates remains open, apparently on fairly substantive grounds, with at least some BMA studies indicating rather strongly (e.g., with greater than 95% probability) that there is no such association[9]. Lack of consistency in effects across studies, and large, unexplained heterogeneity in apparent C-R functions (including some with negative slopes) across locations, add qualitative reasons to

question whether a stable, coherent association exists[8-10,13]. This uncertainty should be explicitly addressed and, if possible, quantified, as BMA analyses seek to do, rather than being tacitly ignored, e.g., by using only a single average value across all studies[13] (perhaps with subjective confidence intervals) without explaining or resolving the observed negative relations.

Are Reported Statistical Associations Causal?

Even if a real (model-independent) statistical association exists, of course, it might not be causal. Many investigators have recognized that covariates and confounders (such as proportion of high-risk minorities in a city, or correlates of wealth or education or poverty, or residual confounding by weather variables, including high temperatures or barometric pressures, or changes and trends in these variables) might create significant statistical associations between pollution and mortality rates, even if the former does not necessarily cause the latter. Likewise, regressing some trend variables (e.g., declining cause-specific and overall mortality rates in the wake of innovations such as angioplasty, anti-smoking campaigns, and aspirin therapy) against others (such as declining ambient pollution levels in recent decades) can show strong, statistically significant associations between them, with reductions in exposure concentrations routinely being followed (as well as preceded) by reductions in mortality rates, even if there is no causal relation between them.

Such threats to valid causal interpretation of statistical associations are well recognized by many investigators in pollution health effects research, but approaches for trying to address them have varied widely. To meet such challenges and threats to

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valid causal inference more decisively, econometric and statistical tests for potential causation between variables have been extensively developed, using concepts such as conditional independence and Granger causality for multiple time series[14]. However, these methods have generally not yet been applied to $PM_{2.5}$ and mortality data. Thus, the question of whether any statistical associations might be causal has not been settled using such relatively formal, objective tests. (As previously noted, inconsistencies across cities and studies, and large, unexplained heterogeneity in C-R coefficients estimated in different studies, including some significant negative ones, undermine the coherence of proposed causal interpretations. Thus, the question of whether there is any positive *causal* relation between ambient levels of ozone and $PM_{2.5}$ and mortality rates, is a second important, discrete, uncertainty that should be explicitly addressed in uncertainty analysis. It cannot be answered by arguing that there is a positive *statistical* association between them (at least under some model-selection assumptions), since statistical and causal relations have no necessary connection (e.g., omitted confounders can make statistical relations positive even if causal relations are zero or negative). Nor can it be settled by concluding, based on expertise, that the data are *consistent* with such a relationship[2], if the data are at least equally consistent with the opposite conclusion of no relationship[8-10]. We conclude that the question remains unsettled, and that it is appropriate for inclusion in uncertainty analysis.

EPA's benefit assessment[2] (pp 5-7 to 5-10) recognized and addressed the possibility of confounding in its uncertainty analysis, as follows:

"Several other sources of uncertainty exist in the relationship between ambient pollution and the health outcomes, including model uncertainty, potential confounding by factors that are both correlated with the

health outcome and each other, and potential misclassification of the study population exposures. …EPA recently conducted an expert elicitation (EE) study, which is the formal elicitation of subjective judgments, in order to more fully characterize the uncertainty surrounding the $PM_{2.5}$/mortality C-R function. This study allowed experts to consider and integrate several sources of uncertainty in the form of a probability distribution for the C-R function…[W]e rely exclusively on longterm studies to quantify PM mortality effects. This is because cohort studies are able to discern changes in mortality rates due to long-term exposure to elevated air pollution concentrations. …Based on consultations with the Council's Health Effects Subcommittee (HES), the 812 Project Team developed a distribution of C-R function coefficients (i.e., the percent change in annual all-cause mortality per one $\mu g/m^3$ change in annual average $PM_{2.5}$) for use in the PM-mortality C-R function for the Second Prospective study. This distribution is rooted in the epidemiological studies that most inform our understanding of the PM mortality C-R function, but reflects the broader findings of the EE study. We based the primary C-R coefficient estimate of the Second Prospective study on a Weibull distribution with a mean of 1.06 percent decrease in annual all-cause mortality per one $\mu g/m^3$. This mean is roughly equidistant between the results of the two most well-studied PM cohorts, the ACS cohort (0.58, as derived from Pope et al., 2002) and the Six Cities cohort (1.5, as derived from Laden et al., 2006), both of whose results have been robust to continued follow-up and extensive re-analysis."

Thus, EPA explicitly recognized the possibility of confounding. They dealt with uncertainty about whether confounding, model uncertainty, or other sources of non-causal associations (such as exposure measurement error or misclassification) might have created an overall false-positive association between $PM_{2.5}$ concentrations (C) and health responses (R) in past studies, by (a) Relying on two studies that reported significant positive associations; (b) Discarding, or leaving unexplained, studies that reported significant negative or non-significant C-R associations; and (c) Applying subjective expert judgments, encoded as a Weibull distribution (which cannot show zero or negative relationships), to conclude that a positive causal relation exists with 100% subjective confidence probability. (The Weibull distribution implicitly assigns a subjective probability of zero to the discrete possibility that fully controlling for all

relevant confounders and trends would yield a negative or zero causal estimate of the percent decrease in annual all-cause mortality per $\mu g/m^3$ of $PM_{2.5}$.)

Whether or not their conclusion is correct, this *process* – considering only data and probability distributions that support or logically require, *a priori*, the conclusion of a positive relation between exposure and health effects – is surely not adequate for characterizing uncertainty about whether the underlying assumption that the true (unconfounded) C-R relation is positive is correct. The results of expert elicitation, expressed in the form of a distribution for a (causally interpreted) C-R coefficient, are also of uncertain value as a guide to objective truth, insofar as (a) The elicited distribution does not match, and hence does not explain, the empirically observed distribution of C-R coefficients in meta-analyses of dozens of reputable studies, about a third of which are negative[11]; and (b) No one currently knows how or whether further reducing ambient concentrations of $PM_{2.5}$ *per se* – as opposed to reducing other activities, conditions (e.g., temperature extremes), and pollutant constituents (e.g., various oxides and sulfates) that are strongly correlated with $PM_{2.5}$ – would cause any incremental reductions in mortality risks.

Experts, like other people, may have opinions on these matters. But one cannot elicit from experts knowledge that they do not have. In this case, correct "substantive knowledge" of causal relations showing how reducing current and future ambient $PM_{2.5}$ concentrations would affect human health, or how and whether other confounders and their interactions affect the estimated C-R relations for $PM_{2.5}$ is not yet available. We do not yet even know which components of $PM_{2.5}$ (if any), possibly interacting with which other pollutants, cause adverse health effects under present ambient exposure

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conditions. This does not necessarily imply that no new action should be taken. But it does imply that, if $PM_{2.5}$ *per se* is not involved in causing increased mortality rates, then further reductions in ambient $PM_{2.5}$ levels may not produce any health benefits. This possibility should be acknowledged in uncertainty analysis of human health benefits by including a substantial discrete (non-zero) uncertainty about causation.

Do C-R Relations Have Thresholds or J-Shapes?

Even if historical data showed a clear, unambiguous, causal relation between concentration and response, with past declining levels of $PM_{2.5}$ (or C) consistently causing proportionally declining levels of mortality rates (or R), it would be important to establish whether further reductions in C would produce further reductions in R. At some point, C might reach (or might already have decreased below) a threshold below which no further reductions in R are gained. Uncertainty about that threshold, and about whether current standards are already below it, should then be quantified. Or, conceivably, continuing reductions in C might eventually pass a point after which further reductions in C actually increase R, as suggested by a few of the U-shaped or J-shaped empirical C-R model curves fit to PM_{10} data for the twenty largest U.S. cities[15]. (This might also explain the previously noted disconcerting finding of negative C-R coefficients in approximately a third of cities examined[11].) The probability of this contingency, and the conditional probability that we have already approached or passed the bottom of such a J shape if it exists (at least in some cities), should limit the certainty with which additional reductions in C can be projected to cause additional reductions in R.

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Existing discussions in the air pollution health effects literature of the possibility of a threshold for the C-R function largely recapitulate the technical issues in discussions of whether a non-zero C-R coefficient exists at all. Those who favor a linear, no-threshold model argue that model selection criteria such as the Akaike Information Criterion (AIC) can be used to support it[12], insofar as other models tested typically do not give significantly better AIC scores. Those who are more agnostic about the linear no-threshold model point out that the AIC criterion is not appropriate for this use: in simulation experiments (for which the correct model is known) it only identified the correct model about half the time, and assuming a linear no-threshold model can greatly under- or over-estimate true mortality risks if non-linearities are present but are mistakenly assumed away based on AIC[16]. Defenders of the linear no-threshold model further counter that population data exhibit no thresholds, but appear to be linear down to the lowest levels measured[15]. Skeptics could respond that this pattern is precisely what one might expect if there really is a population threshold, but individual exposure estimates contain unmodeled errors, as in past studies; thus, the observed population C-R function is irrelevant to determining whether there is a true C-R threshold[6]. That errors in past exposure estimates cast doubt on inferences about health effects is starting to be more widely acknowledged[17], but no one has yet advanced a model that clearly fits most of the data, reconciles past inconsistencies, accounts for past measurement errors, and resolves the debate with an obviously correct C-R relation.

As in the case of uncertainty about whether a positive C-R coefficient exists, the role of uncertainty analysis is not to resolve whether threshold or J-shaped C-R relations exist (at at least some locations), but only to make sure that any significant

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uncertainties about these possibilities are identified and explicitly addressed in the presentation and evaluation of uncertain health benefits projected from reductions in exposure concentrations. However, EPA's quantitative uncertainty analysis implicitly assumes that there are *no* uncertainties about the correct form (linear, no-threshold with probability 100%) or sign (positive with 100% probability, zero or negative with 0% probability) of the C-R relation. Admitting that there are such uncertainties would substantially change both the uncertainty analysis and the evaluation of projected health benefits, as explained in Section 5.

How Much Smaller Will Future C-R Coefficients be than Past Ones?

Finally, suppose that a true, causal, linear C-R coefficient were to be confidently identified in historical data. Even this would not warrant a conclusion that *future* reductions in pollutant levels would achieve proportionate reductions in mortality rates and gains in life-years. Progress in medicine, including preventive medicine, is steadily shrinking the pool of highest-risk individuals whose lives might, under the above assumptions, be most prolonged by reducing pollutant levels. Long-term trends such as improved diet and exercise among adults, greater use of low-dose aspirin regimens and other medications to successfully prevent cardiovascular disease events, smoking reduction and cessation programs, and new treatment and therapeutic options (such as angioplasty) have led to a long-term trend of declining mortality risks from key diseases identified by EPA as being reduced by lower pollutant levels.

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Some experts interpret epidemiological data as showing that "Short-term and long-term studies clearly indicate that relatively modest exposures to particulate matter in the ambient air are associated with increased morbidity and mortality due to coronary heart disease."[20] Death from coronary heart disease (CHD), especially among the elderly and patients with pre-existing cardiovascular diseases, has been proposed as a specific mortality risk caused by high levels of particulate pollution[20, 21]. The future relation between $PM_{2.5}$ and mortality risks, therefore, may be affected by trends in CHD risk. These trends show very significant declines in CHD mortality risks over the past four decades, with further declines expected. For example, a recent review[22] that quantified temporal trends in cardiovascular mortality risks in Minneapolis-St Paul, MN found that mortality rates for non-hospitalized men fell by about 2/3 between 1985 and 2008 (from about 150/100,000 in 1985 to about 50/100,000 in 2008). Similarly, for the United States as a whole, a recent World Health Organization (WHO) study[23] found that "Since the late 1970s, age-adjusted CHD mortality rates have been halved in most industrialized countries, including the United States. ...Approximately 44% of the substantial CHD mortality decline in the United States between 1980 and 2000 was attributable to changes in major risk factors [smoking, systolic blood pressure, total blood cholesterol, body mass index], and 47% to specific cardiological treatments. These findings resembled those from other industrialized countries. ...In conclusion, implementing evidence-based policies to better control tobacco use and achieve a healthier diet across the population could potentially halve future CHD deaths in the United States." Although future reductions in risk will depend on future trends in diet, exercise, obesity, aging of the population, and medical interventions and treatments,

there appear to be continued large opportunities for continued risk reductions in the United States (*ibid*). As such trends continue, the incremental benefits from additional pollution control might also be expected to shrink, as fewer people remain at high risk of mortality from pollution-associated diseases such as CHD. Thus, analysis of projected future benefits should include uncertainty about the size of future C-R coefficients, rather than assuming that C-R coefficients estimated from historical data will remain undiminished by current and future trends.

5. Discrete vs. Continuous Uncertainty Analysis

The major uncertainties about the health effects of reducing pollutant concentrations in air can be summarized as the following series of questions.

- *Is there a true C-R association?* What is the probability that there is a true (independent of model selection assumptions) statistical association between lower pollutant concentrations (C) and lower mortality rates (R)?
- *Is it causal?* Assuming that there is a true C-R association, is it causal? That is, will future reductions in $PM_{2.5}$ and ozone cause corresponding reductions in future mortality rates? Or, to the contrary, is the association non-causal, e.g., reflecting past downward trends in both variables that do not represent a causal relation, and that do not support manipulating future mortality rates by changing future ambient pollutant concentrations? What is the probability that the C-R association (if there is one) is causal?

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- *Is it linear non-threshold (or are present and future concentrations above any applicable threshold, or on the ascending part of any J-shaped C-R function)?* Assuming that a causal C-R relation exists in past data, for concentration levels prevalent then, how likely is it that a similar C-R coefficient will continue to hold in future, as ambient concentrations continue to fall? What is the probability that we are *not* yet at or below a nadir, threshold, or threshold-like nonlinearity, in the C-R function, which would cause future reductions in C to produce no further reductions in R, and hence no incremental health benefits? Colloquially, we might wonder: How clean is clean enough to achieve the possible health benefits, and have we already reached a point past which no additional health benefits will accrue to additional reductions in concentrations? What is the probability that this is not the case?
- *Is it stable over time?* What is the probability that C-R coefficients will remain approximately the same, despite improvements in prevention and medical treatments for the diseases that are associated with pollutants? If the C-R coefficient does decline in future, as the at-risk population declines, then what is its new expected value?

A notable aspect of these uncertainties is that they are discrete: one can imagine answering yes or no to each one, if perfect information were available, and can therefore envision assigning a discrete probability (a number between 0 and 1) to each of these possibilities now, based on the imperfect information available now.

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For purposes of plausible numerical illustration and sensitivity analysis, suppose that the quantitative probabilities for answers to these questions are as follows:

- *Probability that there is a true association* = 50%. As discussed previously, the data on associations are conflicting, with both positive and negative significant C-R associations being reported, and with results of individual studies appearing to be sensitive to choices of statistical methods and modeling assumptions[8]. Bayesian Model Averaging (BMA) analyses that permit the possibility of no association between $PM_{2.5}$ and mortality rates generally find little support for the hypothesis that such an association exists at ambient concentrations; the probability that it does exist was estimated as between about 2% and 7% in a recent BMA analysis[9]. Against this conclusion, many experts are convinced that the combined findings from multiple epidemiological studies "clearly indicate that relatively modest exposures to particulate matter in the ambient air are associated with increased morbidity and mortality due to coronary heart disease,"[20] and that the main remaining scientific challenge is to figure out why and how this occurs. It is not necessary to choose between these conclusions for purposes of illustrating how such uncertainties affect final benefits estimates. Instead, we will use a 50% probability of a true association as a point of departure for quantitative analysis, and then use sensitivity analysis to understand how changes in this probability affect conclusions.
- *Probability that a true association, if it exists, is causal* (and not explained away by trends, confounding, or the distinction between statistical and causal associations) ≤ 0.5. The inconsistencies and large unexplained differences in

estimated C-R functions, signs, and magnitudes across studies – even for the same chemical, such as ozone – and failure to find clear evidence of a coherent causal relation at ambient levels in clinical, laboratory, or experimental studies despite decades of evidence might suggest a "more likely than not" conclusion that there is not a causal relation. A probability interval of ≤ 0.5 captures this uncertain probability. This is strengthened by some past reviews and conclusions, e.g. that, "Because the mortality risk estimates from important observational epidemiologic studies are extremely weak, derived from studies unable to control for relevant confounding causes, and inconsistent by location, toxicologic and clinical information is necessary to judge the likelihood and degree to which such findings are causal. Toxicologic data on typical forms of pollution-derived PM strongly suggest that current ambient concentrations in the U.S. are too small to cause significant disease or death. ...The expectation that lives will be saved by reducing ambient $PM_{2.5}$ in the U.S. is not supported by the weight of scientific evidence, although other bases for regulating PM may be justifiable."[18]

- *Probability that currently permitted concentrations are above any threshold* or nadir in the C-R function (if any; or probability that there is no such threshold or nadir) ≤ 0.5. Repeated finding of negative as well as positive C-R coefficients might suggest the possibility of a J-shaped function, and other reasons for expecting a threshold have previously been discussed[6]. The inconsistencies and difficulties in identifying any clear positive C-R association[18] also suggest that we could now be below the clearly rising portion of a C-R function.

- *Expected reduction factor in C-R coefficient by 2020* ≤ 0.5, assuming that a linear no-threshold causal C-R coefficient exists. Improved medical diagnosis, intervention (e.g., with aspirin therapy, smoking cessation programs, or cholesterol-reducing measures, including changes in diet and exercise), and treatment, which are increasingly being used, can potentially reduce premature CVD mortalities by 80%-90% or more, but an aging or more obese population over the next decade could modestly increase the C-R slope[23]. Based on these opposed trends, and in light of the past four decades of declining CVD risks, an overall reduction factor of 0.5 might not be implausible as a starting point for the reduction in any real C-R coefficient, although higher or lower values might be developed with additional modeling. We will use 0.5 as a point of departure for understanding the sensitivity of estimated benefits to this factor.

Each of these factors is conditioned on the outcomes of all of its predecessors being such that a positive linear no-threshold causal C-R coefficient exists.

With these rough estimates of factors (using the upper end of each uncertainty interval, e.g., 0.5 for the interval ≤ 0.5), the health benefits estimated by EPA would be adjusted as follows:

(1.8 trillion initial estimate) x (1/6 reduction factor for $VSL if age or $VSLY is considered) x (0.5 probability that a true association exists) x (0.5 probability that a true association is causal, given that one exists) x (0.5 probability that ambient concentrations are above any thresholds or nadirs in the C-R function, given that a true causal C-R relation exists) x (0.5 expected reduction factor in C-R coefficient by

2020 due to improved medication and prevention of disease-related mortalities) = (1/6)*0.5*0.5*0.5*0.5 = $19 billion.

In round numbers, the combination of assumptions shown here reduces the estimated value of health benefits in 2020 one hundred-fold, from two trillion dollars to $20 billion. Instead of being much greater than the estimated compliance costs of $65 billion, the estimated value of health benefits is substantially less. This conclusion is robust to changes in any of the above factors, in that replacing any of them with 1 (no reduction) would not change the conclusion that benefits are less than costs. Sensitivity analysis of this product is trivial: changing any factor by *k*-fold changes the entire product by *k*-fold, for any $k > 0$.

The point of departure values for this calculation were deliberately chosen realizing that they might be conservative (erring in the direction of over-stating C-R relations and health benefits), with all factors ≤ 0.5 being rounded up to 0.5 for purposes of this initial calculation. Two main changes that might increase realism would significantly reduce estimated benefits. One would be to accept at face value the BMA results indicating that a true positive association between present ambient levels of $PM_{2.5}$ and mortality rates is unlikely[9]. This could reduce the point of departure for this probability by about a further order of magnitude, from 0.5 to about 0.05, and hence reduce the plausible high estimate for monetized value of annual health benefits from $19 billion to $1.9 billion. (A strong conviction that causality is very unlikely would have a similar effect.) The other main change would be to replace the 1/6 reduction factor for $VSL with a reduction factor of 1/10 for $VSLY (or value of a QALY), as discussed

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earlier. This would reduce annual benefits estimates by a further factor of 0.6 (e.g., from $1.9B to approximately $1B). Such numbers are well below the $65B in annual compliance costs estimated by EPA. If these two alternative values were used as points of departure, then the conclusion that expected benefits are less than expected costs would be robust to changes that increased any or all of the remaining factors to 100%.

These calculations are all based on expected values (albeit for upper bounds, if the points of departure are indeed conservative). For a risk-averse individual or society, however, the economic value of an uncertain benefit is *less* than its expected value, by an amount that depends on the risk premium for uncertainty. A further reduction in the evaluation of the uncertain benefits (by perhaps a further factor of 2, depending on the risk premium) would be needed to take into account risk aversion for uncertain gains.

Such further adjustments and refinements, while possibly producing a more realistic answer, might also invite inessential controversy. Our main conclusion, that the 1990 CAAA benefits plausibly amount to only a small fraction of their direct compliance costs (the only costs considered in the $65 billion estimate), does not depend on choosing very small probabilities as points of departure, nor on greatly revising EPA's value judgments about $VSL or $VSLY, nor on incorporating risk aversion for uncertain benefits. Rather, it is a robust result of the combination, in series, of multiple substantial uncertainties. The result is robust in the sense that no particular one of these uncertainties (and no small subset, if the suggested smaller points of departure are adopted) is essential for reaching this conclusion.

However, the conclusion that the 1990 CAAA human health benefits are very probably substantially smaller than compliance costs offers a sharp contrast to EPA's more reassuring conclusion that *"**The extent to which estimated benefits exceed estimated costs** and an in-depth analysis of uncertainties **indicate that it is extremely unlikely the costs of 1990 Clean Air Act Amendment programs would exceed their benefits under any reasonable combination of alternative assumptions or methods identified during this study.**"* What explains the difference? The key is that *EPA's uncertainty analysis ignores discrete uncertainties,* such as those we have enumerated, in favor of a continuous, non-negative probability distribution – the Weibull distribution – that puts zero probability density on zero or negative numbers as possible values. Applied to the crucial C-R coefficient, the Weibull uncertainty distribution implies 100% confidence that the coefficient is positive, notwithstanding the numerous studies that have reported zero or negative coefficients. This framing of the uncertainty analysis only allows one to ask (and experts to answer) *how large* are the assumed benefits, but not to question (or provide opinions on) whether they exist. Thus, the major discrete uncertainty about whether positive benefits exist at all – the main focus of our analysis – is simply assumed away in EPA's Weibull uncertainty distribution.

In this context, EPA's conclusion that "it is extremely unlikely the costs of 1990 Clean Air Act Amendment programs would exceed their benefits under any reasonable combination of alternative assumptions or methods identified" is no surprise. It is little more than an assertion of a tautology, similar to, "Assuming that I am right, it is extremely unlikely that any reasonable combination of alternative assumptions would show that I am wrong." But this style of uncertainty analysis fails to cast any light on

uncertainty about the major premise. The not-implausible numbers offered above suggest that that probability of zero human health benefits might well exceed 1 - (0.5*0.5*0.5) = 87.5% based solely on uncertainties about whether there is a positive, causal (not due to confounding or coincidence of trends), non-threshold C-R relation for current and future ambient pollutant concentrations (assuming, conservatively, that there is a 50% probability for each of these three uncertainties – if smaller points of departure are used, then the probability of zero human health benefits exceeds 99%). Thus, assuming that the probability of zero (or negative) human health benefits is zero substantially understates the true uncertainty, and hence substantially overstates the uncertain benefits of the CAAA.

The use of a Weibull uncertainty distribution also conceals other discrete uncertainties, arising from blinkered analysis and failure of imagination. For example, suppose that the CAAA creates more clear days and bright skies. How, if at all, would this affect peak temperatures during the summer, and mortality rates among people without air conditioners? How, if it all, would it affect the future burden of skin cancer? The cost-benefit analysis does not say, and the Weibull uncertainty analysis implicitly disregards all such uncertainties due to drivers of possible costs and benefits not already identified in the analysis. Or suppose that, contrary to our expectations, the CAAA does prolong the last year of life for a substantial fraction of elderly patients suffering from heart, lung, and circulatory diseases. How would this affect health care costs and living costs, and the benefits of longer life, as evaluated by patients and their families? These costs and uncertainties are likewise implicitly assumed away in EPA's analysis, but considering them might further increase the probability that the net benefits

of the CAAA are negative, and further increase the estimated ratio of costs to benefits, beyond the roughly 65-to-1 value (or more) suggested by some of our calculations.

6. Conclusions

EPA's cost-benefit assessment indicates that the CAAA offers the United States an admirable return on investment: an expenditure of only $65 billion per year secures health benefits valued at nearly two trillion dollars per year. If this is credible, any policy maker would be foolish to refuse it. EPA's uncertainty analysis suggests that the large excess of estimated costs over estimated benefits is not only credible, but virtually certain: it is deemed to be "extremely unlikely" that any reasonable changes in assumptions would reverse the sign of net benefits.

However, these promising conclusions depend essentially on the use of a Weibull distribution in the uncertainty analysis, which tacitly assumes away any possibility of serious, discrete errors or uncertainties in the key assumptions – especially about whether future reductions in $PM_{2.5}$ and ozone will necessarily cause future increases in life expectancy. Yet, this is exactly the uncertainty that a large, data-driven literature questions. Numerous reported findings of unexplained negative and highly heterogeneous positive C-R coefficients call into question the assumption that any such single, positive, causal coefficient exists.

Taking into account such discrete uncertainties suggests that the probability of achieving positive benefits could well be small (e.g., less than 12.5%, or less than 1%, if some BMA results[9] are used) so that EPA's uncertainty analysis assuming that this

probability is 100% may be more misleading than informative. A policy maker to whom the CAAA costs and benefits are presented as: "Pay $65 billion for a chance of probably much less than 20% to achieve benefits of about $300 billion," as our numbers suggest, might well decide that the cost is too great for the uncertain benefits. Even if all of our suggested specific numbers are rejected and replaced by more carefully developed ones, it seems that considering discrete uncertainties has important effects on the analysis, and that such uncertainties should be presented to policy makers if they are to make well-informed decisions to serve the public interest.

We do not believe that the calculations presented here prove beyond doubt that the CAAA costs far more than it produces in benefits. We do think that they make this possibility very likely, and hence well worth including, instead of assuming away, in any uncertainty analysis of CAAA cost-benefit comparisons.

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REFERENCES

1. EPA, 2011. The Benefits and Costs of the Clean Air Act from 1990 to 2020: Summary Report. EPA. March, 2011

2. EPA, 2011. The Benefits and Costs of the Clean Air Act from 1990 to 2020

3. Yabroff KR, Bradley CJ, Mariotto AB, Brown ML, F Estimates and projections of value of life lost from cancer deaths in the United States. J Natl Cancer Inst. 2008 Dec 17;100(24):1755-62

4. Aldy JE, Viscusi WK. Age differences in the value of statistical life: Revealed preference evidence. Review of Environmental Economics and Policy. 2007. 1(2):241-260.

5. Murphy K, Topel R. The economic value of medical research. In Murphy K and Topel R. (Eds), *Measuring the Gains from Economic Research: An Economic Approach.* University of Chicago Press. 2003: 9-40. http://faculty.chicagobooth.edu/kevin.murphy/research/murphy&topel.pdf

6. Cox LA Jr. An exposure-response threshold for lung diseases and lung cancer caused by crystalline silica. *Risk Analysis.* 2011

7. Stoeger T, Reinhard C, Takenaka S, Schroeppel A, Karg E, Ritter B, Heyder J, Schulz H. Instillation of six different ultrafine carbon particles indicates a surface area threshold dose for acute lung inflammation in mice. Environ Health Perspect. 2006 Mar;114(3):328-33.

8. Clyde M . Model uncertainty and health effect studies for particulate matter. Environmetrics. 2000 Nov-Dec; 11(6):745-63

9. Koop G, Tole L. Measuring the health effects of air pollution: To what extent can we really say that people are dying from bad air? Journal of Environmental Economics and Management. 2004. 47:30-54. See also: http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.164.6048

10. Koop G, Tole L. An investigation of thresholds in air pollution–mortality effects. Environmental Modelling & Software 2006. 21(12):1662-73.

11. Thomas DC, Jerrett M, Kuenzli N, Louis TA, Dominici F, Zeger S, Schwartz J, Burnett RT, Krewski D, Bates D. Bayesian model averaging in time-series studies of air pollution and mortality. J Toxicol Environ Health A. 2007 Feb 1;70(3-4):311-5

12. Schwartz J, Coull B, Laden F, Ryan L. The effect of dose and timing of dose on the association between airborne particles and survival. Environ Health Perspect. 2008 Jan;116(1):64-9.

13. Franklin M, Zeka A, Schwartz J. Association between PM2.5 and all-cause and specific-cause mortality in 27 US communities. J Expo Sci Environ Epidemiol. 2007 May;17(3):279-87.

14. Faes L, Nollo G, Chon KH. Assessment of Granger causality by nonlinear model identification: application to short-term cardiovascular variability. Ann Biomed Eng. 2008 Mar;36(3):381-95.

15. Daniels MJ, Dominici F, Samet JM, Zeger SL. Estimating particulate matter-mortality dose-response curves and threshold levels: an analysis of daily time-series for the 20 largest US cities. Am J Epidemiol. 2000 Sep 1;152(5):397-406.

ED_002496_00001812-00037

16. Roberts S, Martin MA. The question of nonlinearity in the dose-response relation between particulate matter air pollution and mortality: can Akaike's Information Criterion be trusted to take the right turn? Am J Epidemiol. 2006 Dec 15;164(12):1242-50.

17. Lianne Sheppard, Richard T. Burnett, Adam A. Szpiro, Sun-Young Kim, Michael Jerrett, C Arden Pope and Bert Brunekreef. Confounding and exposure measurement error in air pollution. Air Quality, Atmosphere & Health 2011.

18. Green LC, Armstrong SR. Particulate matter in ambient air and mortality: toxicologic perspectives. Regul Toxicol Pharmacol. 2003 Dec;38(3):32

19. Gold M, Siegel JE, Russell LB, Weinstein MC (Eds), *Cost-Effectiveness in Health and Medicine.* Oxford University Press. New York. 1996. www.amazon.com/Cost-Effectiveness-Health-Medicine-Marthe-Gold/dp/0195108248.

20. Simkhovich BZ, Kleinman MT, Kloner RA.Particulate air pollution and coronary heart disease. Curr Opin Cardiol. 2009 Nov;24(6):604-9.

21. Simkhovich BZ, Kleinman MT, Kloner RA. Air pollution and cardiovascular injury epidemiology, toxicology, and mechanisms.J Am Coll Cardiol. 2008 Aug 26;52(9):719-26.

22. Adabag AS, Luepker RV, Roger VL, Gersh BJ. Sudden cardiac death: epidemiology and risk factors. *Nature Reviews Cardiology* 2010 (Apr) **7**, 216-225

23. Capewell S, Ford ES, Croft JB, Critchley JA, Greenlund KJ, Labarthe DR. Cardiodiovascular risk factor trends and potential for reducing coronary heart disease mortality in the United States of America. Bulletin of the World Health Organization. 2010 (Feb) 88(2):81-160. www.who.int/bulletin/volumes/88/2/08-057885/en/index.html (Last accessed 7-17-2011).

24. Krewski, D., M. Jerrett, R.T. Burnett, et al. (2009). Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality. Res Rep Health Eff Inst. 140: 5-114

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From: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
Sent: 12/11/2018 10:57:24 PM
To: Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]
Subject: DRAFT to provide to reporters tomorrow

Couple things about the draft below. I added the bios of the members because you can't hyperlink to them. Can we cut this first part down in anyway? If I'm a reporter I'm ignoring all of this because it's too long.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

participated in previous NAAQS reviews for ozone and particulate matter. The full line up: Dr. Anthony (Tony) Cox, Cox Associates (Chair); Dr. James Boylan, Georgia Department of Natural Resources; Dr. Mark Frampton, University of Rochester Medical Center; Dr. Sabine Lange, Texas Commission on Environmental Quality; Dr. Timothy Lewis, U.S. Army Corps of Engineers; Dr. Corey Masuca, Jefferson County (AL) Department of Health; Dr. Steven Packham, Utah Department of Environmental Quality

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Dr. Louis Anthony (Tony) Cox, Jr.

Dr. Tony Cox is President of Cox Associates, a Denver-based applied research company specializing in quantitative health risk analysis, epidemiology, causal analytics, and operations research. Since 1986, Cox Associates' mathematicians and scientists have applied epidemiological and biomathematical models, biostatistical and computational risk analyses, causal data mining, machine learning, artificial intelligence, bioinformatics, and operations research models to measurably improve health risk assessment and decision-making for public and private sector clients. In 2006, Cox Associates was inducted into the Edelman Academy of the Institute for Operations Research and Management Science (INFORMS), recognizing outstanding real-world achievements in the practice of operations research and the management sciences. In 2012, Dr. Cox was inducted into the National Academy of Engineering (NAE), "For applications of operations research and risk analysis to significant national problems." He has served as a member of the National Academies' Board on Mathematical Sciences and their Applications (BMSA) (2012-2016) and has served on many National Academies and National Research Council committees dealing with health and safety risk analysis. In 2013, he co-founded NextHealth Technologies, a Denver-based company offering advanced data analytics solutions to healthcare plans to reduce health, financial, and member attrition risks. Since 2015, Dr. Cox and Cox Associates have received funding from the George Washington University Regulatory Studies Center to develop statistical software for causal analysis of epidemiological data; the American Chemistry Council to develop predictive analytics software and research lung diseases caused by crystalline silica and other poorly soluble particles; the American Petroleum Institute and its members for research on methods of causal analysis applied to epidemiological data on asthma, coronary heart disease, all-cause mortality, and other adverse health effects associated with exposure to fine particulate matter (PM2.5) and ozone (O3); the U.S. EPA for expert review of research proposals; the National Stone, Sand, and Gravel Association for research on the statistical reliability and variability of laboratory measurements of crystalline silica in air filters; the European petroleum consortium CONCAWE for research on low-dose metabolism of benzene among Chinese workers; plaintiff's attorneys for expert opinions on the use of statistical methods and models in construction defect litigation; and telecommunications companies for research and software on high-reliability optical networks.

Dr. Cox holds a Ph.D. in Risk Analysis (1986) and an S.M. in Operations Research (1985), both from MIT; an AB from Harvard University (1978); and is a graduate of the Stanford Executive Program (1993). He is Clinical Professor of Biostatistics and Informatics at the University of Colorado Health Sciences Center and has served at the University of Colorado, Denver as Honorary Full Professor of Mathematics, lecturing on decision and risk analysis, biomathematics, health risk modeling, computational statistics and causality; and on the Faculties of the Center for Computational Mathematics and the Center for Computational Biology. He has taught many graduate and professional courses in decision and risk analysis, causal analytics, computational statistics, and biomathematical modeling. Dr. Cox is Editor-in-Chief of Risk Analysis: An International Journal. He is Area Editor for Real World Applications for the Journal of Heuristics and is on the Editorial Board of the International Journal of Operations Research and Information Systems. He is an Edelman Laureate of INFORMS, a member of the American Statistical Association (ASA), and a lifetime Fellow of the Society for Risk Analysis (SRA). He has authored and co-authored over 200 journal articles and book chapters on these fields. His most recent books are Breakthroughs in Decision Science and Risk Analysis (Wiley, 2015), Improving Risk Analysis (Springer, 2013), Risk Analysis of Complex and Uncertain Systems (Springer, 2009) and the Wiley Encyclopedia of Operations Research and Management Science (Wiley, 2011), which Dr. Cox co-edited. He has over a dozen U.S. patents on applications of artificial intelligence, signal processing, statistics and operations research in telecommunications. His current research interests include computational statistical methods for causal inference in public health risk analysis, data-mining, and advanced analytics for risk analysis and public policy applications.

Dr. James Boylan

Dr. James Boylan is currently the Manager of the Planning & Support Program in the Air Protection Branch of the Georgia Environmental Protection Division. His modeling team consists of eight Ph.D. engineers/scientists, his emission inventory team consists of four environmental engineers/scientists, and his regulatory development team consists of seven environmental engineers/scientists. Dr. Boylan is responsible for air dispersion modeling with AERMOD and CALPUFF required for PSD permit applications (SO2, NO2, CO, PM2.5, and lead); photochemical grid modeling with CMAQ and CAMx required for Georgia's ozone, PM2.5, and regional haze State Implementation Plans (SIPs); meteorological modeling with MM5 and WRF; emissions modeling with SMOKE and MOVES; the development of annual state-wide emission inventories for criteria pollutants; and the technical analyses for nonattainment area designation recommendations (ozone, PM2.5, lead, SO2, NO2). In addition, he is responsible for updating Georgia's Rules for Air Quality Control and developing and submitting all attainment demonstration SIPs, infrastructure SIPs, and rule revision SIPs to EPA. Previously, he worked at the Florida Department of Environmental Protection performing regulatory audits of stationary sources. He has a B.S. in Chemical Engineering from the University of Notre Dame, a M.S. in Chemical Engineering from Auburn University, and a M.S. and Ph.D. in Environmental Engineering from the Georgia Institute of Technology (under the direction of Dr. Armistead "Ted" Russell). Dr. Boylan's Ph.D. research included the development of the first comprehensive three-dimensional Eulerian photochemical grid model (URM-1ATM) that included full ozone chemistry, heterogeneous sulfate chemistry, aerosol thermodynamics, wet deposition and scavenging, and the decoupled direct method (DDM) for ozone and particulate matter. This model was applied as part of the Southern Appalachian Mountain Initiative (SAMI) to simulate 1-hour maximum ozone, W126 ozone, speciated PM2.5, acid deposition (ANC), and regional haze. Also, he developed and published the first model performance goals and criteria for PM2.5 which has become the benchmark for most PM2.5 modeling projects both nationally and internationally. Dr. Boylan was one of the first modelers to merge traditional air permit dispersion modeling with photochemical grid models (PGMs) when he applied a PGM to evaluate the single source impacts on ozone and secondary PM2.5 from a coal-fired power plant as part of a PSD permitting review in 2009. In addition, he developed the "Inter-Pollutant Trading Ratio Approach" for accounting for secondary PM2.5 formation from SO2 and NOx in EPA's AERMOD steady-state dispersion model. Over the past several years he has held numerous leadership positions within many regional and national workgroups. Currently, he is the chair of the Southeastern States Air Resource Managers (SESARM) Technical Analysis Workgroup, leader of the SESARM Emissions and Air Quality Modeling Workgroup, and co-chair of the Association of Air Pollution Control Agencies (AAPCA) Modeling Committee. Dr. Boylan has authored 18 peer-reviewed journal articles on ozone and PM2.5 formation, has presented research findings at over 200 national, regional, and local conferences/meetings, and was awarded "Outstanding Reviewer Status" by Atmospheric Environment in 2015. In 2001, Dr. Boylan was inducted into the Sigma Xi Scientific Research Honor Society. Currently, Dr. Boylan serves on the CASAC Sulfur Oxides Review Panel where he specializes in the analysis of ambient SO2 concentrations from measurements and modeling.

Dr. Mark W. Frampton

Dr. Mark W. Frampton is Professor Emeritus in Medicine in the Pulmonary & Critical Care division, at the University of Rochester Medical Center (URMC), Rochester, NY. Dr. Frampton holds an M.D. from New York University. During pulmonary specialty training at URMC in the late 1980s, Dr. Frampton became interested in the adverse health effects of air pollution, at a time when epidemiology studies were beginning to provide strong links between ambient particulate air pollution and mortality. Working with Dr. Mark Utell and utilizing the human clinical studies facility at URMC, he expanded the focus of human clinical air pollution studies beyond pulmonary function effects to include effects on airway inflammation, host defense against viral infection, and cardiovascular effects. Dr. Frampton's laboratory was the first to conduct human clinical studies of ultrafine particles (smaller than 100 nm), first using laboratory generated elemental carbon particles, and subsequently with concentrated ambient ultrafine particles, using the Harvard ultrafine concentrator system. Over the years his laboratory has studied healthy subjects as well as those considered to have increased susceptibility, including older subjects and people with mild asthma, chronic obstructive pulmonary disease, type 2 diabetes, and even genetic susceptibility. Dr. Frampton's laboratory is one of three centers completing a study of the cardiovascular effects of ozone exposure in healthy older subjects, funded by the Health Effects Institute. These studies have helped to understand the physiological changes and pathways to adverse effects that occur in response to pollutant exposure, and have helped to inform the EPA's promulgation of rational ambient air quality standards. Funding for these studies has come from the National Institutes of Health, the U.S. EPA, the Health Effects Institute, the New York State Energy Research and Development Authority, CONCAWE, ExxonMobil, the American Petroleum Institute, and others.

Dr. Frampton has served on numerous scientific review panels with the National Institutes of Health and other scientific funding organizations. He has been active in the Environmental and Occupational Health Assembly of the American Thoracic Society, serving as its Chair in 2001-2003. At the request of the ATS President at the time, Dr. Frampton chaired a Task Force on Bioterrorism, and helped to form a new Section on Bioterrorism, serving as its first Chair in 2003-2005. He recently served as a member of the ATS committee preparing a revision of the important and oft-cited document, "What Constitutes a Health Effect of Air Pollution?", which has now been published. Dr. Frampton has served as a consultant and reviewer for the Health Effects Institute, a health research organization jointly funded by EPA and the automobile industry. He is currently a member of the Science Review Committee for the Health Effects Institute. He participated in an HEI review panel on the health effects of traffic-related air pollution, and chaired an HEI Review Panel on ultrafine particles, which produced a recent HEI Perspectives, "Understanding the Health Effects of Ambient Ultrafine Particles". Dr. Frampton has served as a consultant to the EPA in developing and reviewing Integrated Scientific Assessments (formerly Criteria Documents) for nitrogen dioxide, ozone, and particulate matter. In addition, he has served on several EPA grant and fellowship review panels and scientific workshops, and has been invited to speak at EPA functions. He currently serves on the CASAC PM Review Panel.

Dr. Sabine Lange

Dr. Sabine Lange is the section manager for the Toxicology Division at the Texas Commission on Environmental Quality (TCEQ). Dr. Lange's responsibilities include overseeing health effects risk assessments of air permit applications, ambient air monitoring projects, and hazardous waste sites; overseeing the development of chemical toxicity factors; and conducting and overseeing systematic reviews and independent analyses of risk assessments. Dr. Lange serves as a technical resource for the State and citizens of Texas for human health and environmental risk assessment, especially related to air and water quality. Dr. Lange's research interests include the toxicology of criteria air pollutants, and risk assessment methods used for derivation of toxicity factors. In these areas she has published articles, given invited talks, presented posters, and served as a workshop panel member. On behalf of the TCEQ, she has intensively reviewed the documents released by the US EPA on the National Ambient Air Quality Standards (NAAQS) for ozone, particulate matter, sulfur dioxide, nitrogen dioxide, and lead. Dr. Lange and colleagues have provided comments to the US EPA on the assessment documents supporting these standards, particularly as they relate to principles of toxicology, risk assessment, and the State's perspective on these rules. She has also served as a peer reviewer for EPA on chemical hazard assessments for regulations under the Toxic Substances Control Act. Dr. Lange's work since joining TCEQ has been entirely funded by the State of Texas. Dr. Lange received a Bachelor's degree from the University of Western Ontario in Canada, and completed a Ph.D. and post-doctoral training in biochemistry and molecular carcinogenesis at the University of Texas at Houston and MD Anderson Cancer Center. Dr. Lange is a Diplomate of the American Board of Toxicology.

Dr. Timothy Lewis

Tim Lewis is a supervisory research ecologist with the U.S. Army Corps of Engineer, Engineer Research and Development Center, Environmental Laboratory in Vicksburg, MS. He worked for Lockheed Engineering, primary contractor for the U.S. EPA, serving as Project Leader and Principal Scientist on studies related to the National Surface Water Survey, the Direct Delayed Response Project (soil acidification), and the Environmental Monitoring and Assessment Program (EMAP). He accepted a position with the Bureau of Land Management in 1993 and served as the National Indicator Development Coordinator for the U.S. EPA's EMAP - Forest Health Monitoring program. He edited and authored a CRC Press book entitled Tree Rings as Indicators of Ecosystem Health. He went on to become Effectiveness Monitoring Coordinator for the Northwest Forest Plan. In 1996 Tim became the first Director of the Forest Science Project at Humboldt State University, where he applied his regional aquatic and terrestrial monitoring experience to private and public lands in Northern California. In 2001, Dr. Lewis accepted a position as senior ecologist with the U.S. EPA's National Center for Environmental Assessment, where he was involved in the assessment of ecological risks due to air pollutants. He served as associate editor of the premier journal Ecological Indicators during its startup. In 2007 Tim joined the Environmental Laboratory at the USACE's Engineer Research and Development Center in Vicksburg, MS as Chief for the Aquatic Ecology and Invasive Species Branch. The branch is actively engaged in ecosystem restoration and the assessment of the impact of Corps projects on habitat for threatened and endangered species and prevention and reduction of impacts of invasive plants and animals in the nation's waterways.

Education

B.A., West Chester University, West Chester, PA, 1977, Biology

M.S., Rutgers University, New Brunswick, NJ, 1980, Plant Pathology Ph.D., Rutgers University, New Brunswick, NJ, 1984, Environmental Science.

Dr. Corey Masuca

Corey Masuca, PE, PhD, JD is currently the Principal Air Pollution Control Engineer with the Jefferson County Department of Health. As the leader of the Air Pollution Control Program with the Jefferson County of Health he is responsible for overseeing a staff of approximately 35 persons who responsibilities include regulating industrial sources of emissions, area and point sources of emissions such as dry cleaners/gasoline stations and open burning, respectively. In addition, he oversees the ambient air monitoring program which is responsible for measuring air contaminant concentrations within Jefferson County, Alabama to ensure compliance with healthy clean air standards set by the United States Environmental Protection Agency (USEPA). Since he graduated from Auburn University with a Bachelor of Chemical Engineering degree, he has continued to work in the environmental arena, specifically air quality and air pollution. As a student at Auburn University, he completed a cooperative education program rotation with the Tennessee Valley Authority in Muscle Shoals, Alabama where he completed stack testing of fertilizer plant residuals including stack testing equipment preparation and calibration. After he graduated from Auburn University, he was employed as an Environmental Engineer with the State of Connecticut Department of Environmental Protection where he regulated sources of air pollutant emissions and was responsible for the implementation of a major new air regulatory USEPA program as part of the 1990 Clean Air Act Amendments. Following his tenure with the Connecticut Department of Environmental Protection, he worked as a consulting engineer with the environmental consultant firm, CH2M Hill, in the Atlanta, Georgia area. With CH2M Hill, he prepared air program applications for several industrial air-polluting facilities applying for applications to operate. This involved extensive regulatory review and complex, mathematical calculations to determine compliance and/or regulatory applicability. Next, he returned to Alabama where he worked an Environmental Engineer with the Alabama Department of Environmental Management where he continued his work as an Environmental Engineer where he was responsible for permitting, determining compliance, inspecting, and initiating enforcement actions, where applicable, of industrial sources of air pollution. Finally, he was initially employed as an Air Pollution Control Engineer with the Jefferson County Department of Health where, again, his primary duties entailed permitting, determining compliance, inspection, and initiating enforcement actions of industrial sources of air pollutant emissions. While with the Jefferson County Department of Health, he continued his professional and academic pursuits where he was promoted to the position of a Senior Air Pollution Control Engineer, became a registered/licensed Professional Engineer with the State of Alabama, and obtained a doctoral degree in Environmental Health Engineering from the University of Alabama in Birmingham. His doctoral degree research consisted of completing an epidemiology study of air pollutant concentrations and pre-term birth defects for populations within Atlanta, Georgia. After obtaining his doctoral degree and while still working full-time as a Senior Air Pollution Control Engineer with the Jefferson County Department of Health, he was also employed an adjunct professor both with the University of West Alabama (where he continues to be an advisory board member for the Environmental Sciences section of the Biology Division) and with the University of Phoenix (Birmingham campus). He taught classes in environmental science, environmental ethics, and general environmental air pollution health effects with both the University of Phoenix (Birmingham campus) and the University of West Alabama. In addition, during and subsequent to this time, he acted as a professional consultant providing air pollution data and review/analyses for three (3) epidemiological studies being performed/conducted by the University of Alabama at Birmingham, School of Public Health, Department of Epidemiology, which involved determining the relationship between ambient air pollution and emergency room visits for cardiovascular disease in Jefferson County, Alabama; ambient air pollution and emergency room visits for respiratory disease among adults in Jefferson County, Alabama; and ambient air pollution and respiratory diseases in children in Jefferson County, Alabama. During and subsequent to this time, he was promoted to his current position of Principal Air Pollution Control Engineer with responsibility for all of the various components of the Health Department's Air Pollution Control Program. Following his teaching stints with the University of West Alabama and with the University of Phoenix (Birmingham campus), all the while still being employed with the Health Department, he undertook an initiative to pursue as Juris Doctorate degree from the Miles College School of Law in Birmingham. He completed his requisite law studies and recently graduated from law school (May 2018). He is still employed as the Principal Air Pollution Control Engineer with the Jefferson County Department of Health Air Pollution Control Program and is currently planning to sit for the Alabama State Bar in July 2018, after which he will continue to work at/with the Health Department in a lead scientific and administrative capacity, and, hopefully, legal capacity subsequent to passing the Alabama State Bar.

Steven C. Packham

Dr. Steven Packham is an inhalation toxicologist with 28 years of regulatory experience with the Utah Division of Air Quality. Foremost among his responsibilities has been public education and communication of the scientific basis and intent of USC Title 42, Chapter 85 (particularly Sections 7409 and 7412): To protect human health with an ample margin of safety "requisite to protect" public health. His actual regulatory experience includes: Preparation of case-specific HAPs residual risks and leaking underground storage tank vapor intrusion risk assessments. Development of State Implementation Plans. State adoption of Federal NESHAP MACT's, and annual reviews of Utah's NATA Urban Air Toxics program. His research has focused on causal biologic mechanisms of dose-dependent health effects from breathing air pollution. He has developed a model to estimate margins of safety for mobile app users based on EPA Air Quality Index (AQI) values for sensitive and normal groups who may wish to engage in fitness improvement training and enjoy physical recreational activities outdoors under fluctuating air quality conditions.

Dr. Packham is an Adjunct Associate Professor in the University of Utah College of Health Sciences Department of Family and Preventative Medicine and a member of the Advisory Board of the Rocky Mountain Center for Occupational and Environmental Health in Salt Lake City. Past professional activities include: Editorial Board, Journal of Fire Sciences. Chairman, American Society for Testing and Materials (ASTM) Task Group E5.21.05. Member, Toxicity Advisory Committee National Fire Protection Association. Member, ASTM Committee on Toxic Hazard Assessment of Materials used in Transportation Vehicles. United States of America Member, Technical Advisory Committee, ISO/TC 92/SC 3. Convener: ISO Technical Committee 92, Subcommittee 3, Working Group 1 on Fire Model. United States of America Assigned Expert: ISO/TC 92/SC 3/Working Group on Bio-assays.

Message

From: Dunlap, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591EB15A268249DDA0C05A7451F765C3-DUNLAP, DAV]
Sent: 10/18/2018 2:10:30 AM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Re: Transmittal of draft PM ISA for CASAC review

Clint,

I discussed with Jennifer yesterday. **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

The sooner we receive OAR input on the charge questions the better.

Let's discuss in the AM

DDD

Sent from my iPhone

On Oct 17, 2018, at 6:39 PM, Woods, Clint <woods.clint@epa.gov> wrote:

> Any answer on this front?
>
> ---
>
> **From:** Dunlap, David
> **Sent:** Monday, October 15, 2018 9:03 PM
> **To:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
> **Cc:** Woods, Clint <woods.clint@epa.gov>
> **Subject:** Fwd: Transmittal of draft PM ISA for CASAC review
>
> Jennifer,
>
> I'm the new guy, so I apologize in advance. **Deliberative Process / Ex. 5**
>
> **Deliberative Process / Ex. 5**
>
> DDD
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **From:** "Vandenberg, John" <Vandenberg.John@epa.gov>
> > **Date:** October 15, 2018 at 1:19:18 PM EDT
> > **To:** "Yeow, Aaron" <Yeow.Aaron@epa.gov>
> > **Cc:** "Bahadori, Tina" <Bahadori.Tina@epa.gov>, "Brennan, Thomas" <Brennan.Thomas@epa.gov>, "Buckley, Barbara" <Buckley.Barbara@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Dunlap, David" <dunlap.david@epa.gov>, "Dutton, Steven" <Dutton.Steven@epa.gov>, "Greaver, Tara" <Greaver.Tara@epa.gov>, "Hagerthey, Scot" <Hagerthey.Scot@epa.gov>, "Jarabek, Annie"

<Jarabek.Annie@epa.gov>, "Jenkins, Scott" <Jenkins.Scott@epa.gov>, "Jones, Samantha" <Jones.Samantha@epa.gov>, "Jones, Ryan" <Jones.Ryan@epa.gov>, "Johnston, Khanna" <Johnston.Khanna@epa.gov>, "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>, "Robbins, Chris" <Robbins.Chris@epa.gov>, "Rodan, Bruce" <rodan.bruce@epa.gov>, "Ross, Mary" <Ross.Mary@epa.gov>, "Sacks, Jason" <Sacks.Jason@epa.gov>, "Sasser, Erika" <Sasser.Erika@epa.gov>, "Vette, Alan" <Vette.Alan@epa.gov>, "Wayland, Robertj" <Wayland.Robertj@epa.gov>, "Wesson, Karen" <Wesson.Karen@epa.gov>, "Johnson, Aaron" <Johnson.AaronK@epa.gov>, "Johnson, Maureen" <Johnson.Maureen@epa.gov>
Subject: Transmittal of draft PM ISA for CASAC review

Aaron,

Please see the attached memorandum transmitting the draft PM ISA to you as DFO, and the instructions for HERONet access.
I have provided a draft Charge for the PM ISA review to you in a separate email, for review by the CASAC Chair, Tony Cox.
Please let me know if you have any questions.
Thank you

John

John Vandenberg, PhD
Director, Research Triangle Park Division
National Center for Environmental Assessment/ORD
U.S. Environmental Protection Agency/B243-01
Research Triangle Park, NC 27711
(919) 541-4527

Message

From: Sasser, Erika [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=477638FE84004800BFDF8E62FE3CAFC8-ESASSER]
Sent: 10/22/2018 10:20:32 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Tsirigotis, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d19c179f3ccb4fadb48e3ae85563f132-PTSIRIGO]; Koerber, Mike [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c513901d4fd49f9ab101a6f7a7a863e-Koerber, Mike]
Subject: RE: Revised Charge questions -- PM ISA

Flag: Flag for follow up

Thanks Clint. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

comments. How does it look to you?

From: Woods, Clint
Sent: Monday, October 22, 2018 6:36 AM
To: Sasser, Erika <Sasser.Erika@epa.gov>; Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>; Koerber, Mike <Koerber.Mike@epa.gov>
Subject: Fwd: Revised Charge questions -- PM ISA

FYI - Thanks!

Begin forwarded message:

> **From:** "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>
> **Date:** October 22, 2018 at 4:56:57 AM EDT
> **To:** "Woods, Clint" <woods.clint@epa.gov>
> **Cc:** "Dunlap, David" <dunlap.david@epa.gov>
> **Subject: Fwd: Revised Charge questions -- PM ISA**
>
> Updated. Thanks Clint
>
> Jennifer Orme-Zavaleta, PhD
> Principal Deputy Assistant Administrator for Science
> Office of Research and Development
> US EPA
> Ce Cell Phone / Ex. 6
> DC
> RT
>
> Begin forwarded message:
>
> > **From:** "Vandenberg, John" <Vandenberg.John@epa.gov>
> > **Date:** October 22, 2018 at 1:25:06 AM EDT
> > **To:** "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>
> > **Cc:** "Bahadori, Tina" <Bahadori.Tina@epa.gov>, "Dunlap, David"

<dunlap.david@epa.gov>, "Rodan, Bruce" <rodan.bruce@epa.gov>
Subject: Revised Charge questions -- PM ISA

Jennifer,

Deliberative Process / Ex. 5

Tony Cox, CASAC Chair, Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

The initial draft Charge stated:

Deliberative Process / Ex. 5

Dr. Cox had suggested:

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Please let me know if you'd like to see a Track Changes version.

Deliberative Process / Ex. 5

Thank you,

John

From: Orme-Zavaleta, Jennifer
Sent: Thursday, October 18, 2018 11:27 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: RE: Charge questions -- PM ISA

Helpful, thanks Tina

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
Office of Research and Development
US Environmental Protection Agency
Ce
DC Cell Phone / Ex. 6
RT

From: Bahadori, Tina
Sent: Thursday, October 18, 2018 10:58 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: RE: Charge questions -- PM ISA

Deliberative Process / Ex. 5

We will send a revised version to you soon.

Thanks,
Tina

From: Orme-Zavaleta, Jennifer
Sent: Thursday, October 18, 2018 10:24 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: FW: Charge questions -- PM ISA

See below from Clint. Send an updated charge. thanks

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
Office of Research and Development
US Environmental Protection Agency
Cell
DC 2 Cell Phone / Ex. 6
RTP

From: Woods, Clint
Sent: Thursday, October 18, 2018 9:43 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>
Subject: Re: Charge questions -- PM ISA

Jennifer,

Thanks for the chance to look at these charge questions. Realizing a version went to CASAC leadership for their response, I wanted to share a bit of feedback from conversations with OAQPS.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks again!

Clint

On Oct 12, 2018, at 12:11 PM, Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov> wrote:

> Clint, to follow up on the latest, attached are the draft charge questions. Note a copy also shared w Erika. Have a good wkend!
>
> Jennifer Orme-Zavaleta, PhD
> Principal Deputy Assistant Administrator for Science
> Office of Research and Development
> US Environmental Protection Agency
> Cel
> DC Cell Phone / Ex. 6
> RT
>
> ---
>
> **From:** Bahadori, Tina
> **Sent:** Friday, October 12, 2018 10:47 AM
> **To:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
> **Cc:** Vandenberg, John <Vandenberg.John@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>
> **Subject:** Charge questions -- PM ISA
> **Importance:** High
>
> Hi Jennifer,
>
> Deliberative Process / Ex. 5
>
> Thanks,
> Tina
>
> <PM ISA Charge to CASAC unsigned 10-12-18.docx>

November 26, 2018

Louis Anthony (Tony) Cox, Jr., Ph.D.
President, Cox Associates
Denver, CO 82018
and
Chair, Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
Washington, DC 20460

Subject: CASAC Advice on the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft).

Dear Dr Cox:

We were members of the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel from the 2009 to 2015 review of the primary and secondary National Ambient Air Quality Standards (NAAQS) for ozone. We also include former chairs and members of the chartered 7-member CASAC. This letter represents our consensus. In this letter: (1) we review the statutory requirements for scientific review of NAAQS; (2) we describe our role and experience in the previous NAAQS review; and (3) based on our experience, we advise the current CASAC of our lessons learned from the many scientific reviews that we conducted.

In addition, we provide our advice regarding: (4) the impacts of recent changes to the criteria for membership on the CASAC and to the NAAQS review process; (5) the recent decision not to form an ozone review panel for the current review of the primary and secondary ozone standards; and (6) the Integrated Review Plan for the current review.

Our advice is summarized in the form of **seven findings** and **thirty recommendations** for the CASAC. The seven **findings** are summarized in **Table 1**. The thirty **recommendations** are summarized in **Table 2**. The main points in this letter, including the findings and recommendations, are supported by details in this letter and attached comments from individual members.

Statutory Requirements

Section 108 of the Clean Air Act requires that the Administrator periodically review and update the air quality criteria for an air pollutant so that they "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, in varying quantities." Section 109 requires the Administrator to adopt NAAQS that are requisite to protect public health with an adequate margin of safety and to protect the public welfare.

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Table 1. Major Findings

MAJOR FINDING 1:	The myriad of changes to the NAAQS review process are collectively harmful to the quality, credibility, and integrity of the scientific review process and CASAC as an advisory body.
MAJOR FINDING 2:	The current 7-member CASAC does not have the depth or breadth of expertise needed for the ozone review, nor could a group of this size cover the needed scientific disciplines.
MAJOR FINDING 3:	The late 2020 deadline for completing the ozone review does 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, even if the committee were supported by a robust panel of experts in the multiple disciplines involved.
MAJOR FINDING 4:	CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields toward a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state government, rather than scientific expertise first and foremost. The statute requires only "one person representing State air pollution control agencies."
MAJOR FINDING 5:	An underlying principle is to maintain distinction between science and policy issues. The Pruitt May 9, 2018 memorandum violates this principle by commingling science and policy considerations.
MAJOR FINDING 6:	In 2014, the CASAC provided advice to the Administrator regarding how CASAC's role in reviewing adverse effects of NAAQS implementation should be structured. This advice has been ignored by EPA.
MAJOR FINDING 7:	There are numerous deficiencies in EPA's Integrated Review Plan related to the above findings. EPA's proposal in the IRP to structure the Ozone ISA with appendices rather than chapters is contrary to the requirement for EPA to thorough review" of the "latest scientific information" of the "kind and extent" of "all identifiable effects" as required by the Clean Air Act.

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Table 2. Recommendations

With regard to **MAJOR FINDING 1**: Changes to the NAAQS review process are harmful.

Recommendation 1: The CASAC should recommend that the EPA rescind the October 31, 2017 and May 9, 2018 memoranda by former Administrator Scott Pruitt.

Recommendation 2: CASAC should recommend a wider consideration of approaches to streamlining the NAAQS review process, including opportunity for input from EPA staff in ORD and OAQPS, CASAC, and other stakeholders including the public.

Recommendation 3: CASAC should advise EPA that, if it wishes to change the criteria for appointments to EPA advisory committees including CASAC, it should provide opportunity for input on such criteria from EPA staff in ORD and OAQPS, the EPA Science and Technology Policy Council, CASAC, and other stakeholders including the public.

Recommendation 4: CASAC should not agree to changes to the review process or to the schedule proposed by EPA.

With regard to **MAJOR FINDING 2**: Lack of breadth and depth of expertise.

Recommendation 5: CASAC should acknowledge and advise the current Acting Administrator that it does not have adequate breadth and depth of scientific expertise to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to either the Ozone or the Particulate Matter NAAQS.

Recommendation 6: CASAC should remind the current Acting Administrator that it has been long-standing practice to augment the 7-member CASAC with additional independent expert consultants, and this augmentation is essential to a high quality review.

Recommendation 7: CASAC should remind the current Acting Administrator that in all past reviews conducted by CASAC, it has always been the 7-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator.

Recommendation 8: CASAC should immediately call for the formation of an Ozone Review Panel and for the reinstatement of the CASAC PM Review Panel.

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Table 2. Recommendations, Continued

With regard to **MAJOR FINDING 3**: Inadequate review time.

Recommendation 9: CASAC should reject EPA's proposed accelerated schedule. EPA should allow time for an adequate review by relaxing its 2020 deadline.

Recommendation 10: CASAC should reject EPA's proposal for one draft of an Integrated Science Assessment and one draft of a Policy Assessment.

Recommendation 11: The CASAC should advise the current Acting Administrator that the CASAC, supported by an augmented panel of scientific experts, requires typically three years to conduct this review.

Recommendation 12: CASAC should remind EPA that the courts have recognized the importance of CASAC's role and the need for adequate scientific review time.

Recommendation 13: The CASAC should affirm that delays in initiation of the review cycle by EPA should not infringe on the adequacy of the time frame needed by CASAC to properly do its job with adequate quality and integrity.

Recommendation 14: CASAC should affirm the important role of public comments.

Recommendation 15: EPA should immediately begin the review cycle for carbon monoxide. CASAC should form a Carbon Monoxide Review Panel augmented with additional experts. EPA should allow adequate time for this review.

Recommendation 16: EPA should immediately begin the review cycle for lead. CASAC should form a Lead Review Panel augmented with additional experts. EPA should allow adequate time for this review.

Recommendation 17: EPA should immediately begin the review cycle for oxides of nitrogen. CASAC should form an Oxides of Nitrogen Review Panel augmented with additional experts. EPA should allow adequate time for this review.

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Table 2. Recommendations, Continued

With regard to **MAJOR FINDING 4**: Committee composition is based on non-scientific criteria.

Recommendation 18: Scientific expertise for panels should be relevant to the particular review. Different NAAQS reviews require different expertise. CASAC should re-affirm that membership criteria for the chartered CASAC and for its augmented panels should emphasize scientific expertise, not geographic diversity nor affiliation with state, local, and tribal agencies, other than to meet the Clean Air Act requirement for "one person representing State air pollution control agencies."

Recommendation 19: CASAC should affirm that receipt of an EPA research grant should not disqualify membership on the CASAC or CASAC review panels.

Recommendation 20: CASAC should affirm that its members should not be dismissed *en masse* or appointed *en masse*, and turnover in a given year should be limited to a minority fraction of the total panel. Members should be eligible for reappointment to a second term especially if such appointments would provide continuity, key scientific expertise, and institutional memory.

With regard to **MAJOR FINDING 5**: Science and policy are commingled.

Recommendation 21: CASAC should reject EPA's proposal to combine the REA into the PA for the Ozone review. Further, the CASAC review of the REA should not be concurrent with the PA for the Ozone review.

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Table 2. Recommendations, Continued

With regard to **MAJOR FINDING 6**: Inappropriate strategy to review implementation effects.

Recommendation 22: CASAC should not commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS pertaining to public health and welfare.

Recommendation 23: CASAC should consider both adverse and beneficial effects.

Recommendation 24: To develop advice on implementation effects, CASAC should be augmented with a panel of appropriately selected national and international experts. Such a panel may be able to address more than one NAAQS.

Recommendation 25: To avoid illegally commingling implementation issues when formulating a NAAQS, review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards.

Recommendation 26: CASAC must take a scientific approach to providing advice regarding implementation effects, and such a review should be done with the same scientific rigor as the CASAC review of other aspects of the process.

Recommendation 27: EPA should develop one or more appropriate and relevant implementation assessment documents, which could build upon existing documents such as retrospective and prospective studies of the benefits and costs of the Clean Air Act. Such documents from EPA should be developed with the same level of scientific rigor and analysis as the other documents, with similar requirements in regards to the supporting literature.

Recommendation 28: CASAC should advise the EPA that the first attempt at doing this will involve the development of new data, methods, and analyses of adequate scientific validity and policy-relevance, which will take time.

With regard to **MAJOR FINDING 7**: Deficiencies in the Ozone Integrated Review Plan

Recommendation 29: The ISA for the current ozone review should be consistent with the now well-established structure and content of CASAC-reviewed ISAs, such as from the previous ozone review.

Recommendation 30: EPA should 'start over' with the scientific review of the primary and secondary NAAQS for ozone. Specifically, EPA should set aside the current Integrated Review Plan and develop a new Integrated Review Plan that is appropriately formulated to take into account the findings and recommendations provided herein. Given the extensive revisions needed to the IRP, the CASAC and the public should have an opportunity to comment on a new IRP.

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based on the scientific knowledge embodied in the air quality criteria. Section 109 requires EPA to conduct a "thorough review" of the air quality criteria and the NAAQS at five-year intervals. As part of this review, Section 109 also requires that the Administrator "appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies." This scientific review committee must review the air quality criteria and the NAAQS, and recommend any "appropriate" revisions to the criteria and the NAAQS, consistent with the obligations of Sections 108 and 109. The scope of scientific issues involved in satisfying Section 108's requirements means that a broad range of scientific expertise is needed to conduct the comprehensive scientific assessments needed for the periodic NAAQS reviews.

For this review to be "thorough", "accurate", and reflect "the latest scientific knowledge ... of all identifiable effects", a broad range of scientific expertise is needed. The CASAC charter reflects the need for this breadth of expertise. Thus, the charter states that "[m]embers will be persons who have demonstrated high levels of competence, knowledge, and expertise in scientific/technical field relevant to air pollution and air quality issues". Moreover, for the past four decades, comprising well over 20 reviews, CASAC has recognized that the chartered CASAC requires participation of additional experts, acting as consultants, in order that its review be "accurate" and "thorough". This augmentation of chartered CASAC expertise again is reflected in the CASAC charter, which states "EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter. Such 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."

The combined implications of Sections 108 and 109 of the Clean Air Act, as well as the CASAC charter and historic practice, are that the role of the scientific review committee (i.e. CASAC) requires that scientists who are at the leading edge of research in their respective fields be involved, either directly as members of CASAC or through CASAC involving consultation with these experts. The Act clearly requires that EPA appoint a committee comprised of scientific experts, and that EPA obtain the advice of scientists with breadth and depth of expertise appropriate to the required scope of "accurate" and "thorough review," "latest scientific knowledge" and "kind and extent" of "all identifiable effects" required by law.

From a scientific perspective, scientific experts who are qualified to conduct a "thorough review" based on the "latest scientific knowledge" are those who are engaged in peer-reviewed scientific research in pertinent scientific disciplines and areas of study. This is why the SAB Staff Office sought "nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone" in its July 27, 2018 Federal Register notice on "Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel."

The 2009 to 2015 CASAC Ozone Review Panel

Review panels are comprised of additional scientific experts appointed as special governmental employees to supplement the chartered CASAC. As noted in attached individual comments, CASAC has a long history of being augmented with additional experts to support its review activities. Our panel was comprised of the seven members of the chartered CASAC and 13 additional experts. The augmentation of CASAC with panels has been well-established for four decades, as detailed in attached member comments. This has ensured a multidisciplinary, comprehensive, integrated and thorough review of massive amounts of scientific literature encompassing wide-ranging and complex scientific studies.

Augmentation of the expertise of the chartered CASAC with that of the panel members was critical to the quality, credibility, and integrity of our scientific review process. The panel members provided needed breadth and depth of expertise beyond that of the chartered CASAC. Specifically, as noted in a January 29, 2009 EPA memorandum, our panel was appointed to assure coverage of expertise in atmospheric science, exposure modeling and assessment, dosimetry, toxicology, controlled human exposure, epidemiology, risk assessment and biostatistics, ecological effects, and ecological resource valuation.

The panel met and deliberated in public according to requirements of the Federal Advisory Committee Act. Members of the panel were subject to the same financial disclosures and ethics requirements as members of the chartered CASAC.

In each review activity, the panel deliberated and developed draft advice for the Administrator in public meetings and in an advisory role to the chartered CASAC. The members of the chartered CASAC conducted a "quality review" of each draft CASAC report in public meetings. The quality reviews provided the chartered CASAC with opportunities to modify draft reports prior to a vote by the chartered CASAC to approve the final report for submission to the Administrator. Reports submitted by the chartered CASAC to the Administrator were on behalf of the chartered CASAC, not on behalf of the panel. The formation of a review panel is, therefore, not mutually exclusive with the chartered CASAC being the body that provides comments to the Administrator.

CASAC Activity in the Previous Ozone Review

The chartered CASAC produced reports to the EPA Administrator from 2010 to 2014 regarding:

- Consultation on EPA's Integrated Review Plan (Report No. EPA-CASAC-10-004, dated December 3, 2009);
- Consultation on the Scope and Methods Plan for the health and welfare Risk and Exposure Assessments (REAs) (EPA-CASAC-11-008, June 21, 2011);
- Review of the first draft of the Integrated Science Assessment (ISA) (EPA-CASAC-11-009, August 10, 2011);
- Review of the second draft of the ISA (EPA-CASAC-12-004, March 13, 2012);

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- Review of the third draft of the ISA (EPA-CASAC-13-001, November 14, 2012);
- Review of the draft health and welfare REAs (EPA-CASAC-13-002, November 19, 2012);
- Review of the first draft of the Policy Assessment (PA) (EPA-CASAC-13-003, November 19, 2012);
- Review of the second draft of the health REA (EPA-CASAC-14-005, July 1, 2014);
- Review of the second draft of the welfare REA (EPA-CASAC-14-003, June 18, 2014); and
- Review of the second draft of the policy assessment (EPA-CASAC-14-004, June 26, 2014).

For each activity listed above, CASAC held one or more public meetings announced in the Federal Register, during which there was opportunity for public comment.

Timeframe for NAAQS Review

We understand from the historical record and from the last ozone review that the timeframe for NAAQS review cycles usually has taken longer than the statutory mandate for reviews "at five-year intervals." Concern about the length of review cycles was a clear motivating factor for the May 9, 2018 memorandum by Administrator Scott Pruitt regarding "Back to Basics Process for Reviewing National Ambient Air Quality Standards." It is a matter of public record that the review cycle for ozone in the last review took more than five years. It is a matter of public record that nearly all of the NAAQS review cycles for various combinations of criteria pollutants and standards (primary, secondary) since the inception of the NAAQS have taken more than five years.

As noted in attached individual comments, the NAAQS review process was revised in 2006 in large part to shorten the duration of NAAQS review while maintaining or enhancing its scientific rigor and credibility, taking into account key factors such as the need to promote separation between science and policy issues. The duration of NAAQS review has generally decreased in the last decade compared to prior decades. However, challenges clearly remain in achieving the statutory mandate for a five year review.

The May 9, 2018 memorandum implies that delays in review cycles beyond the five year statutory requirement are significantly related to the scientific aspects of the review process, including aspects involving CASAC. The memorandum fails to acknowledge the following key points:

(1) EPA controls the duration of time between the conclusion of a prior review cycle and the initiation of the subsequent review cycle;
(2) EPA decides the allocation of resources for development of assessment reports by EPA staff that are part of the scientific review process;
(3) EPA decides when to release a draft document for CASAC review;
(4) EPA has been responsible for delays in providing draft assessments to the CASAC for review;
(5) Whether a draft EPA document requires further iteration depends on its initial scientific quality; and

(6) EPA has control over the timing of the NAAQS review process from the time that it receives closure on advice from CASAC until it promulgates a final decision.

Although the May 9, 2018 memorandum gives some attention to the last point in the list above, it fails to take specifically into account the first five listed EPA-driven factors that lead to delays in review cycles. Based on incomplete diagnosis of leading causes of delay, and without due consideration for statutory requirements as described above, including the need for a "thorough review" based on the "latest scientific knowledge" of the "kind and extent of... effects," the May 9, 2018 memorandum, inappropriately targets measures to reduce the duration of CASAC's engagement in the review process.

Although the 2009 to 2015 review of the primary and secondary ozone NAAQS clearly took longer than five years, these delays are mainly attributable to actions of the EPA, as detailed below. Our panel reacted in an appropriate and reasonable time frame to all draft reports submitted for our review in terms of developing comments from individual members, conducting public meetings, deliberating in public, and providing our consultations or advice.

Thus, we reject the implication that delays in the NAAQS review process are in any substantial way due to CASAC's role. Delays in the current NAAQS review for ozone cannot be attributed to CASAC. For example, the last ozone review cycle resulted in a final rule on October 26, 2015. EPA did not begin the current NAAQS review cycle until a June 26, 2018 Federal Register notice of a "call for scientific and policy-relevant information." Thus, EPA waited two years and eight months to start the current review cycle. This is more than half of the five year review interval called for in the Clean Air Act. It is unreasonable for EPA to ask its staff in ORD and OAQPS, and CASAC, to sacrifice a reasonable schedule for the scientific aspects of the NAAQS review to compensate for EPA's delay in starting the review.

To reduce delays in the NAAQS review process, CASAC should advise EPA to do the following:

(1) Begin a new review cycle in a timely manner after ending the prior review cycle;
(2) Develop assessment documents for CASAC review in a timely manner; and
(3) As needed, provide revised documents for CASAC review in a timely manner.

We note also that the duration of time from closure of CASAC's role to promulgation of a final rule is at least in part at the discretion of EPA.

Furthermore, we note, as mentioned in attached individual member comments, that the courts have recognized the important role of CASAC in the NAAQS review process. Even for reviews for which EPA has been under a court order or a consent decree for a NAAQS review schedule, the courts have allowed adequate time for CASAC's review. Thus, EPA should not abridge CASAC's review time, nor truncate the process, to achieve a self-imposed schedule. As further noted in attached individual member comments, this schedule is self-imposed because EPA is selectively choosing when it will or will not comply with the statutory requirement for a 5-year review. For example, EPA has not started review cycles for carbon monoxide, lead, or oxides of nitrogen.

Timeframe for the Last Ozone Review

As noted in individual member comments, the time frame for CASAC's role in the review process has varied, but averages 3.2 years in the most recent cycle of reviews of primary NAAQS for each criteria pollutant. CASAC's involvement for the most recently completed ozone review spanned 4.7 years, which is longer than this recent average. There were several reasons for this, that are provided below.

The call for information for the ozone review was announced in the Federal Register (FR) on September 29, 2008. The FR notice for a workshop to inform development of the Integrated Science Assessment (ISA) was 13 months later, on October 29, 2009. EPA issued its Integrated Review Plan also on October 29, 2009. CASAC provided its consultation on the Integrated Review Plan (IRP) on December 3, 2009.

The first draft of the Integrated Science Assessment (ISA) was not provided to CASAC until March 2011, 15 months after CASAC's consultation on the IRP. CASAC met on May 20, 2011 to review the first external review draft (ERD) of the ISA. CASAC transmitted its advice on the first ERD of the ISA on August 10, 2011. As detailed below, CASAC had extensive concerns with the first ERD of the ISA.

The second ERD of the ISA was received by CASAC on September 2011. Given the need for a thorough review and challenges in scheduling meetings near the holidays, CASAC met on January 9-10, 2012, to review the 2nd ERD of the ISA, and communicated its advice on March 3, 2012. As detailed below, CASAC identified numerous scientific issues that needed to be addressed, and requested a third ERD of the ISA.

EPA responded with the third ERD of the ISA in a timely manner, such that CASAC was able to review it on September 11, 2012 and complete its final advice on the ISA on November 14, 2012. Detailed findings of the CASAC on the third draft of the ISA noted the adequacy of many of the changes compared to the second draft.

The first drafts of the health and welfare REAs were reviewed by CASAC concurrently with the 3rd draft of the ISA. CASAC completed its advice on the first drafts of the REAs in November 2012 (EPA-CASAC-13-002). CASAC found that the "draft HREA and WREA documents are works in progress." The health REA required substantial scientific revisions pertaining to:

- The analysis framework;
- Background ozone;
- Comparison of risk estimates based on lowest measured level (LML) and zero ozone;
- A model-based approach for risk estimates "just meeting" the current standard;
- Performance and validation of the exposure model;
- Relevance and representativeness of human activity data used in the exposure model;
- Consideration of additional sources of uncertainty in exposure assessment;
- Choice of data and models for risk assessment; and

- Discussion of exposure measurement error in the selected epidemiologic studies.

The welfare REA required substantial revisions pertaining to:

- Effects of ozone on competition among species;
- Scaling from tree seedlings to mature trees;
- Impacts on individual sensitive species;
- Regional variability in impacts;
- A model-based approach to estimate risk at ambient levels meeting the current standard; and
- Analysis of crop yield loss.

Given the extent of the needed scientific revisions, it would not have been reasonable for CASAC to concur that these REAs could be finalized by EPA without further review by CASAC.

The second drafts of the health and welfare REAs were provided to CASAC 15 months later, in February 2014. In June 2018, the CASAC found that the revised REAs were substantially improved and that, with some further revisions that did not require further CASAC review, they would be adequate for their intended purpose.

The CASAC was asked to review a first draft of the policy assessment (PA) concurrently with the first draft of the health and welfare REAs. This is not a preferred sequencing because the PA should be developed after the scientific basis pertaining to the health and welfare REAs is well-established based on CASAC input. In its public meeting held from September 11 to 13, 2012, CASAC reviewed the 3rd draft of the ISA first, then the draft REAs, and lastly the draft PA, to sequence the deliberations such that scientific issues were identified before discussing the draft PA.

The draft PA brought to CASAC for deliberation at its September 13, 2012 meeting was characterized both by EPA and CASAC as preliminary. For example, although EPA staff proposed to find that the current standards were not adequate to protect public health and welfare, the EPA staff did not propose alternatives for revised standards, leaving these sections of the draft PA blank. Thus, this was not a 'full' PA. This lack of completeness was appropriate, since CASAC had not yet concluded deliberations on scientific issues for the ISA or the REAs. Hence, it would have been premature for EPA staff to propose alternatives to the existing NAAQS at this early stage in the review process. CASAC stated, "overall, the CASAC finds that the PA needs substantial improvement, reflecting the still very preliminary first draft that was brought to the CASAC."

This experience clearly demonstrates that if a draft PA is provided to CASAC for review before science issues are fully vetted in the ISA and REAs, substantial revisions are very likely to be required. Furthermore, science issues must be resolved in the ISA and REA before reviewing a PA.

The second draft of the PA, provided to CASAC in January 2014, deliberated by CASAC at a face-to-face meeting on March 24 and follow-up teleconferences on May 28, 2014 and June 4, 2014,

was found to be (EPA-CASAC-14-004): "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 second draft of the PA was a substantive and very useful basis for CASAC to deliberate on the formulation of its own recommendations regarding the primary and secondary standards.

Whether by teleconference or in-person, CASAC held public meetings on:

- November 13, 2009 (teleconference);
- May 19-20, 2011 (in person and teleconference);
- July 6, 2011 (teleconference);
- January 9-10, 2012 (in person and teleconference);
- March 9, 2012 (teleconference);
- September 11-13, 2012 (in person and teleconference);
- November 5, 2012 (teleconference);
- March 25-27, 2014 (in person and teleconference);
- May 28, 2014 (teleconference); and
- June 4, 2014 (teleconference).

At each of these public meetings, the public had opportunity to provide comment. The public comment periods were highly valuable to informing the CASAC of scientific and policy matters relevant to CASACs deliberations. For example, there were valuable comments regarding background ozone and regarding the statutory mandate to CASAC regarding the scope of its advisory activities. Public comments provide an opportunity for scientists and stakeholders to provide input to CASAC. CASAC should affirm and advise the EPA of the importance of public comments. However, this clearly does not mean that public comments can substitute for the formation of an augmented review panel.

Some lessons learned from the last ozone review are the following:

(1) Primary and secondary NAAQS for ozone depend on a "thorough review" of the "latest scientific knowledge" in many scientific disciplines regarding 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, in varying quantities";
(2) For many of these disciplines, the perspectives of multiple experts are needed as provided by an augmented panel of additional experts in this field of study;
(3) The review must be conducted by scientific experts with the "latest scientific knowledge," which specifically includes active researchers;
(4) Stakeholders and other members of the public provide comments to CASAC that inform CASAC's deliberations;
(5) The number of drafts needed for a given assessment document depends on the scientific completeness and quality of EPA's initial and revised drafts;
(6) The number of drafts of assessment documents necessary for a "thorough review" of the "latest scientific knowledge" is determined by the scientific judgment of the CASAC; and

(7) Policy issues should not be addressed until the underlying science has been adequately vetted by CASAC.

These lessons should be considered in planning the current review of the primary and secondary NAAQS for ozone.

Factors Affecting Review Duration for the Integrated Science Assessment

We are aware of concerns about the amount of time required in the last review cycle for ozone to complete the ISA. There are two factors to consider in the duration of CASAC's review of the ISA in the last review cycle:

(1) The length of time it took EPA to provide CASAC with drafts; and
(2) The need for three drafts.

With regard to the former, the amount of time taken by EPA to provide CASAC with drafts was lengthy for the first draft. However, we have no direct knowledge of factors that might explain the duration for preparation of the ISA, such as budgetary or resource constraints, or other priority setting decisions. With regard to the second factor, there were scientific deficiencies in the first and second drafts of the ISA. Here, we review the public record regarding these factors. Based on this record, we provide advice to CASAC.

Regarding the first draft of the ISA, CASAC found that (EPA-CASAC-11-009):

- "The ISA's coverage of Policy Relevant Background (PRB) ozone concentrations is still a work in progress";
- "characterization of the temporal and spatial variability of ozone could be improved";
- "more description of some of the respiratory effects of ozone, especially on lung structure and host defenses, is needed";
- "The links between this literature [on epidemiological, human clinical, animal toxicological, and mechanistic studies], as it contributes to the biological plausibility of chronic effects, should be strengthened";
- EPA should "deepen and reorganize the discussion of susceptibility to explain how its definition of susceptibility was applied and how the identified susceptibility-determining factors apply specifically to ozone"; and
- "more attention should be given to methane as the only ozone precursor for which control would directly reduce climate forcing."

These are scientific issues that needed to be addressed to meet requirements for a "thorough review" based on the "latest scientific knowledge" and regarding the "kind and extent" of impacts indicated in the Act. Given the extent of the needed scientific revisions, it would not have been reasonable for CASAC to concur that the first ERD of the ISA could be finalized by EPA without further review by CASAC.

Regarding the second ERD of the ISA, CASAC stated (EPA-CASAC-12-004): "The CASAC commends EPA for substantial revisions to the first draft ISA based upon its prior advice

(August 2011). Nevertheless, the CASAC has further recommendations for improving the document and recommends that EPA develop a third draft of the ISA and provide it to the CASAC for a review focused on the key changes called for in this letter."

Both CASAC and EPA understood that this was an exceptional request. However, based on its expert scientific review, CASAC was not able to find that the 2nd ERD of the ISA was adequate for its intended purpose without substantial revisions. It is well established scientific practice that substantial revisions require further review.

Based on its expert scientific review of the 2nd ERD of the ISA, CASAC found that:

- "the discussion of background ozone concentration needs a stronger synthesis of current knowledge along with a quantitative assessment of the related uncertainties";
- "a discussion of long-term ozone exposures should be included";
- "discussions on the results from personal exposure simulations at several different NAAQS level scenarios should be reconsidered or deleted, as the findings of geographic variability in the 8-hour ozone exposures of children are not supported by the data";
- "analysis of population proximity to ozone monitors should be tied to maps of ozone concentrations";
- "findings from exposure studies should be integrated with discussions ... related to exposure error, confounding, and highly exposed populations";
- "the connection between dosimetry principles and theoretical or experimental observations of dose distribution and tissue damage should be discussed with greater clarity and detail";
- "EPA should give consideration to the totality of the evidence on cardiovascular effects" in its causal determination;
- "conceptual and definitional issues" need to be further addressed, including for populations at "increased risk"";
- "additional synthesis highlighting the key conclusions" for health effects was needed,"
- revisions are needed to "the reference to "sensing of ozone" by plants, which does not describe the process as currently understood; the lack of clear, unambiguous statements regarding the impact of ozone on root growth; and the lack of emphasis on ambient ozone effects on native vegetation";
- "The consideration of radiative forcing from ozone precursor emissions is inadequate"; and
- "the effect of expected tropospheric ozone changes on UV-B radiation is quite small and provide a quantitative upper limit on the effect."

This extensive list of substantive scientific deficiencies in the 2nd ERD of the ISA is why we called for a third draft. The third draft was necessary to assure the quality, credibility, and adequacy of the ISA for its intended purpose of establishing the scientific foundation for use in the REAs and to inform the PA. Given the extent of the needed scientific revisions, it would not have been reasonable for CASAC to concur that the second ERD of the ISA could be finalized by EPA without further review by CASAC.

We note that it has been common occurrence for there to be two external review drafts of ISAs in all of the recent NAAQS reviews, including particulate matter, carbon monoxide, oxides of nitrogen, and sulfur oxides. In the most recent lead review, a third draft of the ISA was requested by CASAC.

We find that the duration of review time for the ISA was related in large part to the duration of time for EPA to develop the first draft for CASAC review and to scientific deficiencies in draft ISAs that had to be addressed. With regard to the first point, the EPA staff need adequate time to prepare a document of the scope and complexity of an ISA.

Therefore, we advise that adequate time must be allowed for scientific review of the ISA. Although EPA may propose to provide CASAC with only one draft of an ISA, as it has done in the current Integrated Review Plan, this does not obligate CASAC to provide 'closure' on the ISA after reviewing only one draft. Because the ISA is a key component of the scientific review process, the ISA is key foundation for demonstrating that EPA satisfies the statutory mandate for a "thorough review" based on the "latest scientific knowledge" of the "kind and extent" of effects that pertain to the primary and secondary NAAQS for ozone. As a body independent of EPA, CASAC may refuse to concur that a given draft is adequate, and may ask for additional drafts. Thus, it is also in EPA's interest to recognize that a realistic schedule is needed and to take into account the possibility, if not likelihood, of revisions that require further CASAC review. Conversely, if CASAC were to agree in advance to review only one draft of an ISA, this would be an *a priori* judgment that the draft would not require major reviews. Such a judgment cannot be nor ever should be made until the ISA is reviewed.

The Current Integrated Review Plan for Ozone

We have serious concerns and reservations regarding EPA's Integrated Review Plan in addition to the points raised above and other points detailed in attached individual comments. For example, we understand that EPA proposes that the ISA will include prefatory material and integrated synthesis, which is consistent with past ISAs. However, EPA proposes that subsequent parts of the ISA would be treated as appendices rather than chapters, which would be inappropriate.

The May 9, 2018 memorandum by Administrator Pruitt states, without proper context, that "CASAC has frequently identified reducing the length and complexity of the ISA as a key process improvement for streamlining NAAQS reviews." While it is true that, from time to time, various review panels and the CASAC have made comments regarding a preference for more concise documents, the 'as revealed' preference of CASAC, in terms of what it has recommended and agreed with, is clearly for an ISA that provides a thorough review of the latest scientific knowledge of the kind and extent of scientific issues pertaining to a given review cycle.

CASAC has provided 'closure' on ISAs that are lengthy documents. The final ISAs for various review cycles have been 260 pages for Oxides of Nitrogen in 2008, 479 pages for Sulfur Oxides in 2008, 898 pages for Oxides of Nitrogen and Sulfur – Ecological Criteria in 2008, 1,071 pages for Particulate Matter in 2009, 593 pages for CO in 2010, 1,885 pages for lead in 2013, 1,251 pages for Ozone in 2013, 1,148 pages for Oxides of Nitrogen in 2016, and 696 pages for Sulfur Oxides in 2017. A document that is scientifically concise is not necessarily a short document. Moreover, EPA is required to meet the statutory requirements for a "thorough review" of the "latest scientific knowledge" of the "kind and extent" of scientific issues pertaining to a given review cycle.

ISAs were introduced as a result of 2006 revisions to the NAAQS review process. It is not surprising that there was a 'learning curve' by EPA staff and CASAC regarding how to structure and organize these documents that cover a large and complex scope of scientific issues. In the various review cycles alluded to in the previous paragraph, CASAC has repeatedly reviewed and commented on the structure and organization of the ISAs, which has led to ISAs that are comprised of a preface, executive summary, integrative synthesis, and chapters on major scientific issues that support the integrative synthesis. These chapters include, for example, atmospheric chemistry and ambient concentrations, exposure, dosimetry, health effects, and at-risk populations, among others. The scope of chapters is tailored to the particular review. EPA has created a separate Preamble to the ISAs that document general frameworks that are applied to each ISA regarding literature review, causal determination, and characterization of at-risk populations. These frameworks have been reviewed numerous times by CASAC.

Thus, the proposal in the IRP to substantially change the structure and content of the ISA is a substantial deviation from established practice. EPA needs to be more specific regarding this proposal, the extent to which it is based on pertinent and appropriately interpreted CASAC advice in proper context, and the extent to which it supports or compromises a "thorough review" based on the "latest scientific knowledge" of the "kind and extent" of effects that pertain to the primary and secondary NAAQS for ozone.

EPA Plans for the Current Review of the Primary and Secondary NAAQS for Ozone

As detailed in attached individual member comments, we find that the changes to the NAAQS review process called for in the May 9, 2018 memorandum from former Administrator Scott Pruitt were developed in a non-transparent manner without input from CASAC or the public.

EPA's strategy and plans for the current review of the primary and secondary standards for the NAAQS for ozone are indicated in a recent series of documents, including:

- A July 27, 2018 Federal Register notice requesting nominations for a CASAC Ozone Review Panel,
- An EPA press release of October 10, 2018 announcing new appointments and instructions to CASAC,
- An email sent by EPA on October 11, 2018 to candidates for a CASAC Ozone Review Panel informing them that a panel will not be formed,

- A November 7, 2018 "determination" memorandum from the EPA Science Advisory Board office that the chartered CASAC will conduct the ozone review, and
- The Ozone Integrated Review Plan provided by EPA for consultation with CASAC.

These recent documents are based, at least in part, on October 31, 2017 and May 9, 2018 memoranda by former Administrator Scott Pruitt that revised criteria for appointment to EPA Federal Advisory Committees, including CASAC, and the NAAQS review process itself, respectively. The implications of these recent changes are analyzed in detail in the attached member comments.

Based on this collective record, we state the seven major findings given in Table 1. Based on the seven major findings in Table 1, we make 30 recommendations as given in Table 2.

Both EPA and CASAC are required to conduct the scientific review in a manner that meets the statutory requirements of the Clean Air Act.

Sincerely,

/signed/

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Glenn E. Futrell Distinguished University Professor
Department of Civil, Construction, and Environmental Engineering
North Carolina State University
Raleigh, NC

Chartered CASAC: Member 2008-2012, Chair 2012-2015
CASAC Ozone Review Panel: Member 2009-2012, Chair, 2012-2014
CASAC PM Review Panel: Member 2007-2010, 2015-2018
CASAC Sulfur Oxides Review Panel: Member 2008-2009, 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2008-2009, Chair 2013-2015, Member 2015-2017
CASAC Lead Review Panel: Chair 2011-2013
SOx/NOx Secondary Standard Review Panel: Member 2009-2011
CASAC Carbon Monoxide Review Panel: Member 2008-2010

/signed/

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Chartered CASAC: Member 2006-2008, Chair 2008-2012
CASAC Ozone Review Panel: Chair 2009-2012
CASAC PM Review Panel: Member 2008, Chair 2009-2010
CASAC PM Review Panel: Member 1995-1996

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Chartered CASAC: Member 2012-2015, Chair 2015-2017
CASAC Ozone Review Panel: Member 2012-2014
CASAC Sulfur Oxides Review Panel: Chair 2013-2017
CASAC PM Review Panel: Chair 2015-2018

/signed/

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Northeast States for Coordinated Air Use Management
Boston, MA

Chartered CASAC: Member 2010-2016
CASAC Ozone Review Panel: Member 2009-2014
CASAC Sulfur Oxides Review Panel: Member 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2013-2017
CASAC Lead Review Panel: Member 2011-2013
CASAC Ambient Air Monitoring and Methods Subcommittee: Member, 2005-2010, Chair, 2011-2014

/signed/

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CASAC Ozone Review Panel: Member 2009-2014
CASAC PM Review Panel: Member 2007-2010
CASAC Oxides of Nitrogen Review Panel: Member 2007-2009
CASAC Sulfur Oxides Review Panel: Member 2007-2009

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CASAC Ozone Review Panel: Member 2009-2014
CASAC PM Review Panel: Member 2007-2010
Contributor and Reviewer, Air Quality Criteria for Ozone and Related Photochemical Oxidants, Criteria Document released February 2006
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/signed/

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CASAC Ozone Review Panel: Member 2009-2014
CASAC PM Review Panel: Member 2015-2018
CASAC Sulfur Oxides Review Panel: Member 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2013-2017

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CASAC Ozone Review Panel: Member 2009-2014
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Chartered CASAC: Member 2016-2017, 2007-2010
CASAC Ozone Review Panel: Member 2009-2010
CASAC Sulfur Oxides Review Panel: Member 2016-2018, 2007-2008
CASAC Secondary SOx/NOx/PM Review Panel: Member 2016-2018
CASAC Secondary SOx/NOx Review Panel: Member 2007-2010
CASAC Lead Review Panel: Member 2007
CASAC PM Review Panel: Member 2007-2010
CASAC Oxides of Nitrogen Review Panel: Member 2008-2009
CASAC Ambient Air Monitoring and Methods Subcommittee: Pb FRM, Ozone monitoring consultations

/signed/

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Chartered CASAC: Member 2000—2006
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CASAC PM Review Panel: Member 2007-2010

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Chartered CASAC: Member 2007-2012
CASAC Ozone Review Panel: Member 2006-2008, 2009-2014
CASAC NO_x-SO_x, Secondary NAAQS Review Panel: Chair 2008-2010
CASAC Oxides of Nitrogen Review Panel: Member 2007-2009
CASAC PM Review Panel: Member 2007-2010
CASAC Sulfur Oxides Review Panel: 2007-2010
CASAC Ambient Air Monitoring and Methods Subcommittee: Chair 2009-2011

/signed/

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Chartered CASAC: Member 2009-2014
CASAC Ozone Review Panel: Member 2009-2014
CASAC PM Review Panel: Member 2007-2010

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CASAC Ozone Review Panel: Member 2005-2008, 2009-2014
CASAC Oxides of Nitrogen Review Panel: Member 2007-2009
CASAC Sulfur Oxides Review Panel: Member 2007-2009, 2013-2018

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CASAC Ozone Review Panel: Member 2009-2014
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EPA SAB Biogenic Carbon Emissions Panel Member: 2011-2012, 2015-2018

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Ron Wyzga, Ph.D.
Palo Alto, CA

Chartered CASAC: Member 2012-2017
CASAC Ozone Review Panel: Member 2009-2014
CASAC Sulfur Oxides Review Panel: Member 2013-2018
CASAC PM Review Panel: Member 2008-2011, Member 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2008-2010, 2013-2017

Attachments

Attachment A: Written Statement from H. Christopher Frey (44 pages)
Attachment B: Written Statement from David A. Grantz (3 pages)
Attachment C: Written Statement from Howard S. Neufeld (2 pages)
Attachment D: Written Statement from James S. Ultman (2 pages)

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WRITTEN STATEMENTS FROM

INDIVIDUAL FORMER MEMBERS OF THE

2009-2014 CASAC OZONE REVIEW PANEL

Public Comment on the Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards

Attachment A: Written Statement from H. Christopher Frey (44 pages)

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Attachment D: Written Statement from James S. Ultman (2 pages)

WRITTEN STATEMENT

Public Comment on the Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards

PREPARED BY:

H. Christopher Frey, Ph.D.

SUBMITTED TO

Clean Air Scientific Advisory Committee

U.S. Environmental Protection Agency

Washington, DC

DATE

November 26, 2018

DISCLAIMER

H. Christopher Frey is the Glenn E. and Phyllis J. Futrell Distinguished University Professor in the Department of Civil, Construction, and Environmental Engineering at North Carolina State University. He was Chair of the EPA Clean Air Scientific Advisory Committee (CASAC) from 2012 to 2015. He was a member of the chartered CASAC from 2008 to 2012. He was chair of the CASAC Lead Review Panel (2011-2013), CASAC Ozone Review Panel (2012-2014), and CASAC Oxides of Nitrogen Review Panel (2013-2015). He served as a member of two CASAC PM Review Panels (2007-2010, 2015-2018), a Carbon Monoxide Review Panel (2008 to 2010), two Oxides of Nitrogen Review Panels (2008-2009; 2015-2017), two Sulfur Oxides Review Panels (2008-2009, 2015-2018), and a SO_x/NO_x Secondary Standard Review Panel (2009-2011). From 2012 to 2018, Dr. Frey was a member of the EPA Science Advisory Board. These are Dr. Frey's personal views. They do not represent any official position of NCSU, EPA, the CASAC, or the SAB.

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1.0 INTRODUCTION

This written statement is organized as follows:

- Section 2: Executive Summary of Major Findings and Recommendations (same as Tables 1 and 2, respectively, from the main letter).
- Section 3: Explanation of Major Findings and Recommendations
- Section 4: Comments on the Integrated Review Plan
- Section 5: Analyses of the May 9, 2018 "Back to Basics" and October 31, 2017 "Strengthening and Improving Membership on EPA Federal Advisory Committees" Memoranda
- Section 6: CASAC Should Recommend Formation of an Ozone Review Panel
- Appendix 1: Email sent to Members of the CASAC Particulate Matter Review Panel
- Appendix 2: Email sent to Candidates for the Ozone Review Panel

The recommendations are based on information from the comments on the IRP and the Appendices.

Major changes have recently been made to the National Ambient Air Quality Standard (NAAQS) review process based on Administrator memoranda issued on October 31, 2017 regarding "Strengthening and Improving Membership on EPA Federal Advisory Committees," and on May 9, 2018 regarding "Back to Basics Process for Reviewing National Ambient Air Quality Standards." It is not readily apparent to external observers that these changes were based on a deliberative process within EPA that welcomed or considered input from the EPA staff who are tasked with development of this document. It is clear that these changes were based on a secretive process that did not include opportunity for public comment nor any public consultation with CASAC. Thus, this November 29, 2018 meeting of the CASAC to review the IRP for Ozone is the first opportunity for the public to comment on the implementation of the October 31, 2017 and May 9, 2018 memoranda with respect to the NAAQS review process.

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2.0 Executive Summary of Major Findings and Recommendations

The **7 Major Findings** and **30 Recommendations** are given in Tables 1 and 2, respectively. These correspond to Tables 1 and 2, respectively of the written statement co-signed by 17 former members of the 2009 to 2014 CASAC Ozone Review Panel. The co-signers include:

- Three former chairs of the chartered CASAC (Samet, Frey, and Diez Roux),
- The two former chairs of the 2009 to 2014 CASAC Ozone Review Panel (Samet and Frey), and
- Ten former members of the chartered CASAC (Allen, Diex Roux, Frey, Harkema, Kenski, Miller, Russell, Samet, Suh, Wyzga).

The 17 co-signers have a combined 60 person-panels of experience (1 person-panel is one person serving on one panel); thus, each has served on an average of more than three CASAC panels.

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Table 1. Major Findings[a]

MAJOR FINDING 1:	The myriad of changes to the NAAQS review process are collectively harmful to the quality, credibility, and integrity of the scientific review process and CASAC as an advisory body.
MAJOR FINDING 2:	The current 7-member CASAC does not have the depth or breadth of expertise needed for the ozone review, nor could a group of this size cover the needed scientific disciplines.
MAJOR FINDING 3:	The late 2020 deadline for completing the ozone review does 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, even if the committee were supported by a robust panel of experts in the multiple disciplines involved.
MAJOR FINDING 4:	CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields toward a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state government, rather than scientific expertise first and foremost. The statute requires only "one person representing State air pollution control agencies."
MAJOR FINDING 5:	An underlying principle is to maintain distinction between science and policy issues. The Pruitt May 9, 2018 memorandum violates this principle by commingling science and policy considerations.
MAJOR FINDING 6:	In 2014, the CASAC provided advice to the Administrator regarding how CASAC's role in reviewing adverse effects of NAAQS implementation should be structured. This advice has been ignored by EPA.
MAJOR FINDING 7:	There are numerous deficiencies in EPA's Integrated Review Plan related to the above findings. EPA's proposal in the IRP to structure the Ozone ISA with appendices rather than chapters is contrary to the requirement for EPA to thorough review" of the "latest scientific information" of the "kind and extent" of "all identifiable effects" as required by the Clean Air Act.

[a] These major findings are from Table 1 in Frey, H.C., J.M. Samet, A.V. Diez Roux, G. Allen, E.L. Avol, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, F.J. Miller, H.S. Neufeld, A.G. Russell, H.H. Suh, J.S. Ultman, P.B. Woodbury, and R. Wyzga, "CASAC Advice on the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft)," Letter to L.A. Cox, Clean Air Scientific Advisory Committee, November 26, 2018.

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Table 2. Recommendations[b]

With regard to **MAJOR FINDING 1**: Changes to the NAAQS review process are harmful.

Recommendation 1: The CASAC should recommend that the EPA rescind the October 31, 2017 and May 9, 2018 memoranda by Administrator Scott Pruitt.

Recommendation 2: CASAC should recommend a wider consideration of approaches to streamlining the NAAQS review process, including opportunity for input from EPA staff in ORD and OAQPS, CASAC, and other stakeholders including the public.

Recommendation 3: CASAC should advise EPA that, if it wishes to change the criteria for appointments to EPA advisory committees including CASAC, it should provide opportunity for input on such criteria from EPA staff in ORD and OAQPS, the EPA Science and Technology Policy Council, CASAC, and other stakeholders including the public.

Recommendation 4: CASAC should not agree to changes to the review process or to the schedule proposed by EPA.

With regard to **MAJOR FINDING 2**: Lack of breadth and depth of expertise.

Recommendation 5: CASAC should acknowledge and advise the current Acting Administrator that it does not have adequate breadth and depth of scientific expertise to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to either the Ozone or the Particulate Matter NAAQS.

Recommendation 6: CASAC should remind the current Acting Administrator that it has been long-standing practice to augment the 7-member CASAC with additional independent expert consultants, and this augmentation is essential to a high quality review.

Recommendation 7: CASAC should remind the current Acting Administrator that in all past reviews conducted by CASAC, it has always been the 7-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator.

Recommendation 8: CASAC should immediately call for the formation of an Ozone Review Panel and for the reinstatement of the CASAC PM Review Panel.

With regard to **MAJOR FINDING 3**: Inadequate review time.

Recommendation 9: CASAC should reject EPA's proposed accelerated schedule. EPA should allow time for an adequate review by relaxing its 2020 deadline.

Recommendation 10: CASAC should reject EPA's proposal for one draft of an Integrated Science Assessment and one draft of a Policy Assessment.

Recommendation 11: The CASAC should advise the current Acting Administrator that the CASAC, supported by an augmented panel of scientific experts, requires typically three years to conduct this review.

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Table 2. Recommendations, *Continued*

With regard to **MAJOR FINDING 3**: Inadequate review time, *Continued.*

Recommendation 12: CASAC should remind EPA that the courts have recognized the importance of CASAC's role and the need for adequate scientific review time.

Recommendation 13: The CASAC should affirm that delays in initiation of the review cycle by EPA should not infringe on the adequacy of the time frame needed by CASAC to properly do its job with adequate quality and integrity.

Recommendation 14: CASAC should affirm the important role of public comments.

Recommendation 15: EPA should immediately begin the review cycle for carbon monoxide. CASAC should form a Carbon Monoxide Review Panel augmented with additional experts. EPA should allow adequate time for this review.

Recommendation 16: EPA should immediately begin the review cycle for lead. CASAC should form a Lead Review Panel augmented with additional experts. EPA should allow adequate time for this review.

Recommendation 17: EPA should immediately begin the review cycle for oxides of nitrogen. CASAC should form an Oxides of Nitrogen Review Panel augmented with additional experts. EPA should allow adequate time for this review.

With regard to **MAJOR FINDING 4**: Committee composition is based on non-scientific criteria.

Recommendation 18: Scientific expertise for panels should be relevant to the particular review. Different NAAQS reviews require different expertise. CASAC should re-affirm that membership criteria for the chartered CASAC and for its augmented panels should emphasize scientific expertise, not geographic diversity nor affiliation with state, local, and tribal agencies, other than to meet the Clean Air Act requirement for "one person representing State air pollution control agencies."

Recommendation 19: CASAC should affirm that receipt of an EPA research grant should not disqualify membership on the CASAC or CASAC review panels.

Recommendation 20: CASAC should affirm that its members should not be dismissed en masse or appointed en masse, and turnover in a given year should be limited to a minority fraction of the total panel. Members should be eligible for reappointment to a second term especially if such appointments would provide continuity, key scientific expertise, and institutional memory.

With regard to **MAJOR FINDING 5**: Science and policy are commingled.

Recommendation 21: CASAC should reject EPA's proposal to combine the REA into the PA for the Ozone review. Further, the CASAC review of the REA should not be concurrent with the PA for the Ozone review.

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Table 2. Recommendations, *Continued*

With regard to **MAJOR FINDING 6**: Inappropriate strategy to review implementation effects.

Recommendation 22: CASAC should not commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS pertaining to public health and welfare.

Recommendation 23: CASAC should consider both adverse and beneficial effects.

Recommendation 24: To develop advice on implementation effects, CASAC should be augmented with a panel of appropriately selected national and international experts. Such a panel may be able to address more than one NAAQS.

Recommendation 25: To avoid illegally commingling implementation issues when formulating a NAAQS, review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards.

Recommendation 26: CASAC must take a scientific approach to providing advice regarding implementation effects, and such a review should be done with the same scientific rigor as the CASAC review of other aspects of the process.

Recommendation 27: EPA should develop one or more appropriate and relevant implementation assessment documents, which could build upon existing documents such as retrospective studies of the benefits and costs of the Clean Air Act. Such documents from EPA should be developed with the same level of scientific rigor and analysis as the other documents, with similar requirements in regards to the supporting literature.

Recommendation 28: CASAC should advise the EPA that the first attempt at doing this will involve the development of new data, methods, and analyses of adequate scientific validity and policy-relevance, which will take time.

With regard to **MAJOR FINDING 7**: Deficiencies in the Ozone Integrated Review Plan

Recommendation 29: The ISA for the current ozone review should be consistent with the now well-established structure and content of CASAC-reviewed ISAs, such as from the previous ozone review.

Recommendation 30: EPA should 'start over' with the scientific review of the primary and secondary NAAQS for ozone. Specifically, EPA should set aside the current Integrated Review Plan and develop a new Integrated Review Plan that is appropriately formulated to take into account the findings and recommendations provided herein. Given the extensive revisions needed to the IRP, the CASAC and the public should have an opportunity to comment on a new IRP.

[b] These major findings are from Table 1 in Frey, H.C., J.M. Samet, A.V. Diez Roux, G. Allen, E.L. Avol, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, F.J. Miller, H.S. Neufeld, A.G. Russell, H.H. Suh, J.S. Ultman, P.B. Woodbury, and R. Wyzga, "CASAC Advice on the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft)," Letter to L.A. Cox, Clean Air Scientific Advisory Committee, November 26, 2018.

3.0 MAJOR FINDINGS AND RECOMMENDATIONS

These major findings and recommendations are supported with details in subsequent sections.

MAJOR FINDING 1: **The myriad of recent changes to the NAAQS review process** based on the October 31, 2017 and May 9, 2018 memoranda[1,2] from Administrator Scott Pruitt **are collectively harmful to the quality, credibility, and integrity of the scientific review process and to CASAC as an advisory body.**

> **Recommendation 1: The CASAC should emphasize that the quality, credibility, and integrity of the review process depends on multiple facets of how the review is structured**, including the sequence of documents, the opportunity to review revised drafts, augmentation of the CASAC with additional experts for each review (i.e. for ozone and for PM), opportunity for public input, adequate time in which to conduct the review, engagement of experts based on scientific expertise and not based on geography or affiliation, and engagement of experts with or without EPA research grants based foremost on the relevance of their scientific expertise. **Thus, simply changing one or two of these facets alone will not assure the quality, credibility, and integrity of a "thorough review" based on the "latest scientific knowledge"** as required by Sections 108 and 109 of the Clean Air Act. **The CASAC should recommend that the EPA rescind the October 31, 2017 and May 9, 2018 memoranda by former Administrator Scott Pruitt.**
>
> **Recommendation 2:** In attempting to alter the NAAQS review process, EPA should have followed the kind of open and transparent process undertaken in 2006.[3] Such a process would lead to a better understanding of the key needs and challenges of NAAQS review and perhaps effective ideas for reviews which are more timely. **CASAC should recommend a wider consideration of approaches to streamlining the NAAQS review process, including opportunity for input from EPA staff in ORD and OAQPS, CASAC, and other stakeholders including the public.**
>
> **Recommendation 3:** In revising criteria for membership on EPA Federal Advisory Committees in the October 31, 2017 memorandum[1] from former Administrator Pruitt, EPA should have recognized that such committees may serve different purposes, and should have acknowledged Federal guidance on peer review.[4] The membership criteria for a scientific review committee should not be the same as the membership criteria for a stakeholder committee. **CASAC should advise EPA that, if it wishes to change the criteria for appointments to CASAC, it should provide opportunity for input on such criteria from EPA staff in ORD and OAQPS, the EPA Science and Technology Policy Council, CASAC, and other stakeholders including the public.**
>
> **Recommendation 4**: As a group independent from EPA, **CASAC should not agree to recent changes to the NAAQS review process or to the ozone NAAQS review schedule proposed by EPA.**

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MAJOR FINDING 2: Acting Administrator Andrew Wheeler appointed five members to the CASAC on October 10, 2018.[5] The 7-member CASAC is comprised of four members from state agencies, one member from a Federal agency, a consultant, and an academic researcher. In the same October 10, 2018 press release that announced the new CASAC membership, the Acting Administrator announced that only the 7-member CASAC would conduct reviews of both the ozone and particulate matter standards and that the reviews would be conducted simultaneously on an expedited schedule. On October 11, 2018, members of the CASAC PM Review Panel, which was formed in 2016, were informed that their services were no longer needed, and candidates for the CASAC Ozone Review Panel were informed that a panel would not be formed, even though EPA requested nominations for such a panel in July 2018.[6,7] The 1800+ page Integrated Science Assessment for Particulate Matter was released four days later, on October 15, 2018.[8] **The current 7-member CASAC does not have the depth or breadth of expertise needed for the ozone and particulate matter reviews, nor could a group of this size cover the needed scientific disciplines.**

> **Recommendation 5**: **CASAC should acknowledge and advise the current Acting Administrator that it does not have adequate breadth and depth of scientific expertise to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to either the Ozone or the Particulate Matter NAAQS**. This is generally true given that CASAC is comprised of only seven members, whereas these reviews require multiple experts in each of many scientific disciplines. This is even more true given that the current CASAC was appointed based primarily on geography and affiliation, and not by scientific discipline, in accordance with the October 31, 2017 memo by former Administrator Pruitt.[1,5] According to November 7, 2018 "determination" memos from the EPA SAB office, the CASAC has no epidemiologists, even though epidemiology is a key scientific discipline related to both the ozone and PM reviews.[9,10] The CASAC lacks adequate coverage of many other disciplines, such as exposure assessment, effect of ozone on climate, and other areas, and lacks depth in areas for which CASAC has historically and necessarily engaged multiple experts, such as toxicology.
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> **Recommendation 6**: **CASAC should remind the current Acting Administrator that it has been long-standing practice to augment the 7-member CASAC with additional independent expert consultants, and this augmentation is essential to a high quality review.** It has been long-standing practice since the 1970s (see Section 6) to augment the 7-member CASAC with additional independent expert consultants, so as to have the breadth and depth of expertise required to conduct a "thorough review" based on the "latest scientific knowledge," consistent with requirements of the Clean Air Act. It is not sufficient, as the Administrator suggested, to state that the 7 member committee meets the minimum requirements of the law.
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> **Recommendation 7**: **CASAC should remind the current Acting Administrator that it has always been the 7-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator**. This point is clearly stated in CASAC's charter.[11] CASAC should remind the Administrator that based on long-standing well-established practice, consultants who augment the CASAC to form a review panel provide input and advice that ultimately is considered and vetted by the CASAC, and that it is the CASAC and not its independent consultants who decide on what advice is transmitted to the Administrator. Thus, forming an augmented panel is not mutually exclusive with only the 7-member CASAC providing advice to the Administrator.

Recommendation 8: **CASAC should call for the formation of an Ozone Review Panel and for the reinstatement of the CASAC PM Review Panel** that was disbanded on Oct 11, 2018,[7] only four days before the first draft PM ISA was released on Oct 15, 2018.[8] **CASAC should make these recommendations to the Administrator as soon as possible**.

MAJOR FINDING 3: The late 2020 deadline for completing the ozone review does 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, even if the committee were supported by a robust panel of experts in the multiple disciplines involved.

Recommendation 9: **CASAC should reject EPA's proposed accelerated schedule. EPA should allow time for an adequate review by relaxing its self-imposed deadline of 2020** and instead allow adequate time to complete the ozone NAAQS review process. Given a typical duration of CASAC involvement with NAAQS reviews that have averaged 3 years, and that EPA usually takes another 1 to 2 years to finalize a rule (see Section 5 for details), a more realistic deadline is end of 2023, or five years from now. The actual time to completion could be less but this would depend on interim findings from EPA staff and CASAC in the course of preparing and reviewing the ISA, REA, and PA. To allow adequate time for review, the schedule should be set based on established experience with similar reviews.

Recommendation 10: **CASAC should reject EPA's proposal for one draft of an ISA and one draft of a PA**. CASAC may decide later that the first draft of either of these documents are adequate for their intended purpose, but CASAC should not feel constrained to review only a single draft of each document, and EPA should provide for the possibility and opportunity for CASAC to review a second draft of either the ISA or the PA.

Recommendation 11: Given that the duration of CASAC's role in the most recent six primary NAAQS reviews focused on public health has been 2.2 years to 4.7 years, with an average of 3.2 years (see Section 5 for details), EPA's proposal for CASAC to execute its role in the current Ozone review in only one year is unprecedented, unrealistic, and infeasible if the CASAC is to conduct a review with adequate quality, credibility, and integrity. **The CASAC should advise the Administrator that the CASAC, supported by an augmented panel of scientific experts, requires typically three years to conduct this review**.

Recommendation 12: **CASAC should remind EPA that,** even when EPA has been under a court order or a consent decree to complete a NAAQS review by a court-ordered or court-approved deadline, **the courts have recognized the importance of CASAC's role and the need for adequate scientific review time.** Therefore, EPA should not impose a reduced duration schedule for the scientific review that compromises the scientific review.

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MAJOR FINDING 3: ***Continued.***

Recommendation 13: The CASAC should note that the duration of time to complete a NAAQS review depends in part on CASAC but also on EPA. In particular, EPA controls the timeline with regard to when a new review is initiated. Lapses of time between the end of a prior review up until the start of a new review are entirely at the discretion of the EPA. In the case of the Ozone review, EPA did not start the review process until June 2018, even though the final rule of the prior review cycle was published in 2015. **The CASAC should affirm that delays in initiation of the review cycle by EPA should not infringe on the adequacy of the time frame needed by CASAC to properly do its job with adequate quality and integrity**.

Recommendation 14: CASAC should affirm the important role of public comments in CASAC's review of the NAAQS, noting that a compressed and curtailed review process leads to fewer public meetings and, therefore, fewer opportunities for CASAC to be informed by public comment. CASAC should further note that the shortened duration for the ozone NAAQS scientific review results in fewer opportunities for public input to CASAC. Therefore, CASAC should advise the Administrator that, to promote transparency of the review and opportunity for public input consistent with long-standing practice, the CASAC should have a longer time frame for its deliberations, consistent with historic practice in the last decade, and should not have the public meeting process truncated to meet shortened deadline that resulted from EPA delays in starting the current review.

Recommendation 15: CASAC should advise that, if EPA wishes to fulfill the statutory requirement for a review every five years, **EPA should immediately begin the review cycle for carbon monoxide**, for which the most recent final rule was promulgated on August 31, 2011. However, EPA should allow a five year duration for the cycle, including adequate time for CASAC to formulate its advice based on "thorough review" and the "latest scientific knowledge", as required by the Clean Air Act. **CASAC should form a Carbon Monoxide Review Panel augmented with additional experts. EPA should allow adequate time for this review.**

Recommendation 16: CASAC should advise that, if EPA wishes to fulfill the statutory requirement for a review every five years, **EPA should immediately begin the review cycle for lead,** for which the most recent final rule was promulgated on October 18, 2016. However, EPA should allow a five year duration for the cycle, including adequate time for CASAC to formulate its advice based on "thorough review" and the "latest scientific knowledge." **CASAC should form a Lead Review Panel augmented with additional experts. EPA should allow adequate time for this review.**

Recommendation 17: CASAC should advise that, if EPA wishes to fulfill the statutory requirement for a review every five years, **EPA should immediately begin the review cycle for oxides of nitrogen**, for which the most recent final rule was promulgated on April 6, 2018. EPA should allow a five year duration for the cycle, including adequate time for CASAC to formulate its advice based on "thorough review" and the "latest scientific knowledge." **CASAC should form an Oxides of Nitrogen Review Panel augmented with additional experts. EPA should allow adequate time for this review.**

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MAJOR FINDING 4: Acting Administrator Andrew Wheeler, in making new appointments to the CASAC on October 10, 2018,[5] has implemented provisions of former Administrator Pruitt's October 31, 2017 memorandum.[1] **CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields toward a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state government, rather than scientific expertise first and foremost. The statute requires only "one person representing State air pollution control agencies"**. The appointment of five members at one time is highly unusual, leading to a high degree of turn-over and inexperience on the current CASAC.

> **Recommendation 18**: Scientific expertise for panels should be relevant to the particular review. Different NAAQS reviews require different expertise. CASAC should re-affirm that membership criteria for the chartered CASAC and for its augmented panels should emphasize scientific expertise, not geographic diversity nor affiliation with state, local, and tribal agencies, other than to meet the Clean Air Act requirement for "one person representing State air pollution control agencies." CASAC has always fulfilled this requirement.
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> **Recommendation 19**: **CASAC should affirm that**, per long standing prior practice from the formation of CASAC until October 2017, nationally and internationally prominent researchers who hold peer-reviewed independently managed research grants from the U.S. Environmental Protection Agency are able to offer independent scientific advice to the agency. Per the peer review bulletin of the Office of Management and Budget, for scientists who hold federal research grants, "there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects."[4] Therefore, **receipt of an EPA research grant should not disqualify membership on the CASAC or CASAC review panels**. Further, CASAC should point out that it is illogical to allow persons from state, local, and tribal governments who hold EPA grants to serve on CASAC while preventing persons of other affiliations who hold grants, such as academia, from serving. Moreover, allowing members with funding from regulated industries to serve creates an appearance of lack of impartiality.
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> **Recommendation 20**: **CASAC should affirm that**, while there are benefits to having turnover of membership on the chartered CASAC, there are also significant benefits to continuity and knowledge provided by having some previous members continue to serve for a second term and to have staggered, overlapping terms. Thus, **members should not be dismissed *en masse* or appointed *en masse*, and turnover in a given year should be limited to a minority fraction of the total panel. Members should be eligible for reappointment to a second term especially if such appointments would provide continuity, key scientific expertise, and institutional memory**.

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MAJOR FINDING 5: **An underlying principle** of changes to the NAAQS review process that were implemented in 2006 and revised in 2009 **is to maintain distinction between science and policy issues.**[3,12] **The Pruitt May 9, 2018 memorandum violates this principle by commingling science and policy considerations** via combining steps that should be kept separate.[2]

> **Recommendation 21**: **CASAC should reject EPA's proposal to combine the REA into the PA for the Ozone review. Further, the CASAC review of the REA should not be concurrent with the PA for the Ozone review**. A decision to combine the REA into the PA is doubly premature. First, the REA should not be prepared until the ISA has been adequately reviewed, since the REA is based on the air quality criteria established by and set forth in the ISA. This means that, at the earliest, the REA cannot be credibly prepared until CASAC review of the first draft of the ISA. If CASAC finds that the scientific basis of the review has changed since the last review such that a separate REA is needed, then EPA should provide CASAC with a draft REA. Second, the REA should be properly reviewed before the first draft of the PA. The PA cannot credibly set forth a policy-relevant summary of the REA without adequate review of the REA to know what elements reliably to highlight. Thus, CASAC should receive a first draft of the REA in a review step prior to receiving a first draft of the PA, such that CASAC's scientific advice on the REA is known, at least in large part, prior to the formulation of the first draft of the PA.

MAJOR FINDING 6: While it is appropriate for EPA to ask CASAC to provide advice regarding "any **adverse public health, welfare, social, economic, or energy effects** which may result from various **strategies for attainment and maintenance,**" the Clean Air Act, as interpreted by Federal Courts including the U.S. Supreme Court, is very clear that cost of implementation, and technical feasibility of implementation, are impermissible issues to consider when setting the NAAQS. Setting of NAAQS must be based solely on considerations of public health and public welfare. In 2014, the CASAC provided advice to the Administrator regarding how CASAC's role in reviewing adverse effects of NAAQS implementation should be structured.[13] This advice was not taken into account in the May 9, 2018 memorandum by Administrator Pruitt.

> **Recommendation 22**: With regard to a request from EPA for CASAC to provide advice regarding "any **adverse public health, welfare, social, economic, or energy effects** which may result from various **strategies for attainment and maintenance**" of NAAQS, **CASAC indicated how such advice should be developed in a June 26, 2014 letter to the Administrator.**[13] Because it is illegal to consider cost or feasibility of attainment when setting a NAAQS, **CASAC should not commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS pertaining to protection of public health and welfare.**

> **Recommendation 23**: In its June 26, 2014 letter, CASAC noted that not all implementation effects are adverse; therefore, "any comprehensive assessment would include both adverse and beneficial effects."[13] Most obviously, there are economic benefits from avoided morbidity and avoided premature mortality. Therefore, in considering effects of implementation of NAAQS, **CASAC should consider both adverse and beneficial effects.**

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MAJOR FINDING 6: *Continued*.

Recommendation 24: **To develop advice on implementation effects**, in 2014 CASAC advised that "the SAB Staff Office would form an ad hoc CASAC panel to obtain the full expertise necessary to conduct such a review."[13] The expertise to address social, economic, and energy effects differs from that needed to address other aspects of CASAC's mandate. Thus, **CASAC should be augmented with a panel of appropriately selected of national and international experts** to conduct such a review. **Such a panel may be able to address more than one NAAQS**.

Recommendation 25: **To avoid illegally commingling implementation issues when formulating a NAAQS, review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards.**

Recommendation 26: **CASAC must take a scientific approach to providing advice regarding implementation effects** based on valid methods and data. Such advice cannot be based merely on anecdotes or stakeholder opinions. Such a review should be done with the same scientific rigor as the CASAC review of other aspects of the process

Recommendation 27: **EPA should develop one or more appropriate and relevant implementation assessment documents, which could build upon existing documents such as retrospective and prospective studies of the benefits and costs of the Clean Air Act.[14,15,16] Such documents from EPA should be developed with the same level of scientific rigor and analysis as the other documents, with similar requirements in regards to the supporting literature. EPA should** allow adequate time for review and revision of such documents, with an emphasis on scientifically valid data, methodologies, and analyses relevant to such a review.

Recommendation 28: Because neither EPA nor CASAC have previously conducted an assessment of "adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance," **CASAC should advise the EPA that the first attempt at doing this will involve the development of new data, methods, and analyses of adequate scientific validity and policy-relevance, which will take time**. Thus, such an activity cannot be compressed to a short-time period to meet a near-term EPA self-imposed deadline. In any case, as noted above, this assessment should be kept separate from review of the NAAQS.

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MAJOR FINDING 7: There are numerous deficiencies in EPA's Integrated Review Plan[17] related to the above findings. EPA's proposal in the IRP to structure the Ozone ISA with appendices rather than chapters is contrary to the requirement for EPA to thorough review" of the "latest scientific information" of the "kind and extent" of "all identifiable effects" as required by the Clean Air Act.

> **Recommendation 29: The ISA for the current ozone review should be consistent with the now well-established structure and content of CASAC-reviewed ISAs, such as from the previous ozone review.** Previous ISAs include chapters that pertain to key scientific disciplines (e.g., air quality, exposure, dosimetry, human health effects, at-risk populations, welfare effects). These chapters are critical to demonstration of "thorough review" that "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, in varying quantities." Such chapters identify, based on a thorough literature review, and a thorough assessment of the literature, the policy relevant science that supports scientific determinations in the integrative synthesis.
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> **Recommendation 30: EPA should 'start over' with the scientific review of the primary and secondary NAAQS for ozone. Specifically, EPA should set aside the current Integrated Review Plan and develop a new Integrated Review Plan that is appropriately formulated to take into account the findings and recommendations provided herein. Given the extensive revisions needed to the IRP, the CASAC and the public should have an opportunity to comment on a new IRP.**

References Cited

[1] Pruitt, E.S., "Strengthening and Improving Membership on EPA Federal Advisory Committees," Memorandum, U.S. Environmental Protection Agency, October 31, 2017

[2] Pruitt, S.E., "Back to Basics Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 9, 2018.

[3] Peacock, M., "Process for Reviewing National Ambient Air Quality Standards," Memorandum to George Gray and Bill Wehrum, U.S. Environmental Protection Agency, Washington, DC, December 7, 2006.

[4] Bolten, J.B., "Issuance of OMB's "Final Information Quality Bulletin for Peer Review," Memorandum, Office of Management and Budget, Executive Office of the President, Washington, DC, December 16, 2004.

[5] EPA, "Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee," News Release, October 10, 2018. https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee

[6] Khanna, Johnston, "CASAC Ozone Panel Thank you for your interest. Providing an update." Email to Aaron Yeow, U.S. Environmental Protection Agency, October 11, 2018.

[7] Khanna, Johnston, "CASAC PM Panel Thank you for your service." Email to Aaron Yeow, U.S. Environmental Protection Agency, October 11, 2018.

[8] EPA, "Integrated Science Assessment for Particulate Matter (External Review Draft)," EPA/600/R-18/179, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018.

[9] Yeow, A., "Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Ozone National Ambient Air Quality Standards (NAAQS)," Memorandum to T.H. Brennan, Science Advisory Board, U.S. Environmental Protection Agency, Washington, DC, November 7, 2018.

[10] Yeow, A., "Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Particulate Matter (PM) National Ambient Air Quality Standards (NAAQS)," Memorandum to T.H. Brennan, Science Advisory Board, U.S. Environmental Protection Agency, Washington, DC, November 7, 2018.

[11] EPA, "United States Environmental Protection Agency Charter: Clean Air Scientific Advisory Committee," U.S. Environmental Protection Agency, Washington, DC, EPA Approval Date 5/23/17, Date Filed with Congress 6/5/17. https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2017casaccharter/$File/CASAC%202017%20Renewal%20Charter%20Filed%206-5-17.pdf

[12] Jackson, L., "Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 21, 2009. https://www3.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf

[13] Frey, H.C., "CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards," EPA-CASAC-14-004, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, June 26, 2014.

[14] EPA, "The Benefits and Costs of the Clean Air Act, 1970 to 1990," U.S. Environmental Protection Agency, Washington, DC, October 15, 1997.

[15] EPA, "The Benefits and Costs of the Clean Air Act, 1990 to 2010: First prospective study," U.S. Environmental Protection Agency, Washington, DC, November 15, 1999.

[16] EPA, "The Benefits and Costs of the Clean Air Act, 1990 to 2020: Second prospective study," U.S. Environmental Protection Agency, Washington, DC, March 1, 2011.

[17] EPA, Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards, External Review Draft, EPA-452/P-18-001, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018.

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4.0 COMMENTS ON THE INTEGRATED REVIEW PLAN FOR OZONE

Page 1-3, lines 14-15: The IRP appropriately notes "Issues that are not relevant to standard setting may be relevant to implementation of the NAAQS once they are established." **The IRP should make clear that when developing recommendations to retain, revise, or develop new NAAQS, it is illegal to consider issues related to cost and technical feasibility of implementation**. Thus, any CASAC role in providing advice regarding effects of implementations should be done separately, and on a different timeline, than the development of CASAC's advice regarding the adequacy of current standards or revision or setting of new standards.

Page 1-4, lines 21-24: The document should make clear that **the Peacock, 2006 memorandum was based on a public process for getting input on the NAAQS review process. The Pruitt, 2018 memo was not**. More details in Section 5 of this statement.

Page 1-5, paragraph of lines 7 to 22 is misleading. While it is true that ISAs have been reviewed in draft form by CASAC, since the revised NAAQS review process from the Peacock, 2006 memorandum, **CASAC has reviewed at least two and sometimes three drafts of the ISA, not merely one draft of the ISA**. While it may be possible that a single draft could be adequate (more details on this point below), it is not reasonable to pre-judge that this will be the case. Ozone is one of the most researched and studied of ambient air pollutants, and the ISA for ozone is sure to be complex with many topics and scientific inferences. The scientific credibility of the review process is compromised if an *a priori* judgment is made that only one draft of the ISA will be adequate. Furthermore, CASAC is not required to concur that an ISA is adequate for its intended purpose if it in fact is inadequate. CASAC has both a right and a duty to demand subsequent drafts.

Paragraph of Page 1-5, line 23 to page 1-6, line 8: **EPA is mischaracterizing the NAAQS review process** that has been in place as a result of the Peacock 2006 memorandum. **The risk and exposure assessment (REA) was not originally intended to be a step to be subsumed into the policy assessment (PA)**. The REA deals with fundamental scientific issues addressing the combinations of air pollutants (indicators), averaging times, exposure durations (e.g., long-term, short-term), and effect endpoints for which exposure and risk can be quantified, what appropriate data and method(s) are available and selected for exposure assessment, what appropriate data and method(s) are available for either identifying benchmark exposure levels or quantifying exposure-response relationships, and what metrics are appropriate for risk characterization.

The purpose of having a sequence of documents in the order of ISA, REA, and PA is to distinguish between matters that are purely scientific in nature, as embodied in the ISA, from matters that commingle policy considerations, as embodied in the PA. The REA is a bridge between the ISA and the PA. The REA applies information, data, and methods from the ISA to make estimates and predictions of exposures and risks. As such, the REA is heavily science-based, and merits a science-focused review before it is used in the PA. Combining the REA and the PA into one document or one step commingles science and policy issues, thereby reducing transparency of the scientific aspects of the assessment while introducing the possibility that the REA will be structured based on pre-judged policy outcomes. It also appears to invite violation of one of the objectives stated in Administrator Pruitt's May 2018 memorandum: to "differentiate science and policy judgments in the NAAQS review process."

In recent reviews for which an REA was not done or was combined into the policy assessment, there was reliance on an REA conducted in a prior review cycle for which the science had been well-vetted by CASAC in advance of reviewing the first draft PA (e.g., the Lead review completed by CASAC in 2013). However, here, **EPA appears to be proposing that a new risk and exposure assessment could be developed without providing it to CASAC for review prior to CASAC's review of the PA**. Given that the PA often relies significantly on insights from the REA, **commingling the REA and PA will beg the question of whether the REA was tailored toward particular pre-judged policy outcomes rather than predicated on the best science** in terms of design, input data, modeling framework, and applications. Equally obviously, the PA would inappropriately be drawing conclusions from an REA that had not been properly scientifically vetted by CASAC review.

With regard to the standard charge questions give on page 1-6, line 25 to page 1-7, line 19, these are generally reasonable and appropriate questions but they do not belong together in terms of how they should be addressed by CASAC, as elaborated below.

With regard to how CASAC should provide advice regarding effects of implementation of NAAQS, this was addressed in a June 26, 2014 letter to the Administrator, as described in more detail in Section 5.10 "CASAC Advice on Implementation of NAAQS."

Page 1-7, lines 24-29. Although public comments are always an important part of the NAAQS review process, **it is simply not the case that a public call for information on "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of existing, new, or revised NAAQS for consideration" will adequately form a basis for CASAC to formulate "meaningful advice on these questions."** While it is correct that the Clean Air Act states that CASAC shall provide this advice, CASAC is generally tasked with providing advice based on the "latest scientific knowledge." Therefore, meaningful advice on these questions cannot be predicated on anecdotal information provided only by stakeholders who respond to a request for public comment. **CASAC must take a fair, balanced, and open-minded approach based on valid scientific data and inference methods**. There may or may not be adequate scientific data and methodology to provide advice on all of these issues. **EPA has not provided CASAC with any assessment documents on effects from strategies for implementation of NAAQS. Thus, there is not an existing methodological framework for addressing these issues**. The credibility of CASAC's advice is predicated on development of advice based on appropriate data and methods. Furthermore, **the credibility of CASAC's advice will depend critically on whether the CASAC is augmented with a sufficient number of experts in the relevant disciplines to assure a thorough review based on the latest scientific knowledge.**

Page 1-8, lines 11-12: this document should **explain in detail the process by which the May 2018 "Back to Basics" Memorandum was developed**. When was the process of formulating the key points subsequently included in the memorandum defined and initiated? What EPA staff were consulted with respect to their input and advice on revisions to the NAAQS review process, what was their input, and how was their input taken into account in formulating the memo? What public meetings were held to allow for public input? What stakeholders had opportunities for meetings with EPA senior administrative staff to provide their input to these revisions, and what was their input? What consultations were made between EPA and its scientific advisory committees, including the CASAC, the Science Advisory Board, and the Board of Scientific Counselors, regarding the proposed changes to the NAAQS review process and advice on the proposed changes?

Page 1-8, lines 13-14: Who decided and on what basis that the Ozone review must be completed by 2020? What EPA staff were involved in this decision? What opportunity was given for input by NCEA and OAQPS staff regarding this deadline? What opportunity was given to CASAC to consider and advise regarding recent changes to the NAAQS review process and to the proposal for a highly compressed review schedule? Is EPA under a court order or consent decree to complete the Ozone review by 2020?

The IRP should review the history of past reviews of ozone and other criteria pollutants. For each combination of criteria pollutant, type of standard (primary or secondary), and review cycle, what have been the following durations:

- Date from end of the prior review (i.e. publication of the final rule) to the formal announcement of the start of the next review (e.g., call for information for the ISA)
- Date from receipt of CASAC's "closure" letter in a given review cycle (e.g., the final CASAC advice on a given staff paper, ANPR, or policy assessment) and the date of publication of the subsequent final rule.
- Date from the end of the prior review (i.e. publication of the final rule) to the date of the end of the current review (i.e. publication of the final rule).
- Which of these reviews have been under a court order or consent decree?

Such an analysis will reveal (see Section 5) that **EPA has typically substantially delayed the start of a new review cycle after completion of a final review cycle**. For example, according to the terms of the May 2018 "Back to Basics" memo by Pruitt (2018), EPA should immediately begin review of the carbon monoxide standard, since the last review was completed seven years ago. Yet, EPA has not announced any plan to review the CO cycle.

The 2020 deadline for the ozone review, and for the PM review, are self-imposed deadlines, apparently developed without consideration of the scientific exigencies that should underly each review. **Even in cases for which EPA has been under a court order to complete a NAAQS review, or has entered into a consent decree with a court-supervised schedule, the courts have recognized the importance of the scientific review by CASAC required under the CAA, and have allowed far more time for CASAC's role than EPA is proposing to allow under its self-imposed deadlines**.

Page 1-7, lines 28-29: "The EPA is not planning to develop a Risk and Exposure Assessment (REA) Planning Document in this review." Given that the last ozone review was based on information with a deadline of July 2011, and that ozone is one of the most heavily studied of air pollutants, there may be significant new scientific information identified in the upcoming ISA. As EPA acknowledges later in the IRP. **It is already known that there is significant new scientific information to motivate new REAs for both public health and public welfare**. The more detailed review of new scientific information that will comprise the draft ISA may identify additional new information that would motivate extensions of the currently anticipated scope for new REAs for health and welfare. Thus, a decision on the scope and methods for the REA should be made after taking into account new scientific information that will be reviewed in the ISA. EPA should in the meantime plan to develop a plan for a new REA if one is needed.

Page 1-9, lines 1-5: **The Pruitt, 2018 memorandum** implements major changes to the NAAQS review process. However, the process by which the key changes were formulated lacked transparency. The

memorandum itself is internally inconsistent, and poorly formulated. For example, the memo **mischaracterizes or takes out of context some letter reports from CASAC during the transition in which the revised 2006 NAAQS review process was implemented, and by omission failed to point out lessons learned (more details in Section 5)**. Although claiming to call for more transparency and distinction between science and policy issues, **by arbitrarily speeding up the review process, dropping or combining documents, reducing opportunity for public input, and commingling science and policy issues via combined documents, the memo, if implemented, will significantly compromise the quality and integrity of the scientific review process, and taint CASAC's involvement in the process**.

Combining the REA into the PA means that science issues related to the REA will be pre-judged because those judgments will be made at the same time as formulation of the PA. **Thus, implementation of the May 2018 memorandum will clearly commingle science and policy considerations that were kept appropriately kept separate in the prior ozone review**. The only scenario in which combining the REA into the PA would be appropriate is if there is no new science since the last review that would lead to either a reformulation or re-interpretation of the previous REA. **Yet, as EPA appropriately notes later in the IRP, it is known *a priori* that the data and science *have* changed and that new analyses are needed for both the health and welfare REAs**.

Page 1-9, lines 5-6: **"Further, we are striving to ensure that initial draft documents are sufficiently robust and complete to support a single, full review by the CASAC and the public." While we can all agree that this would be a serendipitous outcome, it has never been achieved in practice in the 10 years that I have been involved in the CASAC review process**. This is a nice aspirational goal, but it is not realistic unless there has been no significant change in the science since the last review. However, until the ISA is written and reviewed by the CASAC, it will not be known whether the science is essentially unchanged since the last review. Therefore, **it is unwarranted, and indeed prejudicial, to assume, *a priori*, that a single draft will prove to be adequate**. This is also not a matter of whether EPA staff work hard enough to produce a "robust" document, whatever that means. EPA staff have demonstrated time and again their commitment to put forth the best document that they can, given time and resource constraints. **These documents involve many scientific issues of great complexity, for which a more integrative interpretation may emerge only after iterative deliberations, not just within EPA staff, but also with the CASAC and reflecting public input. EPA is prejudging that CASAC, and the commenting public, have little or nothing to offer in terms of additional scientific perspective that could lead to substantial improvement of a first draft.**

Page 1-9, lines 6-8: "The successfulness of these and other efficiencies implemented in this review will be considered by the EPA in planning for other future NAAQS reviews." This is an ironic statement, considering that the May 2018 memorandum by Administrator Pruitt did not assess the "successfulness" (sic) of the NAAQS review process based on implementation of a revised process since 2006. **The NAAQS review process in the last decade has in fact been extremely successful. For example, EPA, based on CASAC review and advice, has produced appropriately comprehensive and integrated assessments of the science pertaining to pollutants that affect public health and welfare. By following a carefully planned sequence of documents from the ISA to the REA to the PA, both EPA and CASAC have ensured that the review begins with a strong and sole focus on policy-relevant science and transitions to policy only toward the end, after the science is established and the application of science to the REA is established. Furthermore, the NAAQS review process as it existed prior to May 9, 2018 ensured multiple opportunities for public comment. Both EPA and CASAC, via the carefully**

structured process set in place as a result of a thorough, deliberative, and public review of the process itself, have produced assessments that are "thorough" and that "accurately reflect the latest scientific knowledge," as required under Sections 108 and 109 of the Clean Air Act. Thus, the system has been working. The May 9, 2018 memorandum attempts to 'fix something that ain't broke.'

The only respect in which the NAAQS review process has fallen short is with respect to meeting the five year review requirement of the CAA, but even in this regard EPA has generally been successful at reducing review time – a point not acknowledged in the memo - and has come very close to achieving the 5-year mandate for each of the criteria pollutants for the last few cycles. With increasing experience, both EPA staff and CASAC are able to conduct reviews more efficiently, not as a result of skipping steps, but based on lessons learned and resolved through careful deliberation. While more needs to be done to achieve the 5 year cycle, the review system is not fundamentally broken (see Section 5 for more details). Thus, the drastic changes to the review cycle as described throughout these comments are unwarranted, and are creating numerous adverse consequences that undermine the quality, credibility, and integrity of the review process.

Page 1-9, lines 9 to 18: **This timelime is inconsistent with achieving the breadth, depth, quality, credibility, and integrity of the scientific review process that is required under the Clean Air Act.** Section 109 of the Clean Air Act (CAA) requires the EPA Administrator to "complete a thorough review" of the NAAQS. CAA Section 108 states that the standards "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air." The EPA Clean Air Scientific Advisory Committee (CASAC) is integral to this statutory mandate of thorough and comprehensive review. Section 109 of the CAA states that "an independent scientific review committee" "shall complete a review of the criteria published under section 108 of this title and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 of this title and subsection (b) of this section." EPA should not interfere with CASAC's ability to fulfill the mandate of the CAA to conduct the required "thorough review". **If CASAC needs another draft of a document to enable it to conduct a "thorough" review based on the "latest scientific knowledge," then the EPA should provide CASAC with another draft of the document, whether it is the ISA, REA, or PA.**

The NAAQS review process prior to the May 9, 2018 "Back-to-Basics Process for Reviewing National Ambient Air Quality Standards" memorandum was carefully developed in 2006, and amended in 2007 and 2009, based on a public deliberative process that included input from internal and external stakeholders, including EPA staff in ORD and OAQPS, CASAC, and others. In sharp contrast, **the May 2018 memorandum was developed without a public deliberative process or opportunity for stakeholder input, and the internal process by which ORD and OAQPS, or perhaps other stakeholders, had opportunity to provide input is unknown or did not exist. The lack of an appropriate deliberative process led to a poorly formulated assessment of putative problems with the existing NAAQS review process (see Section 5.4 for examples) and a set of "solutions" that creates larger and more significant problems. EPA should rescind the May 9, 2018 memorandum.**

Page 2-4, line 25. The proposed revision was a range from 0.070 ppm to 0.065 ppm, not 0.07 ppm to 0.065 ppm.

Page 2-6, lines 4-6: this decision was not consistent with CASAC's advice.

Section 2.1 does a good job of reviewing the regulatory history but does not include a review of CASAC's role. **Given that the EPA has very recently made changes to the NAAQS review process, the IRP should clearly explain what was the process for CASAC's role in each of the prior review, and how is the proposed review process for this current review similar to, or different than, the prior reviews?** See Section 5 for details that would support such an overview.

Page 2-10, lines 23-27: This is certainly appropriate, but there is no doubt inter-annual variability in the U.S. background concentrations which also vary at shorter time scales and spatially. Will EPA assess inter-annual variability in U.S. background and its implications? Why would 2016 be a representative year in terms of typical meteorology?

While it is reasonable to use air quality modeling to assess U.S. background, air quality models are imprecise and may have biases. What will EPA do with regard to model evaluation and quantification of bias and imprecision in model predictions? What about uncertainty in emissions, chemical mechanisms, physical transport processes, and boundary conditions? How will these be addressed? For example, will model results with U.S. emissions be compared to monitoring data? Will model predictions be "updated" with monitoring values using Bayesian methods? What monitoring sites might reasonably represent background levels for use in evaluation of model predictions of U.S. background?

Page 3-2, lines 16-19: The text states: the "approach planned for this review of the primary O_3 standard will build on the substantial body of work developed during the course of the last review, taking into account the more recent scientific information and air quality data now available to inform our understanding of the key-policy relevant issues in this review." This implies that **the ISA in this review will be significantly updated compared to that of the last review, which in turn implies a substantial likelihood that the REA will also need to be updated compared to the last review.**

Page 3-3, lines 5-7 "Additionally, the currently available exposure and risk information, whether newly developed in this review or predominantly developed in the past and interpreted in light of current information..." This text implies that it is not yet known whether a new REA is needed. However, if a new REA is needed, then it should be provided for CASAC review as a first draft prior to providing CASAC with a first draft of the PA for review, to avoid commingling science and policy issues prematurely in the review process. However, later text in the IRP (see comments below) clearly indicates the need for a new REAs for both health and welfare.

The key questions on page 3-3 are appropriate. EPA should answer the last question as part of the ISA, at least with respect to whether uncertainties identified in the last review have been reduced. The final assessment of key uncertainties remaining at the end of this review cycle would typically be included in the PA and addressed by CASAC in its advice regarding the PA.

Page 3-4. The text here is generally reasonable but begs the question of what scientific information will be established prior to the first draft of the REA. Logically, there needs to be an REA that includes evaluation of the various alternatives that would provide a foundation for policy recommendations in the PA.

Given that public health and welfare, and billions of dollars in benefits and costs, are at stake, EPA can and should do its "due diligence" in the science review by having a proper review process with

separate ISA, REA, and PA documents that are sequenced such that findings from the previous document — after appropriate scientific vetting — can be taken into account.

Top of page 3-6. **Missing here is the interpretation of "protect public health" with an "adequate margin of safety" is that protection must be afforded to at-risk populations, but not necessarily every individual in an at-risk population.**

Top of page 3-7: The IRP should clearly state what was the cut-off data for the literature review that was the basis of the ISA. This cut-off date is the effective date of the "health effects evidence base". The cut-off date was July 2011. This is mentioned later but it would helpful to mention it here.

Page 3-37: The section that ends on this page is generally good. However, what is not clear from the description is that **the Administrator did not follow CASAC's advice for setting a secondary standard based on a biologically relevant metric.** CASAC considered the concordance between a secondary standard based on a biologically relevant metric versus one based on the same indicator, averaging time, and form as the primary standard. CASAC recommended that the secondary standard be set based on a biologically relevant metric: specifically, the CASAC recommended "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)" (Frey, 2014, CASAC report EPA-CASAC-14-004). Thus, the description of the decision making process would be clearer by including the statement that the Administrator's decision differed from CASAC's recommendation.

Page 4-1, lines 23-25: Given that the cited ISA is exclusively for a secondary standard, it is bit puzzling that EPA uses the secondary NOx/SOx/PM ISA as the model for the planned Ozone ISA, which is in the context of both a primary and secondary standard. Now that the first draft of the PM ISA is available, it may be better to refer to that, since it includes scientific information pertaining to both primary and secondary standards.

The plan for an integrated synthesis is good. CASAC has many times recommended the inclusion of an integrated synthesis. This plan is consistent with prior CASAC advice and with EPA practice.

However, **it is unusual that subsequent parts of the ISA would be treated as appendices rather than chapters. This deviates from well-established practice. What is the reason for this change? Will this affect the content? Is this a substantive change or just one of labeling? If this represents a substantive change that deviates from well-established practices that have emerged from the last decade of CASAC advice, then the IRP should have more clearly explained and attempted to justify such change. Failure to do so undermines the ability of the public to understand and comment on EPA's proposal.**

The content of the Preamble to the ISA (EPA/600/R-15/067, 2015) has been extensively reviewed by CASAC for 10 years in multiple review cycles and is appropriate for continued use in this review.

Page 4-4. Lines 10-19: should add that prior studies may also be included in newer meta-analyses, or might be re-interpreted taking into account new evidence.

Page 4-4, lines 20-29: Missing here seems to be the role of exposure assessment methods not just in the context of epidemiologic studies but in the context of quantifying inter-individual variability in

personal exposures that might be compared with benchmark personal exposure concentrations or used in combination with exposure-response curves inferred form controlled human studies or personal-exposure-based epidemiologic studies. See also comments below.

The priority focus indicated on page 4-5, lines 10-22 is appropriate.

Page 4-5, **"Population, Exposure, Comparison, Outcome, and Study Design (PECOS)." This is a new term to the ISAs. While this seems like a well-founded concept, discussion of whether, how, and to what extent this would fundamentally change how inferences are made in the ISA would be helpful. It seems that each of these elements have already been considered in past ISAs. Is the intent here to add more structure to the identification and assessment of these components?**

Page 4-7, lines 19-20: This appears to the first place that the literature cutoff data for the current review is mentioned. What are the considerations that went into choosing this date? What if CASAC requests a second draft of the ISA? What if the 2020 deadline for this review is relaxed?

Page 4-8: Has SWIFT-AS been used for previous ISAs? Has it been validated in terms of accurately identifying relevant references compared to searches that did not use SWIFT-AS?

Table 4-1 – what about study design?

Page 4-23, line 34: should insert a discussion regarding consistency between multiple epidemiologic studies, before discussing coherence with other lines of evidence.

Page 4-24, line 3. Should add text regarding mode of action.

Page 4-25, line 10 – and to other health endpoints?

Page 4-25, line 16… and accounted for modifiers.

Page 4-26, lines 12-13: **while exposure methods in the context of interpreting epidemiologic results are important, this is not the only role for exposure methods. For example, an exposure simulation model such as APEX could be, and has been, used to assess personal exposures with respect to benchmark exposures or exposure-response relationships inferred from controlled human studies. Thus, the coverage of exposure assessment in the ISA should not be limited only to the context of interpreting epidemiologic studies**. For example, stochastic population-based modeling has had a role in prior REAs for ozone. **This point comes up later in the IRP. The data and methods for such modeling should be within the scope of the ISA. Or EPA should explain why it is not the scope of the ISA. Would the same March 2019 cut-off date for the ISA also apply to the REA?**

Page 4-32: last paragraph. **This paragraph presumes that CASAC will concur that the first draft of the ISA, with modifications if any recommended by CASAC, does not require further review by CASAC and will be adequate for its intended purpose. This may or may not be the actual outcome of the CASAC review of the first draft of the ISA. Since the NAAQS review process was revised after 2006 to include an ISA, there have not been fewer than two drafts of an ISA in any review**.

Page 5-2, lines 17-18: "while also bearing in mind practical and logistical considerations such as available resources and timeline for the review."

- This is a very important statement.

- **EPA should allocate adequate resources for this review.**
- The timeline for the review should be adequate. As noted elsewhere in these comments, the **EPA has imposed a deadline that leads to a curtailed schedule of only about one year for CASAC's role, which is far shorter than CASAC reviews in any other review cycle for ozone or any other pollutant in the last 10 years or more.**
- Whether a new REA is warranted should not be constrained by a self-imposed deadline. **Whether a new REA is warranted should be based on the science, consistent with the requirement under the CAA that the NAAQS review be "thorough" and based on the "latest scientific knowledge."**
- EPA must relax its deadline to allow for the following:
    - **CASAC may need to see second draft of the ISA**
    - **The science evidence base may have changed enough to warrant a new REA**
    - **The first draft of the REA should be available to CASAC and reviewed before EPA completes the first draft of the PA.**
    - **CASAC may need to see second drafts of the REA and PA**
    - **The REA is actually two documents: HREA and WREA.**
    - **CASAC needs adequate time to review all of this information.**

Page 5-2, lines 24-35: **"We are planning that the quantitative exposure and risk analyses newly developed in this review will be presented in the draft PA." This is appropriate only in the circumstance that no update to the HREA or WREA from the last review is warranted. In the event of substantive updates, the new HREA and/or WREA should be submitted as draft(s) for CASAC review PRIOR to providing CASAC with a draft PA. Otherwise, science and policy issues will be commingled, reducing transparency and distinction between science and policy issues.**

Figure 1 is very good and illustrates the key steps in the HREA. **This context for exposure modeling needs to be kept in mind in the ISA, since the ISA should establish the scientific basis for the entire review.** Thus, the ISA should review and evaluate exposure modeling and dosimetry modeling methods.

Page 5-16, lines 7-9: **"In this review, there are newly available ambient air quality data that better reflect concentrations at or near the current standard, updated emissions data and air quality models, and updates to the exposure model to better estimate exposure-based risk": this text implies a strong likelihood of substantial updates to the exposure assessment and dosimetry assessments in the health REA compared to the last review.**

With regard to epidemiologic-based risk approaches, improved air quality data might also be a sufficient basis for new analyses.

Page 5-18, lines 1-2: "we are preliminarily planning to focus new analyses in this review on exposure-based risk analyses." **This seems reasonable, as long as this is in the context of preparing a first draft of the REA that will be reviewed by CASAC before a first draft of the PA.** As noted above, the PA must

take account the findings of the REA, and that REA must therefore receive proper scientific vetting in the form of thorough CASAC review before preparation of the PA. CASAC often has substantial comments on exposure assessment and dosimetry modeling, and **it is not reasonable to presume *a priori* that scientific questions regarding these modeling approaches, and their input data, will be fully resolved without iteration between EPA and CASAC. Given that EPA has already identified that there are expected to be significant changes in the exposure and dosimetry models, a stand-alone first draft REA is needed**.

In contrast, in other review cycles for which an REA was combined into the PA, such as for the most recent lead review, CASAC concurred, after reviewing the ISA, that a new REA was not warranted, and that the previous REA could be reinterpreted. A similar situation is clearly not presented with respect to ozone.

Page 5-18, lines 10-12: "Given the rapid timeline for this review, we would expect to focus on a streamlined set of study areas and air quality scenarios compared to the expansive set assessed in the last review." **CASAC should NOT agree to this time line**. As noted elsewhere in this comments, the **EPA has imposed adeadline that leads to a curtailed schedule of only about one year for CASAC's role, which is far shorter than the duration of CASAC reviews in any other review cycle for ozone or any other pollutant in the last 10 years or more. Whether a new REA is warranted should be based on the science, consistent with the requirement under the CAA that the NAAQS review be "thorough" and based on the "latest scientific knowledge." Neither EPA nor CASCAC should follow a "rapid" timeline that undermines the quality, credibility, and integrity of the science review process. Further, CASAC should not agree to a "streamlined" approach if that means inadequate coverage of key sources of variability that should be considered in the assessment.**

Page 5-28, line 12, with respect to the welfare REA, the IRP has text regarding the "expedited nature of this review". Similar to comments above, this is an artificial situation created by a deadline that does not allow adequate time for scientific review. See comments immediately above.

Page 5-28, lines 14 to 19: **based on this text, it seems likely that a new WREA is warranted. Such a WREA should be provided as a stand alone draft for CASAC review and advice prior to providing CASAC with a draft PA.**

Page 6-1, lines 21-23: "the PA will describe the underlying interpretations of the scientific evidence, risk/exposure information and any other quantitative analyses that might support such alternative policy options." **This text illustrates precisely why the HREA and WREA need to be reviewed by CASAC prior to review of the PA. Risk/exposure information is a precursor to and underlying foundation of the PA. The HREA and WREA involve scientific data and methods. Scientific components of the review should be completed separately from the more policy-focused deliberations by CASAC on the PA**.

Page 6-2, line 7: **should state that "sensitive groups" are conceptualized in the science review as "at-risk" groups. The draft ISA for particulate matter, and other prior ISA's, have text regarding at-risk groups that make clear that some are more at risk than others. This language should be incorporated in the IRP.**

Page 6-2, lines 25-27: **In characterizing the "past practice" of CASAC, EOPA should do so accurately. Past practice of CASAC in the last ozone review was three drafts of the ISA, two drafts of the HREA, and two drafts of the PA.**

Whether one draft of the PA is adequate is highly context and situation dependent. EPA should not prejudge that only one draft of the PA will be adequate, and should allow for the possibility that CASAC will need to see a second draft of the PA, as has been past practice. Here, again, EPA's deadline curtails the science review and the role of both the CASAC and the public in that review.

5.0 Analyses of the May 9, 2018 "Back to Basics" and October 31, 2017 "Strengthening and Improving Membership on EPA Federal Advisory Committees" Memoranda

H. Christopher Frey, Ph.D.

On May 9, 2018, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt issued a memorandum titled "Back-to-Basics Process for Reviewing National Ambient Air Quality Standards" (NAAQS).[1] This appendix provides context for NAAQS review and an analysis of the memorandum.

5.1 Statutory Mandate for Scientific Review of the NAAQS

Section 109 of the Clean Air Act (CAA) requires the EPA Administrator to "complete a thorough review" of the NAAQS at five-year intervals. The CAA further requires the Administrator to "appoint an independent scientific review committee" that "shall complete a review" of existing NAAQS and that "shall recommend to the Administrator any new" NAAQS and "revisions of existing criteria and standards as may be appropriate." CAA Section 108 states that the standards "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air." The EPA Clean Air Scientific Advisory Committee (CASAC) is chartered under this mandate.

5.2 Recent History of the NAAQS Review Process

The process for NAAQS review was revised in 2006 based on consultations within EPA, including the Office of Air and Radiation (OAR) and the Office of Research and Development (ORD), with current and former members of CASAC, and with other stakeholders.[2] The revised process included four major components: planning; integrated science assessment (ISA); risk and exposure assessment (REA); and policy assessment (PA). Separation between these review steps enables differentiation and transparency regarding scientific issues, which are the main focus of the ISA and a major focus of the REA, and policy issues, which is the main focus of the PA.

The ISA reviews, synthesizes, and evaluates policy-relevant science to establish key scientific findings. Such findings include, for example, characterization of physical and chemical processes that lead to ambient air pollutant concentrations, evaluation of air quality monitoring and modeling methods, spatial and temporal variability in ambient concentrations, quantification of background concentrations, quantification of human human exposure, dosimetry and mode of action, identification of adverse effects, causal determination between exposure and adverse effects, characterization of populations potentially at increased risk, environmental and ecosystem effects, and interactions with climate change.[3,4]

The REA is a quantitative analysis of exposure and risk based upon scientific evidence established in the ISA. The REA builds upon the findings of the ISA, such as regarding key adverse effects and populations at increased risk, to provide details regarding input data and modeling methods and results for assessment of exposure and risk.[5,6] The PA was initially in the form of an advanced notice of proposed rulemaking (ANPR). An April 2007 memorandum modified the process to enable CASAC to review a second draft of the REA and for the REA to be finalized before an ANPR was issued.[7] In May 2009, Administrator Lisa Jackson deleted the ANPR and replaced it with a policy assessment (PA).[8] The ANPR is a regulatory document that involves input from politically-appointed leadership, whereas the PA is a staff evaluation of the policy implications of the scientific and technical information in the ISA and REA.

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The PA includes assessment by EPA staff of whether the current standard is adequate and, if not, options for the indicator (pollutant), level, averaging time, and form of possible alternative standards.[9,10] Taking into consideration the PA, CASAC formulates its advice regarding whether an existing NAAQS should be retained or revised, and whether a new NAAQS is recommended. CASAC logically provides this advice before EPA formulates a proposed rule.

Planning has typically included an integrated review plan (IRP) for the review cycle, and a scope and methods plan (SMP) or similar planning document for the REA.[11,12] The scientific basis of the review is logically established in the ISA before the REA can be completed. The methodology, input data, and results of the REA have been scientifically reviewed before the PA is finalized.

5.3 Brief Primer on CASAC

CASAC is comprised of seven members appointed by the EPA Administrator, referred to as the "chartered CASAC". For each NAAQS review, CASAC forms a panel augmented with additional experts and has done so since the 1980s. The augmented panels include multiple experts in each of the many scientific disciplines that pertain to the ISA, REA, and PA. In addition to its mandate under the CAA, CASAC is subject to the Federal Advisory Committee Act (FACA). CASAC meetings must be announced in the *Federal Register*, the public must be allowed to attend, and CASAC must allow for public comments. Public comments provide an opportunity for stakeholder input to the review process. For a full review cycle, there is an initial teleconference to convey individual member comments on the IRP, followed by four face-to-face meetings that typically take two days each and focus on: (1) first draft of the ISA and draft of the REA scope and methods plan; (2) 2nd draft of the ISA and 1st draft of the REA; (3) 2nd draft of the REA and 1st draft of the PA; and (4) 2nd draft of the PA. Panelists receive a draft document (often hundreds of pages, sometimes over a thousand pages) and charge questions from EPA approximately 30 to 60 days prior to a meeting, and submit individual written comments before the meeting.

During the public meeting, the review panel is asked to develop consensus responses to charge questions provided by EPA, but may also provide other advice it deems to be appropriate. After the public meeting, panelists develop a written draft of the responses to charge questions, and may update their individual comments. Although consensus is sought, and often achieved, panelists are always able to convey their individual comments. The panel chair develops a draft letter to the Administrator that conveys the key aspects of CASAC's advice. The draft letter and responses to charge questions are reviewed and deliberated at a teleconference open to the public. The statutory CASAC completes a public "quality review" of each draft report before it is transmitted to the Administrator.

The duration from receipt of a draft EPA report by panelists to the delivery of advice from CASAC to the Administrator is typically 3 to 5 months. EPA staff usually have a good idea of the main points of CASAC's advice at the conclusion of the first public meeting on a particular document, which is typically within 2 months of panel members receiving a draft.

5.4 The Five Year Requirement

EPA has generally failed to meet the CAA requirement for a five year review cycle for the NAAQS. For the most recent reviews of the primary NAAQS that focus on public health, including carbon monoxide, lead, nitrogen dioxide, ozone, and particulate matter (PM), the review cycle took between 4.0 years to 7.1 years from the initial call for information for the ISA to the publication of the final rule, with an

average of 5.9 years. The current review for sulfur oxides is past the proposed rule stage, but not yet finalized, at just over 5 years. However, EPA is generally completing the review process in a more timely manner than in the past.

Based on the time from the consultation on the IRP to its final advice on the PA, the duration of CASAC's role in the most recent six NAAQS reviews focused on public health has been 2.2 years to 4.7 years, with an average of 3.2 years. The scientific aspects of these review cycles have been thorough and of high quality, and have resulted in CASAC advice based on the "latest scientific knowledge" as required under the CAA. The separation between the ISA, REA, and PA facilitates separation of science and policy advice by CASAC. CASAC has also been careful to distinguish policy advice from scientific advice.[13,14]

The most recent review of the carbon monoxide NAAQS was started over 13 years from the prior review completed in 1994, and it is now over 7 years since the last revision of the CO standard in 2011. For the other five criteria pollutants, the amount of time that elapsed from the end of the prior review cycle to the start of the next ranged from 0.5 years to 2.9 years, with an average of 1.6 years. For the five most recent completed primary NAAQS reviews, it has taken EPA between 1.1 to 3.4 years to finalize a rule, with an average of 1.9 years, after CASAC completed its final advice on the most recent policy assessment.

The May 2018 memorandum quotes selectively from CASAC letters from ca. 2006-2008 regarding putative problems with the current review process, implying that these quotes evince CASAC support for speeding up the process.[1] Those letters in fact addressed concerns with the review process prior to modification or during the early part of the learning curve for the new process. There were early challenges with the revised process as both EPA staff and CASAC were determining and clarifying the scope and methods relevant to each review step. A comment from a 2008 letter from CASAC is given without proper context: while it was true at that time that early drafts of ISAs did not exclusively focus on scientific evaluation of the most relevant scientific studies, lessons learned from CASAC's 2008 and other advice have subsequently led to more focused literature reviews and scientific assessments. As another example, CASAC panels for each criteria pollutant deliberated regarding EPA staff proposals for an updated framework for determination of causality of adverse effects from exposure to air pollutants, leading to improved formulation and clarity of the framework and improved consistency and transparency of its application over time. Thus, the issues raised based on the cited letters from a decade ago are of limited current relevance.

5.5 Wait, and Then Hurry Up!

The May 2018 memorandum states that the NAAQS review will be completed by October 2020 for ozone and by December 2020 for particulate matter.[1] Administrator Pruitt took office on February 17, 2017. EPA did not announce the start of the current ozone review until June 26, 2018. Although the current PM review has nominally been underway for more than two years, EPA did not release the first draft of the ISA until October 2018.[15] There are approximately two years from now to the deadlines indicated in the May 2018 memorandum. EPA has never completed a NAAQS review cycle in such a short time.

5.6 Can the Review Process be Shortened?

The ISA is critically important to establishing the scientific findings regarding the determination of causality of short and long term exposures with regard to adverse effects, and the data and methods relevant to later steps of the review. For each primary NAAQS, two drafts of the ISA were reviewed by CASAC. However, in the case of lead and ozone, a third draft of the ISA was required because CASAC found that the second draft did not adequately address CASAC's prior comments. CASAC has recognized that the ISA, as well as the REA and PA, do not have to be perfect, but must be adequate for their intended purpose, taking into account the CAA mandate that NAAQS be based on "a thorough review" and the "latest scientific knowledge."

The ISA may appropriately contain more information than is later used directly in rulemaking, including scientific questions for which the answer was a null finding. For example, in the previous PM review, a scientific assessment was made that there was insufficient health effects evidence to justify developing a new standard for ultrafine particulate matter (UFP).[3,9] EPA and CASAC considered UFP in deciding, at that time, not to recommend a standard for UFP. Identification of key uncertainties is also critical to CASAC's mandate to advise the administrator of areas where new science is needed that may be relevant in the next review cycle.

In cases for which there has been limited new information since the last review, the REA either has been omitted, relying instead on the REA from the prior review cycle, in which case the REA is either minimally updated or combined into the PA. CASAC has been amenable to these adjustments to the review process, *when appropriate*. However, the duration of the review process does not appear to be highly correlated with whether a separate REA is produced. For example, from the initial call for information for the ISA to the publication of the proposed rule, the reviews for which there was not a separate REA took 58 to 66 months. The review for sulfur oxides, with only a single draft of the REA, took 61 months. In contrast, the reviews for carbon monoxide, ozone, and particulate matter, for which there were two drafts of the REA, took 41, 75, and 60 months, respectively.

5.7 Combining Multiple Steps into One Step

The May 2018 memo states that EPA "shall consider combining" the ISA, REA, and PA "into a single review."[1] One of the benefits of sequencing these documents is to avoid a problem with an initial draft of one document, such as the ISA, from propagating to later steps in the REA and PA.[3] Combining these documents into one review could lead to an inadequately developed scientific basis, a premature risk and exposure assessment, and a poorly supported policy assessment. Furthermore, the sequence of these documents increases transparency regarding science and policy issues.

A single review step would imply that EPA staff working on the REA and PA are presuming the outcome of the ISA before the content of the ISA has stabilized based on CASAC review. Combining these steps would presume that the policy outcome is known before the scientific assessment has been finalized. A rushed combined process would be inherently less transparent.

One of the key reasons why EPA discontinued the use of an ANPR and replaced it with a policy assessment was because the former was "vulnerable to the introduction of policy options that are not supported by the relevant scientific information," whereas the PA "presents a transparent staff analysis of policy options...to consider prior to rulemaking."[8] Publication of a PA prior to a proposed rule enables

EPA to demonstrate that it has completed a science-based review and fosters the identification and evaluation of science-based regulatory alternatives.

Merely because EPA might proffer a combined assessment for CASAC to review does not mean that CASAC must concur that the combined assessment is adequate. Scientific shortcomings in a combined assessment could lead to CASAC requests for revised drafts. Logistically, there is also the challenge of asking CASAC to compress its review activities into a much shorter time frame. It is debatable whether a CASAC panel could easily digest a combined ISA-REA-PA and deliberate on its advice without additional review and meeting time, while maintaining the level of quality consistent with current practice and the mandate of the CAA.

5.8 Sudden Death: Eliminating the PM and Ozone Review Panels

On October 11, 2018, members of the CASAC PM Review Panel received an email from EPA stating that "your service on the panel has concluded." The PM Review Panel was appointed in 2015 and originally had 26 members. Also on October 11, 2018, candidates for the CASAC O_3 Review Panel were informed that "the Agency will not form a CASAC Ozone Panel." The ozone review panel for the review cycle completed in 2015 had 20 members. There was no prior consultation with members of the PM Review Panel, nor any public indication that elimination of the panels was being considered, nor any public process for providing input related to this issue.

In an October 10, 2018 press release, EPA announced that the chartered 7-member CASAC would conduct the reviews of both the ozone and PM NAAQS simultaneously. Thus, instead of having approximately 20 or more experts review separate planning, ISA, REA, and PA documents over a period of typically three years, a committee of only seven members will conduct a review in a period that would have to be only about one year, taking into account time for EPA to develop and publish proposed and final rules. Furthermore, rather than have two mostly non-overlapping groups of experts conduct the reviews, subject to approval by the chartered CASAC, the same group of seven will review these two NAAQS concurrently. For PM in particular, there has been a tremendous amount of new research since the last review, as indicated by the over 1800 page length of the first draft ISA released just days after the PM Review Panel was disbanded.[15] EPA has argued that the CAA does not require that CASAC be augmented with additional experts. This rote response does not address the question of what is needed to provide the requisite "thorough review". In fact, it has been clear for the last nearly three decades that a seven member group does not have the breadth and depth of scientific expertise needed for these reviews, nor does the CAA prevent the formation of panels.

5.9 Transforming CASAC from a Scientific to a Stakeholder Committee

Over the decades, CASAC members have been appointed based on their scientific expertise. In contrast, an October 31, 2017 memo from Administrator Scott Pruitt requires that members of EPA federal advisory committees should "reflect prominent participation from state, tribal, and local governments," and that priority should be given to "geographic diversity."[16] There is no mention of the importance of having experts of high stature that represent the wide range of scientific disciplines, and the depth of knowledge and experience, necessary to the work of committees such as CASAC or the EPA Scientific Advisory Board (SAB). On October 10, 2018, EPA announced that Acting Administrator Wheeler appointed five new members to the 7-member chartered CASAC. The current CASAC is comprised of representatives from four state agencies, one federal agency, a consulting firm, and one academic

researcher. For the most part, these members were selected for their geographic location or affiliation, rather than primarily based on depth of expertise.

In the context of the ozone review, the CASAC does not include nationally or international recognized experts in epidemiology, which is a key scientific discipline. The CASAC lacks nationally or international recognized experts in exposure assessment. The CASAC lacks the diversity of multiple expert perspectives on toxicology, including from experts who are at the forefront of toxicological research and recognized as national or international experts. The CASAC lacks adequate breadth and depth of expertise in air quality science, including measurements of background concentrations. The CASAC also lacks proper coverage of expertise pertaining to issues related to the scope of public welfare, such as effect of tropospheric ozone on climate and vegetation. CASAC has typically been comprised of leading nationally and internationally recognized scientific experts, who are active in research in their respective fields and at the forefront of the latest scientific knowledge, not stakeholders selected for their geographic location or governmental affiliation.

The memorandum states that "no member of an EPA federal advisory committee currently receive EPA grants," but that this "principle should not apply to state, tribal, or local government agency recipients of EPA grants."[16] This is illogical for four reasons. One is the obvious inconsistency of implying that receiving a grant creates a conflict of interest for one but not another class of persons. The second is the longstanding recognition that receipt of a peer-reviewed scientific research grant, for which the Agency does not manage the work nor control the output, is not a conflict of interest. Per the Office of Management and Budget (OMB): "When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects."[17] A 2013 report by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest.[18] However, there can be situations in which a member of an advisory committee should recuse themselves from discussions that might pertain to their own work. Thus, third, the CASAC has had recusal policies in place for dealing with this issue and situations in which a member's work may come up for deliberation. Fourth, the memorandum does not acknowledge that persons with financial or professional ties to regulated industries have at the very least, the same appearance of conflict of interest.

The October 31, 2017 memo calls for greater turnover in membership of EPA advisory committees but fails to acknowledge that there are benefits of continuity and knowledge provided by having some previous members continue to serve.[16] Under this new policy, well-qualified scientists have been "rotated" off of the CASAC, in favor of new members without subject matter expertise, selected instead for their affiliation or geographic location.

5.10 CASAC Advice on Implementation of NAAQS

The CAA states that CASAC shall advise the Administrator EPA regarding "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of NAAQS. However, past EPA administrations have typically not asked CASAC for this advice, nor have EPA staff prepared scientific assessment documents for CASAC review that would be

relevant to developing such advice. The May 2018 memorandum indicates that EPA will include a charge question to CASAC seeking such advice.[1]

In a June 26, 2014 letter to the Administrator, CASAC outlined how such advice would need to be developed, taking into account that it is illegal to consider cost or technological feasibility when setting a NAAQS.[13] CASAC stated that it did not want to commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS. CASAC noted that not all implementation effects are adverse; therefore, "any comprehensive assessment would include both adverse and beneficial effects." For example, there are economic benefits from avoided morbidity and premature mortality. CASAC further advised that "the SAB Staff Office would form an ad hoc CASAC panel to obtain the full expertise necessary to conduct such a review." The expertise to address social, economic, and energy effects differs from that needed to address other aspects of CASAC's mandate. Review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards. Furthermore, EPA should recognize that as a scientific advisory committee, it would be CASAC's responsibility to take a scientific approach to providing advice regarding implementation effects based on valid methods and data, and that such advice cannot be based merely on anecdotes or stakeholder opinions.

CASAC historically relies on EPA staff to prepare draft documents and does not have the resources to commission its own studies. The May 2018 memorandum indirectly acknowledges that CASAC needs to be provided with relevant documents. To clearly separate its advice on implementation versus advice on the standards themselves, an appropriately formulated separate CASAC NAAQS implementation review panel should be provided with a separate draft implementation assessment document. It is likely that there will be a significant learning curve for the both the agency and CASAC in dealing with assessment of implementation issues, which should be recognized in setting schedules. The timing of CASAC advice regarding implementation logically would not be the same as that regarding whether to revise a standard, to avoid conflating implementation issues with the development of advice regarding the setting of NAAQS.

5.11 Lack of Transparency about Transparency

The story is not complete without mentioning the proposed rule regarding purported "transparency" in regulatory science. This proposed rule could have the effect of banning some scientific studies that have been influential in prior NAAQS reviews. As the SAB has pointed out, this proposed rule was not developed based on a transparent process.[19] For example, there was no consultation with the SAB or CASAC, nor were EPA staff scientists or external scientists consulted or offered the opportunity for input. Policies regarding how science is conducted at EPA are usually developed as guidance documents, not as regulations. Although increased transparency is a broadly shared goal in the scientific community, there are legitimate scientific studies — replicated many times over — for which the underlying data are necessarily based on confidential human subject data. Both the courts, and OMB in its rules implementing the Data Quality Act, have recognized the appropriateness of utilizing such studies in the regulatory process.

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5.12 A Way Forward

EPA is a science-based agency with a science-based mission to protect the public health, as mandated by the laws under which EPA must operate. The combined effect of multiple rushed and poorly founded ad hoc initiatives, including the October 31, 2017 and May 8, 2018 memoranda, a proposed rule to ban the use of particular types of valid scientific studies, the conversion of CASAC to a stakeholder committee, and the summary dismissal of an existing review panel, arbitrarily undermines the application and evaluation of science in the NAAQS review process.

A two year time frame for NAAQS review by a reconstituted CASAC, for which a highly qualified augmented review panel was dismissed for one pollutant and not formed for another, will create problems that could call into question the quality and adequacy of the review. Although EPA is required to complete NAAQS reviews in five years, EPA clearly has needed additional time to conduct the mandated "thorough review" of the "latest scientific information" . In some cases, EPA has been sued and courts have supervised the timing of the review process. Court approved or ordered completion schedules have taken into account the need for adequate scientific review time. For example, under consent decrees for the recent nitrogen dioxide and sulfur oxides reviews, EPA followed an appropriate process that preserved the integrity of the scientific review. In the current cases for PM and ozone, EPA has spent a lot of time in getting the reviews underway.

EPA could shorten the length of the review process by reducing the time between the conclusion of the prior review and the start of the next review. EPA could also potentially reduce review time if it is able to commit staff resources to the ISA, REA, and PA to shorten the calendar time, but not the scope and quality, of the development effort for each draft report submitted to CASAC. To maintain the credibility of the process, CASAC should continue to review separate ISA, REA, and PA documents, and complete its advice on the PA prior to EPA formulating and issuing a proposed rule. EPA should abandon the arbitrary constraints imposed on CASAC membership. CASAC should continue to engage additional experts as has been the case for approximately three decades, should reinstate the PM Review Panel, and should form an ozone review panel.

EPA staff in ORD and OAR should be lauded for their good faith efforts over the years to shorten the review time for NAAQS, as illustrated by the development and implementation of new processes since 2006. CASAC has generally tried to honor EPA's schedule needs by recognizing that assessment documents must be adequate for their intended purpose but do not need to be perfect. The May 2018 memorandum was not developed based on an open and transparent process. For example, there was no consultation with CASAC. If EPA wants to revise the NAAQS review process, it should do so via an open and transparent process similar to that undertaken in 2006. Such a process would lead to a more accurate understanding of the key needs and challenges of a NAAQS review and perhaps effective ideas for more timely reviews.

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5.13 References Cited

[1] Pruitt, S.E., "Back to Basics Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 9, 2018.

[2] Peacock, M., "Process for Reviewing National Ambient Air Quality Standards," Memorandum to George Gray and Bill Wehrum, U.S. Environmental Protection Agency, Washington, DC, December 7, 2006.

[3] EPA, "Integrated Science Assessment for Particulate Matter," EPA/600/R-08/139F, U.S. Environmental Protection Agency, Research Triangle Park, NC, December 2009

[4] EPA, "Integrated Science Assessment for Ozone and Related Photochemical Oxidants," EPA 600/R-10/076F, U.S. Environmental Protection Agency, Research Triangle Park, NC, February 2013.

[5] EPA, "Quantitative Health Risk Assessment for Particulate Matter," EPA-452/R-10-005, U.S. Environmental Protection Agency, Research Triangle Park, NC, June 2010.

[6] EPA, "Health Risk and Exposure Assessment for Ozone," EPA-452/R-14-004a, U.S. Environmental Protection Agency, Research Triangle Park, NC, August 2014.

[7] Peacock, M., "Modifications to Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, April 17, 2007.

[8] Jackson, L., "Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 21, 2009.

[9] EPA, "Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards," EPA 452/R-11-003, U.S. Environmental Protection Agency, Research Triangle Park, NC, April 2011.

[10] EPA, "Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards," EPA-452/R-14-006, U.S. Environmental Protection Agency, Research Triangle Park, NC, August 2014.

[11] Diez Roux, A., "CASAC Review of the EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016)," EPA-CASAC-16-003, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016.

[12] Samet, J.M., "Consultation on EPA's Ozone National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment (April 2011) and Ozone National Ambient Air Quality Standards: Scope and Methods Plan for Welfare Risk and Exposure Assessment (April 2011)," EPA-CASAC-11-008, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, June 21, 2011.

[13] Frey, H.C., "CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards," EPA-CASAC-14-004, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, June 26, 2014.

[14] Diex Roux, A., and E.A. Sheppard, "CASAC Review of the EPA's Policy Assessment for the Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide (External Review Draft –

September 2016)," EPA-CASAC-17-001, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 7, 2017.

[15] EPA, "Integrated Science Assessment for Particulate Matter (External Review Draft)," EPA/600/R-18/179, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018.

[16] Pruitt, E.S., "Strengthening and Improving Membership on EPA Federal Advisory Committees," Memorandum, U.S. Environmental Protection Agency, October 31, 2017.

[17] Bolten, J.B., "Issuance of OMB's "Final Information Quality Bulletin for Peer Review," Memorandum, Office of Management and Budget, Executive Office of the President, Washington, DC, December 16, 2004.

[18] EPA, "EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees," Report No. 13-P-0387, Office of Inspector General, U.S. Environmental Protection Agency, Washington, DC, September 11, 2013.

[19] Honeycutt, M., "Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science," EPA-SAB-18-003, Science Advisory Board, U.S. Environmental Protection Agency, Washington, DC, June 28, 2018.

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6.0 CASAC Should Recommend Formation of an Ozone Review Panel

Section 109 of the Clean Air Act (CAA) requires the EPA Administrator to "complete a thorough review" (emphasis added) of the NAAQS at five-year intervals. The CAA further requires the Administrator to "appoint an independent scientific review committee" that "shall complete a review" of existing NAAQS and that "shall recommend to the Administrator any new" NAAQS and "revisions of existing criteria and standards as may be appropriate." CAA Section 108 states that the standards "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air" (emphasis added). The EPA Clean Air Scientific Advisory Committee (CASAC) is chartered under this mandate.

The 7-member chartered CASAC has routinely been augmented with additional expert consultants to form review panels for particular criteria pollutants pertaining to review of primary and secondary standards. The review panels are chaired by a member of the chartered CASAC and include members of the chartered CASAC. According to the CASAC charter with Congress, panels are allowable and are advisory to CASAC. The 7-member chartered CASAC must approve any draft reports prepared by a review panel before such a report can be transmitted to the EPA Administrator. The augmented panels are created because **the 7 members of the chartered CASAC do not have the breadth and depth of scientific expertise to adequately cover the myriad of scientific issues that must be addressed as part of the NAAQS review process**. Such review panels have been formed subject to the provisions of the Federal Advisory Committee Act and all applicable procedures and policies of the EPA Science Advisory Board office.

6.1 October 10, 2018 Press Release

In an October 10, 2018 press release, Acting Administrator Wheeler announced that the 7-member chartered CASAC is "tasked ... with leading the review of science for any necessary changes to the NAAQS for ozone or particulate matter." The press release further indicated that "these changes" will be finalized by late 2020. The next day, emails were sent to members of the existing CASAC PM Review Panel indicating that the panel was disbanded and to candidates for the CASAC Ozone Review Panel indicating that a panel would not be formed (see Appendix 1 and 2, respectively).

While there have been many occasions on which there have been simultaneous CASAC reviews of two or more NAAQS, such reviews have been conducted by augmented review panels, thus including a larger number of persons that collectively had more depth and breadth of expertise. Furthermore, the EPA is proposing that CASAC complete its reviews of both ozone and PM on a highly expedited time frame.

Furthermore, **the October 10, 2018 press release was announced without any prior public process for obtaining input from EPA staff, CASAC, or other stakeholders**. As such, **the decision announced in the October 10 press release, as confirmed the next day with an email to candidates for the ozone review panel, to not form an ozone review panel is arbitrary. The ill-founded nature of this decision is readily apparent from the long history of the use of augmented CASAC panels and from EPA's intent to form an Ozone Review Panel as indicated in a Federal Register notice of July 27, 2018. No reasonable explanation was offered regarding why the EPA chose not to form an Ozone Review Panel less than three months after announcing that such a panel would be formed**. Reportedly, EPA has claimed that it can legally ask the 7-member chartered CASAC to conduct the review. There is no question that the 7-

member chartered CASAC that must approve any report from CASAC to the EPA Administrator, which has been long established practice, but as the track record of at least three decades clearly indicates, CASAC benefits from and requires the input of additional scientific experts in formulating its advice to the Administrator. **The arbitrary decision of the Acting Administrator is detrimental to the quality of the scientific review process**.

6.2 July 2018 Call for Nominations for the Ozone Review Panel

On July 27, 2018, EPA announced in the Federal Register (Vol. 83, No. 145, pp. 35635-35636) that it would "form a CASAC ad hoc panel to provide advice through the chartered CASAC on the scientific and technical aspects of air quality criteria and the National Ambient Air Quality Standards (NAAQS) for ozone." The request for nominations stated that EPA "is seeking nominations for subject matter experts to serve on the CASAC Ozone Review Panel for the next review of the Ozone NAAQS that begins in fiscal year (FY) 2018. The Panel will be charged with reviewing the science and policy assessments, and related documents, that form the basis for the EPA's review of the Ozone NAAQS, and will provide advice through the Chartered CASAC."

The breadth of expertise needed for a review panel is illustrated by the July 27, 2018 request for nominations for an Ozone Review Panel: **"The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone. Experts are sought in: Air quality, atmospheric science and chemistry, causal inference, dosimetry, toxicology, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, risk assessment/modeling, uncertainty analysis, ecology and effects on welfare and the environment, and environmental economics."** Beyond the breadth of scientific topics listed here, **it has also been common practice that each panel has more than one expert in a given scientific discipline, so as to achieve a balanced representation of the current state of science pertinent to a review.**

6.3 History of Augmented Review Panels

The previous four ozone review panels have been comprised of members of the chartered CASAC augmented with additional expert consultants. In the 1987 to 1992 review, 12 consultants augmented the 7 member chartered CASAC for a total of 19 members of the "Ozone Review Committee." In the 1995 to 1996 review period, six members of the chartered CASAC were augmented with 10 expert consultants to form a panel with 16 members. In the 2005 to 2008 review activity, the CASAC Ozone Review Panel included 7 members of the chartered CASAC and 18 additional expert consultants, for a total panel of 25 members. In the most recently completed 2010 to 2014 review cycle, the 7-member chartered CASAC was augmented with 13 additional experts for a total of 20 members of the Ozone Review Panel. Thus, the use of augmented ad hoc review panels for ozone dates back more than 30 years.

Table 1 summarizes data regarding ad hoc review panels for review of primary standards for all six criteria, based on review of the CASAC reports to the EPA administrator for each review cycle for each pollutant. For many of the earlier review cycles in the late 1970s and in the 1980s, the letter reports from CASAC do not list the members of the chartered CASAC or consultants who augmented CASAC. Thus, it was not possible to compile data for every CASAC review of a primary standard. However, data

Table 1. Number of CASAC Members and Consultants for NAAQS Review Panels by Topic and Dates[a]

Review	Primary or Secondary	Years	CASAC Members	Consultants	Total
CO Review	P	1999 to 2000	7	5	12
CO Review	P	1991 to 1992	6	5	11
CO Review Panel	P	2008 to 2010	3	13	16
Lead Review Committee	P,S	1986 to 1990	7	12	19
Lead Review Panel	P,S	2006 to 2008	7	17	24
Lead Review Panel	P,S	2011 to 2013	2	18	20
NOx and Sox Secondary Review Panel	S	2008 to 2011	4	12	16
NOx and Sox Secondary Review Panel	S	2013 to present	1	21	22
Oxides of Nitrogen Review Panel	P	2007 to 2009	7	17	24
Oxides of Nitrogen Review Panel	P	2013 to 2017	4	13	17
Ozone Review Committee	P,S	1987 to 1992	7	12	19
Ozone Review Panel	P,S	1995 to 1996	6	10	16
Ozone Review Panel	P,S	2005 to 2008	7	18	25
Ozone Review Panel	P,S	2010 to 2014	7	13	20
PM Review Panel	P,S	1994 to 1996	6	15	21
PM Review Panel	P,S	2001 to 2006	7	15	22
PM Review Panel	P,S	2008 to 2010	7	15	22
PM Review Panel	P,S	2016 to 2018	6	20	26
Sulfur Oxides Panel	P	2007 to 2010	7	17	24
Sulfur Oxides Panel	P	2013 to 2018	6	16	22

[a]*All of this information was obtained from www.epa.gov/casac by review CASAC reports posted online.*

Table 2. Summary of Primary NAAQS Review Panels By Number of Consultants[a]

Description	Number
Consultants: 16 to 20	8
Consultants: 12 to 15	9
Consultants: 5 to 10	3
Total	20

[a]*All of this information was obtained from www.epa.gov/casac by review CASAC reports posted online.*

are available for 20 CASAC reviews of primary standards dating to as early as 1987. As shown in Table 1, although there are a few panels with only 5 to 10 additional expert consultants, it has been more typical that the chartered CASAC has been augmented with 12 or more additional experts in a given review cycle for a given criteria pollutant. **The average number of consultants for these 20 panels is 14, and the average size of the augmented ad hoc review panels is 20 members. The averages for ozone and PM review panels are 15 consulting experts and panels with a total of 21 members**.

As shown in Table 2, of 20 panels for which data could be characterized regarding the number of consultants who comprised review panels, 3 had 5 to 10 consultants, 9 had 12 to 15 consultants, and 8 had 16 to 20 consultants.

The use of augmented panels or subcommittees dates at least to the late 1970s. On October 9, 1979, the Subcommittee on Carbon Monoxide of the CASAC issued its "findings, recommendations and comments." However, a list was not included of members of that subcommittee. Based on the December 1982 EPA report on Air Quality Criteria for Particulate Matter and Sulfur Oxides (EPA-600/8-82-029a), CASAC was augmented with consultants. CASAC Subcommittee on Health Effects of Particulate Matter and Sulfur Oxides included six consultants in addition to members of the chartered CASAC. The CASAC Subcommittee on Welfare Effects of Particulate Matter and Sulfur Oxides included five consultants in addition to members of the chartered CASAC. The consultants were different for these two review activities. Thus, there were 11 consultants who augmented the chartered CASAC for this review cycle. The dates on which these subcommittees met are not readily available, however.

Therefore, although there are not as many details available in the public record to quantify the membership or meeting dates of either subcommittees or augmented panels prior to 1987, there is evidence in the public record that **augmentation of CASAC with additional experts has been a routine practice for four decades**.

6.4 CASAC Does Not Have Adequate Breadth and Depth of Expertise to Review the Ozone Standard

In the case of ozone, for which there are health effects data from multiple scientific disciplines, including epidemiology, toxicology, and controlled human studies, it has been common practice to have multiple experts in each of these disciplines to assure both breadth and depth of expertise. **The ozone review requires many other scientific disciplines as illustrated by the list given in the July 27, 2018 Federal Register request for nominations**.

The 7-member chartered CASAC does not have the breadth of deep expertise required for a review of the ozone NAAQS that meets the requirements of the Clean Air Act for a "thorough review" that "shall accurately reflect the latest scientific knowledge" of the "extent and kind of ... effects". The only credible way to provide a "thorough review" that "shall accurately reflect the latest scientific knowledge" is to engage scientists who are active at the leading edge of scientific work in disciplines and areas related to the subject matter of a review, as described in the July 27, 2018 Federal Register request for nominations, and as illustrated by the history of CASAC Review Panels summarized in Table 1.

The 7-member chartered CASAC is not required to agree with decisions of the EPA that adversely affect the quality of the scientific review process. The CASAC should recognize that it does not have adequate expertise to conduct the scientific review of the ozone without augmentation by "nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone," including multiple experts in key disciplines to assure rigorous depth. **The CASAC should recommend that an Ozone Review Panel be formed** that is augmented with additional experts and that provides both the breadth and depth of expertise required for a thorough review based on the latest scientific knowledge. **CASAC should similarly recommend that the recently disbanded CASAC PM Review Panel be reconvened**.

On November 7, 2018, a memorandum from Aaron Yeow to Thomas Brennan, titled "Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Ozone National Ambient Air Quality Standards (NAAQS)," was issued. This memorandum attempts to justify that the 7-member chartered CASAC is an adequate body to conduct the review of the ozone NAAQS. The memorandum states that the 7-member chartered CASAC has "expertise in toxicology, engineering, medicine, ecology, and atmospheric science." **Compared to the July 27, 2018 call for nominations for the Ozone Review Panel, the 7-member chartered CASAC lacks expertise in the following key areas: dosimetry, epidemiology, biostatistics, human exposure modeling, and environmental economics. Thus, the 7-member chartered CASAC is an inadequate group for conducting an assessment of the ISA, and requires augmentation with additional experts representing missing scientific disciplines. Furthermore, it is not adequate in many cases to have only one member who has expertise in a particular discipline.** For example, it is very clear that review of ozone requires expertise related to toxicological studies, epidemiological studies, clinical human studies, dosimetry, air quality measurement, exposure assessment, foliar injury, climate impacts, and so on, for which relevant expert perspectives, knowledge, and experience are needed to ensure a credible review.

The July 27, 2018 call for nominations sought "nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone." Thus, the 7-member CASAC does not meet EPA's own stated requirements for a properly constituted panel qualified to review the ozone NAAQS.

6.5 CASAC Should Recommend the Immediate Formation of the Ozone and PM Review Panels

The CASAC should recommend that the Ozone and PM Review Panels be formed that are augmented with additional scientists to ensure both the breadth and depth of expertise required for thorough and credible reviews. Failure to form these panels assures lack of credibility of the scientific review of the NAAQS.

Appendix 1: Email sent to Members of the CASAC Particulate Matter Review Panel

From: Johnston, Khanna
Sent: Thursday, October 11, 2018 4:41 PM
To: Yeow, Aaron <Yeow.Aaron@epa.gov>
Subject: CASAC PM Panel Thank you for your service

Aaron,

Can you please forward this email to CASAC PM panel?

Appreciated.

****

Dear CASAC PM Review Panel members,

Yesterday evening on October 10, 2018, Acting Administrator Andrew Wheeler announced five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). Additionally, consistent with the Clean Air Act and CASAC's charter, Mr. Wheeler tasked the seven-member chartered CASAC to serve as the body to review key science assessments for the ongoing review of the particulate matter National Ambient Air Quality Standards (NAAQS).

https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee

Therefore the CASAC PM Review Panel will no longer be involved with the Agency's PM NAAQS review and your service on the panel has concluded. The agency thanks your for your public service on the CASAC PM Panel these past several years and for your contribution in protecting public health and safeguarding our nation's air.

Please feel free to reach out to me or the CASAC Designated Federal Officer, Aaron Yeow, if you have any questions. My team and I are grateful for having the pleasure of working with you as esteemed colleagues over the years on topics and issues that have so greatly benefited the American public.

Thank you kindly,

Khanna

****

Khanna Johnston, Acting Director I Science Advisory Board I U.S. Environmental Protection Agency

1200 Pennsylvania Ave, NW (MC-1400R) I Washington DC 20460 I work 202.564.2820

Appendix 2: Email sent to Candidates for the Ozone Review Panel

From: Johnston, Khanna
Sent: Thursday, October 11, 2018 4:46 PM
To: Yeow, Aaron <Yeow.Aaron@epa.gov>
Subject: CASAC Ozone Panel Thank you for your interest. Providing an update.

Aaron,

Can you please forward this email to CASAC Ozone Panel Candidates?

Appreciated.

****

CASAC Ozone Panel Candidates,

Yesterday evening on October 10, 2018, Acting Administrator Andrew Wheeler announced five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). Additionally, consistent with the Clean Air Act and CASAC's charter, Mr. Wheeler tasked the seven-member chartered CASAC to serve as the body to review key science assessments for the ongoing review of the ozone National Ambient Air Quality Standards (NAAQS).

https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee

Therefore the Agency will not form a CASAC Ozone Panel. We thank you for your interest and encourage you to participate in CASAC activities through our public involvement process.

Please feel free to reach out to me or the CASAC Designated Federal Officer, Aaron Yeow, if you have any questions.

Thank you kindly,

Khanna

****

Khanna Johnston, Acting Director I Science Advisory Board I U.S. Environmental Protection Agency

1200 Pennsylvania Ave, NW (MC-1400R) I Washington DC 20460 I work 202.564.2820

University of California
Agriculture and Natural Resources

Kearney Agricultural
Research & Extension Center

9240 South Riverbend Avenue
Parlier, CA 93648-9757
phone: 559-646-6599
fax: 559-46-6593
dagrantz@ucanr.edu

November 26, 2018

Louis Anthony Cox, Jr., Ph.D.
President, Cox Associates
Chair, Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
Washington, DC 20460

Dear Dr Cox:

As a former member of two CASAC Review panels (Ozone and Particulate Matter) and an author and reviewer of two Criteria Documents (the format that preceded the current Integrated Science Assessment; also on Ozone and PM), I would like to offer some personal perspective and professional judgment regarding the current EPA plan to conduct the 5-year review of the NAAQS for Ozone. By way of introduction, I am a Plant Physiologist with considerable experience and expertise in effects of ozone and of PM on vegetation, particularly crops and weeds.

The intention of the Clean Air Act as amended is to provide a thorough scientific review of current literature on the impacts of Criteria Pollutants, including ozone, on health and welfare endpoints. Recent memoranda issued by the EPA Administrator (specifically on 31 October 2017 and 9 May 2018) seek to establish radically new procedures for this review. In light of my own experience with such reviews, I wish to advise you in the strongest terms that the proposed procedures cannot lead to a scientifically justifiable review of the latest scientific knowledge, as required by statute.

The current, unprecedented, intention of EPA to proceed with this review without an external Review Panel to advise the chartered CASAC, places an impossible burden on the 7-member CASAC. The available, relevant literature is simply too voluminous, and covers too many distinct fields and sub-fields of investigation, to be adequately reviewed by such a small group. This would be true given a much longer time frame than that currently envisioned by EPA.

The composition of the chartered CASAC has been radically altered without adequate public or agency input. What was once a group of preeminent subject matter experts from industry, agencies and academia, now has the appearance of a stakeholders group. Whereas the previous selection process could be justified on the basis of objective criteria, such as scientific publications or other demonstrable experience, the basis of the current appointments is not transparent, leading to questions of potential or apparent conflict of interest. The current exclusion from the possibility of membership in CASAC of academic researchers, but not of other researchers, who have received funding from EPA is without

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justification. The lack of parallelism in allowing those with funding from regulated industries to serve is even less justifiable. Finally, the recent wholesale turnover of 5 out of 7 members of the CASAC leaves the CASAC without the institutional memory or experience to undertake the review in an efficient manner. These factors, singly and taken together, can only weaken the previous strong confidence among the scientific and regulated communities in the deliberations of CASAC.

The timeline that has been established for this Ozone review, with termination in 2020, is inadequate to the task. The Clean Air Act provides for a 5-year period for reevaluation of the NAAQS. Typically, much of this period is required to conduct the review (independent of delays by EPA in initiating the reviews, which have been addressed by the courts). Time-saving procedures such as the predetermination by EPA that a single draft of the Integrated Science Assessment will be sufficient, are without justification. The number of required drafts will depend on the complexity of the new science, the adequacy of its review in the first and subsequent drafts, and on the diligence of EPA in correcting errors and omissions identified by CASAC in each draft. Similarly, the intention to combine a Risk and Exposure Assessment with a Policy Assessment is illogical and cannot lead to an adequate document of either type. A determination not to prepare an updated REA, for health or welfare endpoints, cannot be reasonably made until the state of new science has been evaluated in the ISA. Risks and exposures must be determined objectively and scientifically before they can be interpreted in terms of feasible or desirable policy outcomes. The sequence of ISA followed by REA and only then by PA was specifically intended to separate science from policy. It is essential to maintain this separation in order to preserve the integrity of the CASAC review process, and to continue the general acceptance of legitimacy that has thus far been accorded to CASAC reviews.

CASAC must be free to evaluate both adverse and beneficial effects of current or revised NAAQS and of potential strategies to attain them, without bias or mandate to consider one without the other or one preferentially over the other. These considerations, both of beneficial and adverse effects, must, by statute, be kept separate from the scientific review of the literature and the CASAC recommendation of an appropriate NAAQS.

It is my recommendation to you and the current CASAC, that you formally advise the EPA Administrator that the proposed procedures for an abbreviated review of the new science during this ozone NAAQS review are not adequate. I suggest that you point out that the resulting review will not fulfill the requirements of the Clean Air Act with amendments, will not be considered legitimate by many elements of the scientific and regulated communities, and may ultimately result in the entire process being disallowed. The courts have previously held that advice to EPA from CASAC must be given serious consideration. If, in this case, EPA does not give such serious consideration to CASAC concerns, it may be necessary for CASAC to decline to participate in a flawed process.

Sincerely,

/signed/

David A. Grantz, Ph.D.
Plant Physiologist and Cooperative Extension Air Quality Specialist
University of California at Riverside
Kearney Agricultural Research and Extension Center
Parlier, CA

Member, 2009-2014, Clean Air Scientific Advisory Committee for Ozone--NAAQS Review Panel, Integrated Science Assessment released February 2013

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Member, 2007 to 2010, Clean Air Scientific Advisory Committee for Particulate Matter--NAAQS Review Panel, Integrated Science Assessment released December 2009

Contributor and Reviewer, Air Quality Criteria for Ozone and Related Photochemical Oxidants, Criteria Document released February 2006

Principal Author, Air Quality Criteria for Particulate Matter, Criteria Document released October 2004

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Appalachian
STATE UNIVERSITY

Dr. Howard S. Neufeld, Professor
Department of Biology
572 Rivers Street
ASU Box 32027
Boone, North Carolina 28608
828-262-2683 neufeldhs@appstate.edu

November 26, 2018

Louis Anthony Cox, Jr., Ph.D.
President, Cox Associates
Chair, Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
Washington, DC 20460

Dear Dr. Cox:

As a former member of the CASAC Advisory Panel for the last revision of the ozone NAAQS, I am writing to express my concerns regarding the protocols and timelines of the upcoming review. My expertise is in the area of plant physiological ecology and the responses of native plants to ozone exposure.

The CASAC is tasked with providing expert advice to the EPA Administrator concerning developments in scientific research since the last 5-year review. This involves reviewing thousands of peer-reviewed papers covering a broad range of topics, from public health issues such as chronic respiratory problems, epidemiological studies of populations at risk, and cardio-vascular responses, to secondary welfare issues such as plant and ecosystem responses to ozone exposure. Elimination of the advisory panel to the CASAC puts an undue burden on the 7-members of the CASAC, who have neither the breadth nor depth to assimilate fully this vast literature.

The lack of transparency in the formation of CASAC is troubling, while the constitution of its members seems to accommodate a double standard: those who have accepted funding from industry can serve on the CASAC, whereas academic researchers who have funding from the EPA cannot. Eliminating the expert advice from this latter group diminishes the ability of CASAC to perform its job adequately and reduces trust by the public in the standard setting process.

The self-imposed timelines established for completing the new review process appear arbitrary and are too short. Combining the REA and PA processes results in a conflation of science and policy that compromises the review process and falls far short of the quality and thoroughness required by the Clean Air Act and its Amendments. Failure to allow for revisions of the ISA is without merit and may not allow for the level of scientific rigor that the public expects. In a cascade of failure, this would constrain development of appropriate risk assessments, which, in turn, would limit the ability of OAQPS to develop an acceptable PA. The procedures used in the last assessment, which allow adequate time for revisions, separate timelines for the REA and PA documents, and abundant opportunities for public comment,

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worked well. Any potential benefit from changing the timelines and the review process, simply to accommodate an arbitrary goal of timeliness, will not outweigh the diminishment in the quality of the NAAQS review process by the EPA.

The scientific quality and credibility of the public health and secondary welfare goals are too valuable to risk for the mere sake of efficiency. Under the proposed rule changes, it is not clear that the CASAC will be able to provide advice to the current EPA Administrator of the appropriate quality that meets the requirements of the CAA calling for a thorough review of the latest scientific knowledge. As a result, it runs the risk of losing its integrity and the trust of the public with regard to protecting their health and that of the environment around them.

Sincerely,

/signed/

Dr. Howard S. Neufeld, Professor and
Chair, AppalAIR (Appalachian Atmospheric Interdisciplinary Research Group)

ED_002496_00002249-00073

James S. Ultman
Professor Emeritus, Departments of Chemical Engineering and Biomedical Engineering
Pennsylvania State University
University Park, PA

CASAC Ozone Review Panel: Member 2005-2008, 2009-2015
CASAC Oxides of Nitrogen Review Panel: Member 2007-2009
CASAC Sulfur Oxides Review Panel: Member 2007-2009, 2013-2018

With expertise in the dose distribution of inhaled reactive gases into the respiratory track, I was appointed to five CASAC review panels (RP) over the past ten years. In addition to providing scientific input, I have been able to observe and contribute to the refinement of the various stages of the overall NAAQS review process (i.e. the Integrated Research Plan → Integrated Science Assessment → Risk & Exposure Assessment → Policy Assessment).

The October 10, 2018 decision by EPA Acting Administrator Andrew Wheeler not to form an RP for the current ozone NAAQS review is an effort to shorten this process. In that case, a complete scientific review of the ozone standard is the sole responsibility of the seven member chartered CASAC rather than the larger and more technically multifaceted RP in addition to the CASAC. I am convinced this attempted streamlining of the ozone review will result in a less thorough evaluation of the current scientific literature and therefore a less reliable health risk analysis underpinning the policy assessment.

This decision by the Acting Administrator overlooks the value added by an RP, not only because of its technical diversity, but also by the unique interactions between its members. Several areas of importance in the NAAQS review of ozone (as well as other air pollutants) have and continue to be strengthened by discussions among the RP members. How to account for background ozone concentrations, what groups of individuals constitute susceptible populations, and what criteria should be applied to conclude causal effects of ozone exposure are reoccurring themes during RP discussions. These deliberations provide a firm foundation for the final decisions of the chartered CASAC members.

Another concern I have is the change in direction suggested in the May 9 memorandum by then Administrator Scott Pruitt regarding a "Back to Basics Process for Reviewing National Ambient Air Quality Standards." This memo calls for streamlining the review process by combining documents, possibly creating an ISA-REA-PA hybrid in place of the serial review of the three documents as has been done in the past. What is not fully appreciated by this suggestion is that the conclusions reached in each document serve as the necessary input for the next document in the chain. The ISA establishes the health criteria for the review, the REA establishes the science for quantifying risk, and the PA applies the policy-relevant science from the ISA and REA in formulating policy recommendations for consideration by the Administrator. It is impractical to achieve a sound review by linking the three steps in one document.

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I am troubled by several aspects of the IRP for the current review of the ozone standard. First, for the reasons give above, I am highly skeptical of the plan to combine the REA with the PA documents. The IRP also restricts the review of the ISA to a single draft only. In my experience from reviewing ozone, nitric oxide and sulfur oxide standards, a second draft of the ISA is almost always necessary. Given the complexity of the document and the limited timeframe that EPA staff often has to adequately address all aspects of a complete scientific assessment, restriction to a single draft of an ISA is not reasonable. Whether or not a second draft is needed should be determined by CASAC after reviewing the first draft.

Over these past 10 years I have seen valuable refinements in the organization of the ISA. This has resulted in a more-or-less standardized format consisting of initial chapters that summarize the aims of the scientific review, the history of previous reviews, and highlights of the current review analyses. This introductory material written for a less technical audience is followed by separate detailed chapters regarding each scientific element (e.g. atmospheric chemistry→exposure & dosimetry→animal & human experiments→statistical population studies). The current IRP proposes a less comprehensive ISA that includes only summaries in the main body of the text. The details of the scientific literature review and analyses would be relegated to appendices. Such an approach can obscure many important details and limitations considered in reaching final conclusions and recommendations.

I am in favor of streamlining the review process. However, compressing the content of the ISA, combining the REA with the PA document, and limiting refined drafts of the documents will degrade the soundness of the final recommendations of CASAC to the EPA Administrator. Similarly, I oppose the elimination of the RP whose deliberations are an important, time-tested complement to the deliberations of the chartered CASAC. In light of these observations, I make the following recommendations:

1) The IRP for the current ozone NAAQS review be modified to allow separate reviews of the ISA, REA and PA including the possibility of more than one draft when deemed necessary by CASAC. The final IRP should also allow for the creation of a RP panel to work in conjunction with the chartered CASAC.

2) EPA should form a working group of administrative and scientific staff to systematically identify the financial and procedural bottlenecks in the current review process for all pollutants, and how they can be overcome. Consideration should be given to the participation of EPA as well as CASAC in this process. The deliberations of this working group should be open and transparent as was the case for the 2006 process previously used by EPA to seek input and ideas on ways for streaming the NAAQS review process.

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Appointment

From: Rakosnik, Delaney [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=274573739A9F446883072599086EDEDD-RAKOSNIK, D]
Sent: 7/2/2018 1:46:41 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]

Subject: Pre discussion re: Follow-up call with CASAC chair Dr. Tony Cox
Location: WJC - N 5400

Start: 7/2/2018 4:15:00 PM
End: 7/2/2018 4:30:00 PM
Show Time As: Tentative

Message

From: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
Sent: 8/14/2018 12:12:49 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
Subject: Fwd: CASAC & SAB Chairs in DC next Tuesday - meeting opportunity

FYI

Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

Begin forwarded message:

From: "Brennan, Thomas" <Brennan.Thomas@epa.gov>
Date: August 14, 2018 at 7:50:33 AM EDT
To: "Ross, David" <Ross.David@epa.gov>, "Wehrum, Bill" <Wehrum.Bill@epa.gov>, "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>, "Yamada, Richard (Yujiro)" <yamada.richard@epa.gov>
Cc: "Johnston, Khanna" <Johnston.Khanna@epa.gov>, "Carpenter, Thomas" <Carpenter.Thomas@epa.gov>, "Yeow, Aaron" <Yeow.Aaron@epa.gov>
Subject: CASAC & SAB Chairs in DC next Tuesday - meeting opportunity

Hello OW, OAR, and ORD teammates,

The Acting Administrator is meeting with our Chairs Drs. Cox and Honeycutt on Tuesday 8/21 in the morning. This is a good opportunity for you to meet with them in the afternoon before the travel home.

I will begin to get on your schedules later this week. I will be inviting just those on this e-mail in case you prefer a small meeting. However, please feel free to share the coming invitation with anyone in your Offices that you feel will add value to the discussions.

Per FACA rules, there will be at least one person from the SABSO joining in the meetings. Likely a combo of me and the committee DFOs depending on how the timing works out.

Please feel free to share with me any topics you would like the Chairs to prep for in advance of the meetings. Otherwise we can treat as a quick meet and greet.

Looking forward to the meetings.

Best regards,

Tom

Sent from my iPhone

Message

From: Dunlap, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591EB15A268249DDA0C05A7451F765C3-DUNLAP, DAV]
Sent: 10/16/2018 1:02:43 AM
To: Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]
CC: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: Fwd: Transmittal of draft PM ISA for CASAC review
Attachments: Transmittal of draft PM ISA to CASAC unsigned 10-15-18.docx; ATT00001.htm; README First -HERONet access.docx; ATT00002.htm

Jennifer,

I'm the new guy, so I apologize in advanc **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

DDD

Sent from my iPhone

Begin forwarded message:

From: "Vandenberg, John" <Vandenberg.John@epa.gov>
Date: October 15, 2018 at 1:19:18 PM EDT
To: "Yeow, Aaron" <Yeow.Aaron@epa.gov>
Cc: "Bahadori, Tina" <Bahadori.Tina@epa.gov>, "Brennan, Thomas" <Brennan.Thomas@epa.gov>, "Buckley, Barbara" <Buckley.Barbara@epa.gov>, "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Dunlap, David" <dunlap.david@epa.gov>, "Dutton, Steven" <Dutton.Steven@epa.gov>, "Greaver, Tara" <Greaver.Tara@epa.gov>, "Hagerthey, Scot" <Hagerthey.Scot@epa.gov>, "Jarabek, Annie" <Jarabek.Annie@epa.gov>, "Jenkins, Scott" <Jenkins.Scott@epa.gov>, "Jones, Samantha" <Jones.Samantha@epa.gov>, "Jones, Ryan" <Jones.Ryan@epa.gov>, "Johnston, Khanna" <Johnston.Khanna@epa.gov>, "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>, "Robbins, Chris" <Robbins.Chris@epa.gov>, "Rodan, Bruce" <rodan.bruce@epa.gov>, "Ross, Mary" <Ross.Mary@epa.gov>, "Sacks, Jason" <Sacks.Jason@epa.gov>, "Sasser, Erika" <Sasser.Erika@epa.gov>, "Vette, Alan" <Vette.Alan@epa.gov>, "Wayland, Robertj" <Wayland.Robertj@epa.gov>, "Wesson, Karen" <Wesson.Karen@epa.gov>, "Johnson, Aaron" <Johnson.AaronK@epa.gov>, "Johnson, Maureen" <Johnson.Maureen@epa.gov>
Subject: Transmittal of draft PM ISA for CASAC review

Aaron,

Please see the attached memorandum transmitting the draft PM ISA to you as DFO, and the instructions for HERONet access.
I have provided a draft Charge for the PM ISA review to you in a separate email, for review by the CASAC Chair, Tony Cox.
Please let me know if you have any questions.
Thank you

John

John Vandenberg, PhD

Director, Research Triangle Park Division
National Center for Environmental Assessment/ORD
U.S. Environmental Protection Agency/B243-01
Research Triangle Park, NC 27711
(919) 541-4527

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

October 15, 2018

MEMORANDUM

SUBJECT: HERO access for review of the draft PM ISA

FROM: John Vandenberg, Ph.D. /s/
Director
National Center for Environmental Assessment
Research Triangle Park Division (B243-01)

TO: Clean Air Scientific Advisory Committee via
Aaron Yeow, M.P.H.
Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office (1400R)

To facilitate CASAC review of the draft PM ISA, the PDF available for review has hotlinks to HERONet, the database which provides access to full scientific articles (cited in the ISA), through a HERONet account. HERO is the Health and Environmental Research Online Database System.

For CASAC members, after they have a HERONet account, and if there is any difficulty accessing HERO, please contact [HYPERLINK "mailto:hero@epa.gov.%20"]

Below please find an instruction sheet for gaining access to HERO. The links available are:
[HYPERLINK "https://hero.epa.gov/heronet"] (Access through the EPA Portal, provides full access to articles)
[HYPERLINK "https://hero.epa.gov/hero"] (public side of HERO, does not include links to downloadable PDFs that are copyright protected)

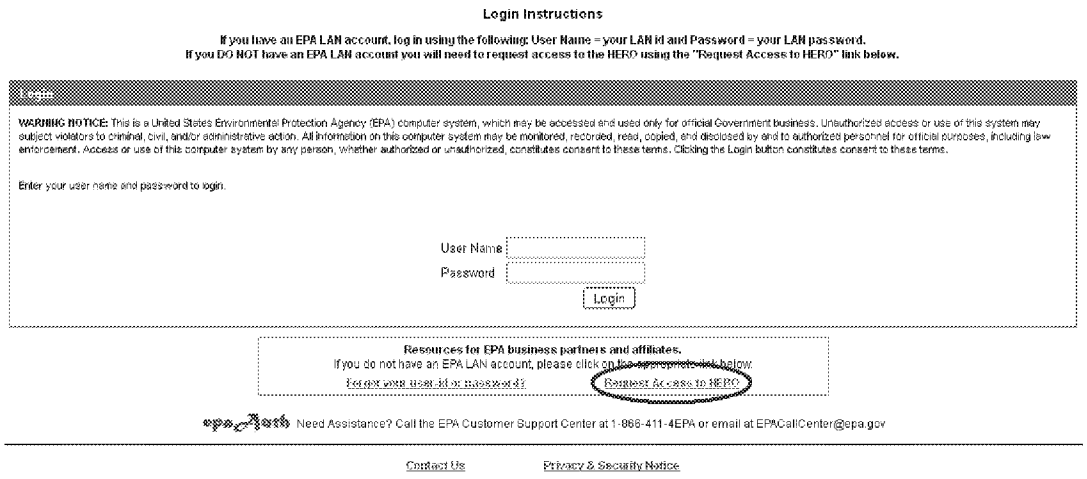
CASAC members:

You will need access to the HERONet community within the EPA Portal to support your review of the draft PM ISA.

Your access will be limited to activity relevant to your review in order to comply with applicable copyright law:

> *Please note that copyright law (Title 17 U.S. Code) governs the making of reproductions of copyrighted material. Section 107 of the copyright act instructs that "the fair use of a copyrighted work for purposes such as ... research is not an infringement of copyright." You are liable for any infringement.*

When you click on a linked reference in the PDF of the ISA, you will see this screen:



If you already have a HERONet account, you will just sign in, and continue on the HERO database.

If you do not already have an EPA Portal account (and access to the HERONet Community), you will need to click on the "Request Access to HERO" link (circled in red in the above figure).

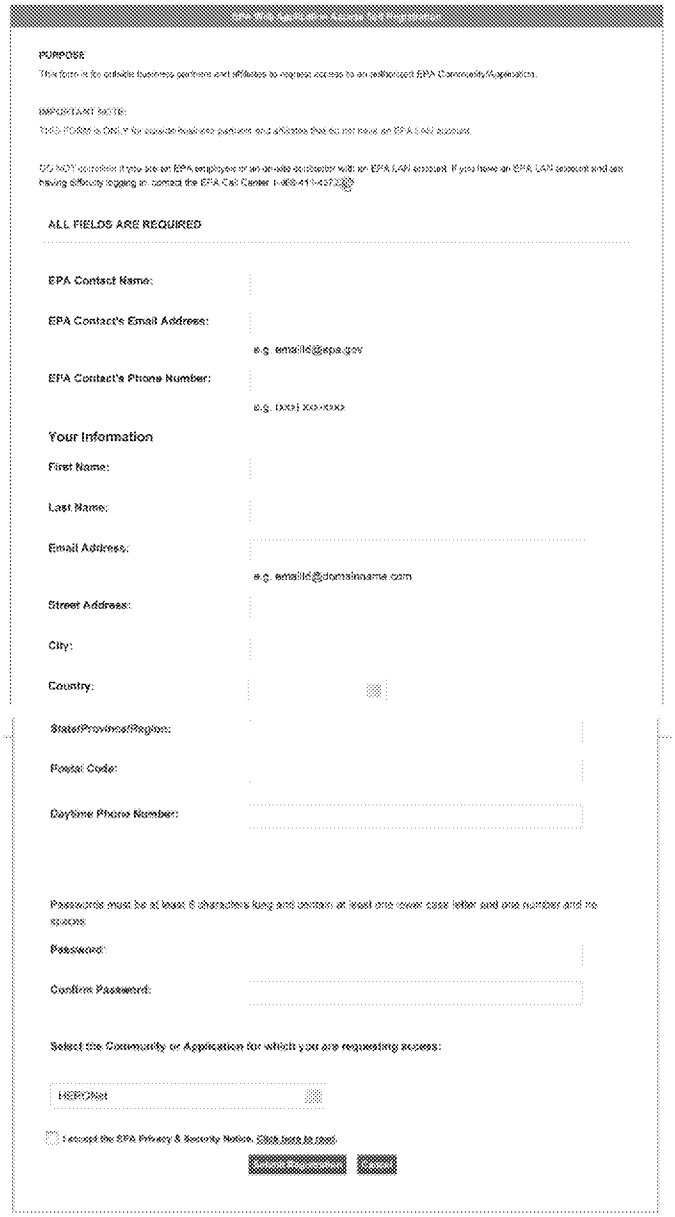
Some reviewers may already have a Portal account. If you do, but cannot remember the password, click on the 'Forgot your user id or password' link.

If you have never had access to the HERONet community, you will see this screen after you click the "Request Access to HERO" link. Fill out the form.

Use Ryan Jones as your EPA Contact Name ([HYPERLINK "mailto:jones.ryan@epa.gov"]) Phone: 919-541-

9415; his alternate is

Shane Thacker at 919-541-5159.



On this screen you'll be asked for identifying information, to select a password, and which community you intend to access. Select 'HERONet' from the community drop-down menu list (the menu drop down list is almost at the bottom of the form), then click on the "Submit Registration" box.

Once you are approved for access to HERONet, we will process your request and you will be able to access HERO. Please note that you will receive immediate email notification once you've gained access to the EPA Portal, but may not be able to access HERO for several hours after that notification.

Access to HERO will be limited to the current review you are conducting and will be deactivated upon completion of the review. Your Portal account, however, remains active and you will receive requests to update your password every six months. If you do not update your password with each request, your Portal account will eventually also be deactivated.

Please let us know if you have any questions by contacting [HYPERLINK "mailto:hero@epa.gov"].

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT
RESEARCH TRIANGLE PARK, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

October 15, 2018

MEMORANDUM

SUBJECT: Transmittal of the External Review Draft Integrated Science Assessment for Particulate Matter to the Clean Air Scientific Advisory Committee

FROM: John Vandenberg, Ph.D. /s/
Director
National Center for Environmental Assessment
Research Triangle Park Division (B243-01)

TO: Aaron Yeow, M.P.H.
Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office (1400R)

The External Review Draft *Integrated Science Assessment for Particulate Matter* (hereafter referred to as the draft PM ISA) prepared by the U.S. Environmental Protection Agency's (U.S. EPA) National Center for Environmental Assessment – Research Triangle Park Division (NCEA-RTP) as part of EPA's ongoing review of the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards for particulate matter is being released for public comment on October 15, 2018. By this memorandum I am transmitting the draft ISA to you to convey it to the Clean Air Scientific Advisory Committee (CASAC) for peer review.

The draft PM ISA is available in electronic form for download at [HYPERLINK "http://cfint.rtpnc.epa.gov/ncea/prod/recordisplay.cfm?deid=341593"]

The Health and Environmental Research Online (HERO) database provides transparency and access to the scientific literature that serves as the foundation for the draft PM ISA. Because some publications are copyrighted, those studies cannot be made available to the public by EPA. To facilitate CASAC review of all scientific literature we provide access to HERONet. Attached to this memorandum are instructions for the CASAC members to register and have access to HERONet.

We look forward to the peer review of the draft PM ISA by CASAC. Should you have any questions regarding the draft PM ISA, please feel free to contact Dr. Tara Greaver (919-541-2435, [HYPERLINK "mailto:greaver.tara@epa.gov"]) or Mr. Jason Sacks (919-541-9729, [HYPERLINK "mailto:sacks.jason@epa.gov"]).

Attachment

cc: Tina Bahadori, ORD/NCEA
Tom Brennan, SAB
Barbara Buckley, ORD/NCEA
Lou D'Amico, ORD/IOAA
David Dunlap, ORD/IOAA
Steven Dutton, ORD/NCEA

ED_002496_00003180-00001

Tara Greaver, ORD/NCEA
Scot Hagerthey, ORD/NCEA
Annie Jarabek, ORD/NCEA
Scott Jenkins, OAR/OAQPS
Maureen Johnson, ORD/NCEA
Khanna Johnston, SAB
Ryan Jones, ORD/NCEA
Samantha Jones, ORD/NCEA
Jennifer Orme-Zavaleta, ORD/IOAA
Chris Robbins, ORD/IOAA
Bruce Rodan, ORD/IOAA
Mary Ross, ORD/NCEA
Jason Sacks, ORD/NCEA
Erika Sasser, OAR/OAQPS
Alan Vette, ORD/A-E
Bob Wayland, OAR/OAQPS
Karen Wesson, OAR/OAQPS

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Message

From: Shoaff, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC16FB09CF2C44ADB34A7405DC331532-JSHOAFF]
Sent: 9/20/2018 6:54:06 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Subject: SAB RTR letter
Attachments: EPA-SAB-18-003 .pdf

Clint,

Here's the most recent letter I mentioned. It was assigned to OAQPS in CMS and Leif's reaching out to them (Kelly R) to learn more on timing and to loop you in so responses are coordinated. Thx.

John

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C. 20460

September 13, 2018

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-18-003

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Review of EPA's draft technical report entitled *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*

Dear Acting Administrator Wheeler:

The Science Advisory Board was asked by EPA's Office of Air Quality Planning and Standards to review the EPA draft document titled, *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis* (May 2017). The draft RTR methods document describes the EPA's methods for conducting initial risk screening analyses in the Clean Air Act mandated assessment of "residual risk", i.e., the risks remaining after application of maximum achievable control technology pursuant to the National Emission Standards for Hazardous Air Pollutants under Title I of the Clean Air Act.

The SAB Risk and Technology Review Methods Review Panel deliberated on the charge questions specific to the Agency's draft RTR methods document during a June 29-30, 2017, face-to-face meeting and discussed the SAB panel's draft report in a subsequent conference call on December 5, 2017. The charge questions focused on eight topics within the Agency's draft RTR methods document, including: a three-tiered multipathway screening approach used in the RTR screening analyses; a risk equivalency factor methodology; fishing, lake and pond assumptions; lake data, plume rise, and meteorological data; a gardener scenario; environmental risk screening methodology; inhalation risk assessment enhancements; and the census block receptor check tool. The enclosed report provides the SAB's consensus advice and recommendations in response to the charge questions. This letter briefly conveys the major findings.

The SAB commends the EPA on the technical quality of the draft RTR document and the effort it has put into developing the residual risk screening methodology. The SAB finds that the overall methodology and specifically the revisions since 2009 are for the most part appropriate and improve the assessment capabilities; opportunities for improvement are documented in the SAB's report. The SAB concludes that the EPA's approach has the potential to achieve the Agency's goal to rapidly and effectively screen facilities, and to focus EPA time and resources on sites of most concern from a public health point of view.

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Insufficient detail was provided in the Agency's draft RTR methods document for the SAB to assess the overall operational effectiveness of the screening methodology such as how many facilities are screened out by each of the three tiers. Some data were provided later by the EPA that did help the SAB to understand the screening efficacy. The SAB recommends the EPA compile summaries of RTR analyses applied in regulatory activities for inclusion in future RTR methodology report documents. Furthermore, in future screening analyses the EPA should compare, for specific facilities, the screening model output to field data where available. These "ground truthing" studies should be included in the next RTR methods document and provided to future reviewers for consideration.

Concerning the lifetime average daily dose (LADD) estimates when calculating exposure equivalency factors, EPA's empirical correlation is a logical step in creating the read-across approach used by the Agency. However, the read-across approach for environmental fate is less well-tested and accepted and thus deserves further consideration[1]. The SAB notes that this read-across extrapolation of environmental fate could be refined and has identified two options for the EPA to consider for improving the LADD estimates.

The SAB finds that the inclusion of the domestic gardener scenario is appropriate, though an evaluation of how many people this applies to should be conducted to determine the efficacy of the addition. The accuracy of dispersion and deposition results from the TRIM.FaTE model should be evaluated by comparing them with the results from a more technically robust dispersion model, such as AERMOD. In addition, while incorporation of turbulence in determining urban/rural selection in dispersion modeling is appropriate, the SAB recommends a different approach suggesting a more physically-based model such as AERMOD and the use of meteorological reanalysis data for both surface-air and upper-air wind speeds. Finally, the SAB finds that the EPA's reliance on census-block centroid locations as surrogates for where people live might not always be sufficient to ensure that receptors are representative of residential areas near facilities, and thus the SAB recommends that additional, reproducible methods should be evaluated.

The SAB recommends the EPA explore a transition for its screening methodology from using single-point estimates of uncertain input values to using distributions for these values. Probabilistic analyses combining the effects of distributions of multiple input values would result in a coherent analysis from which arithmetic means and "conservative fractiles" (e.g., a 90th percentile) could be derived. While in the interim sensitivity analyses on uncertain input values could be performed, the shift to a probabilistic analysis framework would provide a more robust foundation for the screening methodology in higher tiers.

[1] Physicochemical, human health and/or environmental properties may be predicted from information from tests conducted on reference substance(s) within the group, referred to as source substance(s), by interpolation to other substances in the group, referred to as target substance(s). This approach is called "read-across." (https://echa.europa.eu/documents/10162/13628/raaf_en.pdf)

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In summary, the SAB supports the framework and direction of refinements EPA has been making to the screening methodology for the residual risk portion of RTR analyses. The SAB appreciates the opportunity to provide the EPA with advice on this important subject. We look forward to receiving the EPA's response.

Sincerely,

/Signed/

Dr. Michael Honeycutt, Chair
Science Advisory Board

/Signed/

Dr. Jay Turner, Chair
Risk and Technology Review Methods Review Panel

Enclosure

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NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to the 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 Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. Reports of the EPA Science Advisory Board are posted on the EPA website at http://www.epa.gov/sab.

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Acronyms and Abbreviations

AERMOD	AMS/EPA Regulatory [Dispersion] Model
AMS	American Meteorological Society
ATSDR	Agency for Toxic Substances and Disease Registry minimum risk levels
AEGL	Acute Exposure Guidelines Limits
ANPRM	Advanced Notice of Proposed Rulemaking
BaP	benzo(a)pyrene
CalEPA	California Environmental Protection Agency
EEF	exposure equivalency factor
ERA	Ecological Risk Assessment
ERPG	Emergency Response Planning Guidelines
HAP	Hazardous Air Pollutant
K_{ow}	the *n*-octanol/water partition coefficient
IRIS	Integrated Risk Assessment System
LADD	lifetime average daily dose
MACT	Maximum Achievable Control Technology
MTBE	Methyl Tertiary Butyl Ether
NATA	National Air Toxics Assessment
NEI	National Emissions Inventory
NESHAP	National Emission Standard for Hazardous Air Pollutants
NHANES	National Health and Nutrition Examination Survey
NIOSH	National Institute of Occupational Safety and Health
NIST	National Institute of Standards and Testing
NPRM	Notice of Proposed Rulemaking
NWS	National Weather Service
OAQPS	Office of Air Quality Planning and Standards
OPP	Office of Pesticide Programs
OSHA	Occupational Safety and Health Administration
OEHHA	Office of Environmental Health Hazard Assessment
PAH	Polycyclic Aromatic Hydrocarbon
PB-HAP	Persistent Bioaccumulative - Hazardous Air Pollutant
POM	Polycyclic Organic Matter
REF	risk equivalency factor
RTR	Risk and Technology Review
SAB	Science Advisory Board
TEF	toxicity equivalency factor
TEQ	Toxic Equivalents
TRIM.FaTE	Total Risk Integrated Methodology - Fate, Transport and Ecological Exposure
UCL	Upper Confidence Limit
USDA	US Department of Agriculture
USGS	US Geological Survey

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1. EXECUTIVE SUMMARY

This report was prepared by the U.S. EPA Science Advisory Board (SAB.) The Board convened the Risk and Technology Review (RTR) Methods Review Panel for initial deliberations in response to a request by EPA's Office of Air Quality Planning and Standards (OAQPS) to review their draft document entitled, "*Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*" (U.S. EPA 2017). This document (hereinafter referred to as the "Agency's draft RTR methods document") describes portions of the methods used to assess "residual risk" i.e., the potential risks remaining after application of maximum achievable control technology (MACT) pursuant to the National Emission Standards for Hazardous Air Pollutants (NESHAP) regulations.

Screening methodologies are used to quickly identify those facilities in a source category that have little potential for human health multipathway or environmental risk, while also identifying those facilities where a refined multipathway or environmental risk assessment may be needed. The Agency's draft RTR methods document describes several improvements to the screening methods.

The SAB reviewed the draft RTR methods document as requested by considering eight charge questions posed by the EPA (See Appendix A). The SAB provides comments on the RTR screening methods and does not address the regulatory implications of the methods or the document. The SAB also notes that no methods were submitted for review regarding the technology portion of the RTR analysis called for by the NESHAP regulations, nor were charge questions posed regarding the technology review methods to be applied by the EPA.

The SAB RTR Methods Review Panel deliberated on responses to the charge questions specific to the Agency's draft RTR methods document during a face-to-face meeting on June 29-30, 2017, and discussed its draft report in a subsequent conference call on December 5, 2017. The Chartered SAB conducted a quality review of this document on May 31, 2018. The charge questions focused on eight topics within the Agency's draft RTR methods document, including: *the three-tiered multipathway screening approach used in the RTR analyses; the risk equivalency factor methodology; fishing, lake and pond assumptions; lake data, plume rise, and meteorological data; the gardener scenario; environmental risk screening methodology; inhalation risk assessment enhancements; and the census block receptor check tool.*

This Executive Summary highlights the SAB's major findings and recommendations. The SAB commends the EPA on the technical quality of the draft RTR methods document and the thought and effort it has put into developing the residual risk screening methodology. The SAB finds that the overall methodology and specifically the revisions since 2009, are reasonable and should improve the EPA's assessment capabilities. The comments and recommendations offered below are intended to assist EPA staff as they seek to improve their RTR assessments going forward and are not meant to detract from the screening and assessment efforts to date.

The SAB agrees that the three-tier multipathway risk screening approach, starting with health protective parameters and moving to more site-specific parameters in later tiers, is reasonable and logical. The SAB finds the expansion of the endpoints for the environmental risk screen is reasonable and the benchmarks and use of a tiered screening system are

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justified. Overall, the screening methodology has the potential to achieve the EPA's goal to quickly screen facilities, and to focus Agency time and resources on sites of most concern from a public health point of view.

The SAB recommends that future RTR methods documents be written for a primary audience envisioned as a risk assessor trying to reproduce the results of an EPA RTR risk assessment screening, rather than for the audience of peer reviewers.

The SAB finds summary information about overall performance of the methods and case studies to be missing from the report or inadequate for a comprehensive assessment of the methods described. For example, the SAB could not assess the overall operational effectiveness of the screening methods, such as how many facilities are screened out compared to those facilities passed on for more detailed analysis. The SAB very strongly recommends the EPA compile summaries of RTR analyses applied in regulatory activities and include the summaries in future RTR documents for review by the Board. In addition, analysis of the results by source category may indicate that some types of facilities screen out earlier than others and it may point out risk drivers, sensitive parameters and key features that could be refined to improve the screening analysis for particular source categories in the future.

In future screening analyses the EPA should compare, for specific facilities, the screening model output with field data, where available. For example, field measurement data on relevant persistent bioaccumulative hazardous air pollutants (PB-HAPs) in atmospheric deposition, soil, water, and fish could be used to validate key screening model outputs, especially in the Tier 3 evaluation. These "ground truth" studies must be included in the next RTR methods document and provided to future SAB reviewers for consideration.

Data quality considerations are important in RTR assessments. Experience has shown that significant errors can occur in RTR input data, which in turn, can skew risk results, sometimes by material, policy-relevant margins. Accurate input data are the bedrock foundation on which all RTR risk analyses build. The SAB recognizes EPA's past efforts to ensure RTR input data accuracy, and strongly supports and encourages such efforts. Building on the substantial efforts that EPA staff have already made, EPA could further develop and expand its affirmative efforts to ensure RTR input data accuracy. The possibility of such errors and their policy implications should continue to be considered when conducting RTR risk analyses and interpreting results.

The SAB recommends the EPA examine refinements to the tiered screening methodology by conducting sensitivity studies to identify the key input values that drive the risk estimates. EPA also should evaluate the use of probabilistic analyses to estimate more accurately the overall risks. In cases where these input values are uncertain but appropriate, distributions for these parameters could be constructed; probabilistic analysis would provide a more robust foundation for the screening methodology.

Regarding the risk equivalency factor (REF) calculation, the SAB supports the toxicity equivalency factor (TEF) read-across approach as it is well accepted for dioxins and carcinogenic polycyclic aromatic hydrocarbons (PAHs). For the exposure equivalency factor (EEF) estimate, the read-across approach, for environmental fate and transport, is not as well tested and thus deserves further consideration. EPA's empirical correlation between the *n*-octanol/water partition coefficient (K_{ow}) and lifetime average daily dose (LADD) for chemicals

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with sufficient data is a logical step in creating the read-across approach used by the EPA. However, K_{ow} is an imperfect predictor of LADD and incorporation of other factors (e.g., environmental persistence and molecular weight) may improve the estimates. The SAB finds this read-across extrapolation approach could be refined and has identified two options for the EPA to consider for improving the EEF estimates.

The SAB also finds the REF method would greatly benefit from better explanation, documentation and statistical analysis in terms of: (a) documentation of TEFs, including consideration of whether assigning a TEF for carcinogenic activity is appropriate for PAHs not currently identified as carcinogens; and (b) documentation of the methods for the EEF derivation.

The SAB is generally supportive of the assumptions used for human fishing behavior in the refined fishing scenario and offers several specific suggestions for improving the data used, the model versions used, and how to document studies used by the EPA for the data and modeling methods.

Tier 3 screening introduces refinements to the treatment of air pollutant dispersion and deposition. EPA should consider the use of plume-rise models other than those described in the Agency's draft RTR methods document and could test and demonstrate the reliability of plume rise adjustments. The accuracy of dispersion and deposition results from the TRIM.FaTE model should be evaluated by comparing them with the results from a more technically robust dispersion model, such as AERMOD. The SAB suggests EPA evaluate the selection of urban vs. rural terrain in the inhalation risk assessments by comparing TRIM.FaTE-derived screening results to those calculated by a more physically-based model such as the regularly updated AERMOD. For this and other air dispersion and transport modeling, the SAB recommends that EPA consider the use of meteorological reanalysis data for both surface-air and upper-air wind speeds.

The SAB agrees that the proposed gardener scenario is an appropriate addition to both Tier 2 and Tier 3 screening evaluation. However, it is important to distinguish between the gardener and the subsistence farmer. The gardener scenario improves the characterization of potential risk in both rural and urban environments for those who take part in this activity, however the SAB urges the EPA to gather data characterizing the population engaged in this activity and the primary exposure routes in order to evaluate the efficacy of this scenario.

The Agency should consult with colleagues across the EPA who have data and models for addressing parameters used in the screening analysis. For example, the SAB understands the Agency has data or models available for parameters such as lake outflow, chemical runoff and erosion.

The SAB found the methodology for identifying the pollutants to be included in the environmental risk screening activities are clearly stated and the criteria used to prioritize the chemicals are found to be appropriate. The SAB is concerned that selenium is not included as a chemical to screen and recommends that it be added in future RTR screening analyses.

The SAB agrees that characterizing the terrain as urban versus rural and incorporating the effects of turbulence as a dispersion modeling input is appropriate. This refinement has significant value because it avoids the overly conservative assumption of applying the "rural"

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assumption to all facilities. However, the SAB disagrees with the Agency's draft RTR methods document on the procedure of choice and recommends using a land use-based procedure utilizing national land cover data (NLCD).

The SAB finds that insufficient information was provided about the census block receptor check tool, especially regarding criteria used to determine the number and placement of new receptors. The SAB is concerned that the process would not be reproducible if another risk assessor were to subsequently model a facility. Overall, the SAB finds that, while the method's reliance on census block centroid locations may in some cases be sufficient for screening, care must be taken that receptors are well-placed to be representative of residential areas near the facilities. To facilitate tool transparency and results reproducibility, EPA could develop protocols to enable risk assessors to exercise their professional judgment in verifying the tool-based receptor placements and document the decision process for placement (e.g., using Google Earth imagery and preliminary risk calculations) so as to be reproducible by independent expert analysts.

In summary, the SAB supports the framework and direction of refinements EPA has been making to the screening methodology for the residual risk portion of RTR analyses. In many cases, the SAB supports the methodological details used by the EPA; and in other cases, the SAB recommends considering refinements or alternative approaches.

By the EPA's accounting, provided in response to inquiry by the SAB, for the five most recent RTR analyses conducted prior to June 2017, Tier 1 on average screened out 30% of the affected facilities, and the Tier 2 fisher and farmer scenarios on average screened out 60% and 70%, respectively, of the affected facilities. This demonstrates a commitment to effectively manage EPA resources and focus attention on the subset of facilities that are not deemed low-risk based on the screening analysis. However, insufficient information was provided in the RTR methodology report for the SAB to evaluate the overall efficacy of the EPA's methods. EPA's multi-tiered risk screening approach appears designed intending that: (a) high-risk facilities are not prematurely screened out (with adverse public health or environmental implications) and (b) low-risk facilities are not unnecessarily retained for more detailed analysis (with adverse EPA resource implications). The SAB strongly calls for data to be developed and presented in future method reports that indicate how many facilities may be screened out prematurely and how many may be passed on to a full-scale risk assessment that should have been screened out in the screening analysis.

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2. INTRODUCTION

EPA's Office of Air Quality Planning and Standards (OAQPS) requested that the Science Advisory Board (SAB) review the draft document, "*Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*" (U.S. EPA 2017). This document (hereinafter referred to as the "Agency's draft RTR methods document") describes the EPA's recent and proposed refinements to the screening methods for assessing "residual risk" i.e., the risks remaining after application of maximum achievable control technology (MACT) under Title I of the Clean Air Act (CAA).

The CAA establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAPs) from stationary sources. In the first stage, the CAA requires EPA to develop technology-based standards connected to MACT for categories of industrial sources. EPA must review each MACT standard at least every eight years and revise them as necessary. This is the technology review portion of RTR. In the second stage of the process, EPA is required to assess the health and environmental risks that remain after MACT has been applied. EPA must develop standards to address these remaining potential risks if necessary to protect the public health with an ample margin of safety or to prevent adverse environmental effects. This second stage of the RTR is known as the residual risk review and must be completed within eight years of promulgation of the initial MACT standards for each source category.

The EPA, in order to streamline and standardize the residual risk review for the large number of affected source categories, has developed a process by which it: (1) conducts a risk assessment using currently available source and emissions data; (2) requests public comment on the source and emissions data, along with preliminary risk assessment results, through an Advance Notice of Proposed Rule Making (ANPRM); (3) addresses comments received on the ANPRM; and (4) revises the risk assessment as needed. The results of the revised risk assessment are intended to support proposals and promulgation of technology- and risk-based regulatory decisions through a transparent, science based, notice-and-comment rulemaking process.

The Agency's draft RTR methods document describes revisions to the screening methods used when conducting the risk portion of Risk and Technology Review assessments. These assessments evaluate the effects of industrial HAPs emissions on public health and the environment. Screening methods are used to quickly identify, for a particular RTR source category, those facilities that have little potential for human health risk via multipathway exposure or little potential for environmental risk, while also identifying those facilities where a refined risk assessment may be needed.

Previous internal EPA and external peer review panels have reviewed aspects of the RTR methodology, as documented in the following reports:

1) The *Residual Risk Report to Congress* (U.S. EPA 1999), a document describing the EPA's overall analytical and policy approach to evaluating residual risk in the context of setting NESHAP standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methods were described in

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this report, although individual elements have been refined over the subsequent two decades.

2) Individual residual risk assessments – several internal peer reviews and one external peer review were conducted on risk assessments for individual source categories, including Coke Ovens (U.S. EPA 2018a), Perchloroethylene Dry Cleaning (U.S. EPA 2018b), and Halogenated Solvent Cleaners (downloadable from: U.S. EPA 2018c). Each of these assessments used emission estimates from the National Emissions Inventory (NEI), human exposure modeling at the census block level, dose-response methodologies, and risk characterization like those for the ongoing and planned RTR assessments.
3) The National Air Toxics Assessment, or NATA, for 1996 was peer-reviewed by the SAB in 2001-2002 (U.S. EPA SAB 2001). NATA 1996 was a comprehensive and cumulative risk assessment designed to include all mobile sources, small and large industrial sources, and background contributions to air toxics. Because of significant uncertainties, the SAB did not believe that it was appropriate for regulatory purposes. For example, the 1996 assessment had census block-level data resolution available, but the analysis was performed at the census tract level. This approach was refined in subsequent assessments.
4) The AMS/EPA Regulatory [Dispersion] Model (AERMOD), a source-to-receptor air quality dispersion model, was the subject of significant interagency cooperation and peer review. It is now EPA's preferred local-scale air dispersion model for industrial sources of air pollution (U.S. EPA 2018d).
5) The individual dose-response values used in RTR assessments have been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA; and the Agency for Toxic Substances and Disease Registry, or ATSDR). EPA proposes to select dose-response values for long-term exposures from these sources in the same priority order it used for NATA (i.e., IRIS, then ATSDR, then CalEPA). For acute exposure toxicity, EPA arrays several indices without prioritization; this is a source of potentially significant, yet usually unquantified, uncertainty. (IRIS - U.S. EPA 2018e, ATSDR - ATSDR 2018, CalEPA -CalEPA 2018)
6) An earlier peer review of multipathway risk assessment methodologies was conducted by the SAB in 2000 (U.S. EPA SAB 2000).
7) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by the SAB in 2006. The final SAB letter to Administrator Johnson transmitted the Board's comments (U.S. EPA SAB 2007).
8) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009 (U.S. EPA SAB 2010). This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing.

The focus of this review of the Agency's RTR methods document is on several updates and enhancements of the previous versions that were reviewed as documented above. The most important revisions and enhancements since the last SAB review include the following:

- a tiered multipathway screening methodology that determines whether the potential for multipathway human health risk from persistent and bioaccumulative HAP (PB-HAP) emitted from RTR source categories is low or whether more analysis is needed;

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- a tiered environmental screening methodology that determines whether the potential exists for adverse ecological effects from PB-HAP and the acid gases hydrogen chloride (HCl) and hydrogen fluoride (HF) emitted from RTR source categories;
- the potential addition to the screening methodology of a new multipathway exposure scenario to estimate ingestion risk for members of urban or rural households who consume contaminated homegrown fruits and vegetables; and
- enhancements to the previously reviewed inhalation risk screening methodology that allow more accurate modeling of air concentrations where populations reside and better characterization of air dispersion near sources.

The SAB was asked to review the current draft RTR methods document by considering eight charge questions posed by the EPA. The SAB provided comments on the RTR methods and did not address the regulatory implications of the method or the report. The SAB Risk and Technology Review (RTR) Methods Review Panel met in a public meeting on June 29 – 30, 2017 in Arlington, VA, to review the Agency's draft RTR method document. The SAB Panel held a subsequent teleconference on December 5, 2017, to discuss its draft advisory report. The Chartered SAB conducted a quality review of this report on May 31, 2018. The specific charge questions to the SAB are presented in the next chapter, along with the SAB's responses.

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3. RESPONSE TO INDIVIDUAL CHARGE QUESTIONS

3.1 The Three-Tiered Multipathway Screening Approach

Charge Question 1. Does the SAB find that the three-tiered multipathway risk screening approach appropriately eliminates from further consideration those facilities unlikely to emit PB-HAP in concentrations resulting in appreciable multipathway risk and identifies those facilities where additional multipathway analysis may be warranted? Does the SAB have specific suggestions for improvement of the risk screening methodology?

RTR risk assessments provide the basis for decision making on whether a more stringent standard is necessary to protect human health and the environment after implementation of a NESHAP for a specific source category. The risk assessment process is both time and resource intensive. Therefore, EPA first screens affected facilities to determine whether a full-scale facility-specific risk assessment is warranted. Since the 2009 SAB review of RTR methods, the EPA has developed a three-tiered multipathway screening approach that progressively replaces health-protective default assumptions with location and facility specific data. The goal is to "screen out" minimal risk facilities such that only potentially high-risk facilities remain in the pool for further analysis.

EPA's screening methodology for ingestion risks uses a multipathway, tiered approach. Models are used to simulate the transport and fate of HAPs emitted from specific facilities in the source category being assessed. Modeling outputs include estimates of contaminants in the environment and estimates of human health risks primarily from the ingestion of HAPs from food products such as vegetables, fruit, meat, and fish because the focus of this tiered screening is on persistent and bioaccumulative toxicants.

The SAB agrees that the three-tier multipathway risk screening approach, starting with generic health protective parameters and moving to more site-specific and realistic parameters in later tiers, is appropriate. Its general structure is consistent with a long history of EPA multi-tiered risk screening approaches designed with the intent that: (a) high-risk facilities are not prematurely screened out (with adverse public health or environmental implications) and (b) low-risk facilities are not unnecessarily retained for more detailed analysis (with adverse EPA resource implications). While the SAB finds the overall approach is appropriate and has the potential to achieve the EPA's goals, as noted below the overall effectiveness is not clear. EPA should evaluate the current effectiveness and refinements to improve effectiveness.

Based on the information presented in the draft RTR methods document, the effectiveness of the screening methodology could not be confirmed. The SAB strongly calls for data to be developed and presented in future method reports that indicate how many facilities may be screened out prematurely and how many may be passed on to a full-scale risk assessment that should have been screened out in the screening analysis.

Screening efficacy could be examined in two ways. First, the operational effectiveness could be evaluated by reviewing the number of facilities screened out by each tier. While this information was not provided in the Agency's draft RTR methods document, EPA

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subsequently reported that for the five most-recent RTR analyses conducted (at the time of the EPA's correspondence on November 9, 2017), Tier 1 on average screened out 30% of the affected facilities, and the Tier 2 fisher and farmer scenarios on average screened out 60% and 70%, respectively, of the affected facilities. More information included in the report would have been useful when assessing the appropriateness of modeling inputs and assumptions. An analysis of the tier-specific screening efficacy should be conducted for each source category (i.e., an examination of prior RTRs which used the current approach to screening) to assess whether some types of industrial facilities screen out earlier than others. This analysis may point out the risk drivers, sensitive parameters and key features that could be refined to conduct better screening analysis for particular source categories in going forward. Second, the best way to evaluate the three-tiered approach in a scientific manner is to "ground-truth" the evaluations, using monitoring data from either new sites or previously evaluated sites. This type of validation would require focused and deliberate study, yet it would represent an improvement in the understanding of screening procedures. For example, available monitoring data on PB-HAPs in atmospheric deposition, soil, water, and fish could be used to examine the effectiveness of higher-tiered screening and in particular to validate key points in the Tier 3 evaluation.

EPA's tiered approach is geared towards protecting the most highly exposed subpopulations – combined subsistence fishers and farmers and their children who also ingest soil. The first tier is intended to be quite health protective and SAB concurs that it is conservative. Page 15 of the Agency's draft RTR methods document highlights some of the more health-protective assumptions in the Tier 1 screening scenario. However, many assumptions are not transparent in the Agency's draft RTR methods document, making it impossible to assess if there are opportunities for refinement of those assumptions. For example, EPA should list the key assumptions used for the watershed characteristics that enhance chemical loading to the lake and farm via erosion and runoff e.g., it is not clear how the chemical is loaded into the lake and the assumptions for the volume of water transporting the chemical into the lake. This is a particularly relevant example because the scenario does not change across the tiers and there might be opportunities for refinements.

There is concern about the specific values selected for the modeling parameters, both individually and in combination. The use of multiple high-end health protective parameters can result in an excessive overestimate of potential risk. While each health-protective assumption on its own may seem reasonable, combining or overlaying multiple health protective assumptions can lead to more conservatism than is intended. An unintentionally high and unnecessary degree of conservatism likely renders the tiered risk screening ineffective, or at best inefficient. EPA should consider possible refinements to Tier 1 if the overestimation of risk is such that obviously low-risk sites are not screened out.

The SAB recommends the EPA examine refinements to the tiered screening methodology by conducting sensitivity studies to identify the key input values that drive the risk estimates. This could be used to refine Tier 1 if desired and is particularly relevant to Tiers 2 and 3. As one example, the EPA could conduct a sensitivity analysis on the impact of runoff assumptions on modeled human health risk and consider refining the health-protective Tier 1 runoff parameters as the screen moves to Tier 2 and to Tier 3. As the EPA conducts these evaluations, it should have the flexibility to adjust its methods and the parameters as needed

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to ensure health-protective yet efficient RTR screening occurs in future RTR screening analyses.

EPA should evaluate the use of probabilistic analyses, perhaps initially through case studies on Tiers 2 and 3 analyses, to more accurately estimate overall risks. As previously stated, sensitivity analyses can be used to identify key input values that drive the risk estimates. In cases where these input values are also uncertain, probabilistic analysis would provide a more robust foundation for the screening methodology. This would require assessing whether enough data are available to construct distributions for the input parameters. If so, then probabilistic analysis combining the effects of distributions of multiple input values would result in a coherent analysis from which arithmetic means and operationally-defined "conservative fractiles" (e.g. a 90th percentile) could be derived.

Overarching data quality considerations are important in RTR assessments. Errors can occur in RTR input data which in turn can skew risk results, sometimes by material, policy-relevant margins. Data errors can be caused by such factors as reporting mistakes by individual facilities and undetected, incorrect information in publicly-available national, regional, and local emission inventories. The SAB recognizes the fundamental importance of accurate input data as a bedrock foundation on which all RTR risk analyses build. The SAB recognizes EPA's past efforts to ensure RTR input data accuracy, and strongly supports and encourages such efforts. Building on the substantial efforts that EPA staff have already made, EPA could further develop and expand its affirmative efforts to ensure RTR input data accuracy. Possible approaches to reducing such errors were discussed during the panel's public deliberations and are documented in the public records of the meetings available on the EPA website (EPA 2018f). The possibility of such errors and their policy implications should continue to be considered when conducting RTR risk analyses and interpreting results.

Additional comments and recommendations are as follows.

- If EPA seeks to further refine the Tier 1 screening of low-risk facilities, it might reconsider the current approach of combining exposures for farming and fishing on top of other conservative assumptions regarding weather conditions, deposition and runoff. It is unlikely that the same person consumes <u>all</u> food categories from media located close to the facility and these media receive the conservative-estimate high-end chemical loading rates day after day.
- Although there are refinements to the air modeling at Tiers 2 and 3, there is no comparable refinement of chemical runoff and erosion from the watershed. EPA does not provide any information on parameters and assumptions made (including the pond scenario) and thus the SAB cannot provide detailed comments on potential refinements to these models.
- TRIM.FaTE (U.S. EPA 2002) is used to model air dispersion. EPA should indicate if this model has been updated since 2002, and why EPA chose this model over AERMOD, which has been continuously improved and updated many times over the years (as recently as January 2017). It may be useful for EPA to compare estimates based on TRIM.FaTE and AERMOD for a range of representative scenarios.
- As discussed in more detail in the response to Charge Question 3, there is a complicated reasoning underlying the Tier 2 sustainable fishing scenario. Perhaps

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EPA found it necessary to introduce such details at Tier 2 to be able to screen out low-risk facilities. For the purposes of Tier 2, however, it seems that simpler worst-case assumptions could be made that simplify the approach. The SAB recommends the EPA consider other data available to make more realistic assumptions, such as the most recent National Health and Nutrition Examination Survey (NHANES CDC 2018.), to estimate fish consumption.

- Many of the pathways are related to those used by the EPA Office of Pesticide Programs (OPP), which are based on U. S. Department of Agriculture (USDA) Cropland Data Layer and more recent (2005-2010) NHANES dietary consumption data. These could be used to inform EPA's RTR screening approaches[2]
- Regarding some of the individual parameters, from the documentation provided it wasn't clear whether the breastfeeding exposure or other early life pathways would adequately cover these sensitive early life stages. The potential impact of seasonal changes in food-sourcing should also be considered although it was recognized that fishing and gardening/farming can be year-round activities in certain parts of the country.
- The focus only on cancer risk for dioxins and benzo[a]pyrene may underestimate early life (e.g., breastfeeding) risks given these are short-term exposures whose lifetime average daily dose (LADD) will be diluted by the rest of the lifetime at lower exposure. Table 3.2 indicates that non-cancer endpoints are "not critical" for these chemical classes; this is a pre-judgement that should be further explored, especially for early life exposures. The SAB notes that benzo[a]pyrene has a very recent RfD on IRIS that is based upon an early life developmental effect (U.S. EPA 2018g).
- Several polycyclic aromatic hydrocarbons (PAHs) with toxicity equivalency factors (TEF) are not generally considered carcinogens (e.g., pyrene, phenanthrene, fluorene, fluoranthene, and acenaphthalene). These compounds do not appear on the lists of relative potency factors used by EPA (U.S. EPA, 1993) nor are they presented in lists published elsewhere (e.g., Nisbet and Lagoy 1992). These early 1990s references are still relevant as demonstrated by EPA's 2017 IRIS toxicological review for benzo(a)pyrene which refers to the EPA's 1993 guidance as the source of PAH relative potency factors (U.S. EPA 2018h). In addition, the PAHs in question are not listed as carcinogenic by the International Agency for Research on Cancer (IARC) or the National Toxicology Program (NTP) of the U.S. Department of Health and Human Services. The TEF approach for pyrene, phenanthrene, fluorene, fluoranthene, acenaphthalene and several other PAHs should be reconsidered.
- The draft RTR methods document should be modified to be more explicit about the decision-making on transitioning from Tier 1 to Tier 2, and from Tier 2 to Tier 3, particularly with regards to evaluating the potential risks associated with multiple chemicals and combining hazard quotients and risks. In addition, the basis for the inclusion and exclusion of particular chemicals, for example lead, should be more clearly stated.
- Page 16 of the draft RTR methods document indicates that "dermal absorption of originally airborne chemicals similarly has been shown to be a relatively minor

[2] https://websoilsurvey.sc.egov.usda.gov/App/HomePage.htm; https://www.agcensus.usda.gov/Publications/2012/Online_Resources/Ag_Atlas_Maps/; https://www.epa.gov/sites/production/files/2015-09/documents/deem-user-guide-sep30-14.pdf); https://www.epa.gov/sites/production/files/2016-05/documents/public_webinar_overview_of_the_draft_bes_final.pdf

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exposure pathway compared with other pathways" and cites one report from 2000 and another from 2006, to support the statement. The EPA should investigate whether the evidence still supports that conclusion and applies to all classes of chemicals. More recently, several studies have suggested that dermal absorption of certain classes of chemicals in indoor air can contribute significantly to a person's overall dose (Weschler and Nazaroff, 2012, 2014; Morrison et al., 2016).

- The SAB supports the EPA's decision to separate subsistence farmers and subsistence fishers in Tier 2.
- The SAB notes that by conducting the analysis on a chemical-by-chemical basis, limited by law to the industrial category under RTR evaluation, multiple sources of a chemical emitted nearby from other industrial source categories may contribute to cumulative effects and chemical interactions because of multiple exposures. The cumulative risk may be missed by the human health risk screening conducted following the RTR method being reviewed.

3.2 Risk Equivalency Factor Methodology

Charge Question 2. Does the SAB find that the risk equivalency factor methodology appropriately accounts for differences in the environmental fate and transport among polycyclic organic matter (POM) and dioxin congeners?

Previously the RTR screening methods did not account for differences in environmental transport and fate among POM or dioxin congeners in the Tier 1 screening approach. All POM congeners were assumed to be transported, partition, and degrade in the environment identical to benzo(a)pyrene (BaP), and all dioxins were assumed to exhibit the same transport and fate as 2,3,7,8-TCDD. Since 2009 when the RTR Methodology was last reviewed by the SAB, the EPA has significantly refined its approach. Section 3.1.2 of the Agency's draft RTR methods document describes a new risk equivalency factor (REF) methodology that includes an exposure-equivalency factor (EEF) to reflect an individual chemical's transport and fate relative to the index chemical for each group (i.e., BaP for POM and 2,3,7,8-TCDD for dioxin).

The REF methodology has been incorporated as a screening tool into the residual risk assessment of stationary sources. It grapples with a common problem when dealing with complex mixtures – the evaluation of components with poorly characterized environmental fate and toxic effects. The SAB appreciates that when data gaps preclude inclusion of a chemical component of POM in a risk assessment, this component is often assumed to contribute zero exposure and risk. Rather than create such an underestimation, EPA has provided a screening methodology to fill such data gaps and thus include the full array of targeted POM constituents. In general, the SAB finds the overall approach to potentially be appropriate with more work needed to address concerns as described below.

The REF methodology consists of two read-across approaches[3] – one to handle toxicology data gaps, and the other to handle information gaps regarding environmental transport and

[3] Physicochemical, human health and/or environmental properties may be predicted from information from tests conducted on reference substance(s) within the group, referred to as source substance(s), by interpolation to other substances in the group, referred to as target substance(s). This approach is called "read-across." (https://echa.europa.eu/documents/10162/13628/raaf_en.pdf)

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fate. The SAB agrees with the toxicity equivalency factor (TEF) approach as it is well accepted for dioxins and carcinogenic PAHs. The SAB has not checked all the tabulated values for representativeness but notes that some of the PAHs given TEF factors by EPA are not typically considered to be carcinogenic; this was discussed in the SAB's response to Charge Question 1. The selection of TEFs for these and other PAHs is not provided in the Agency's draft RTR methods document and should be documented with references in Table 3.4.

The read-across approach for environmental fate is less well tested and accepted and thus deserves further consideration. EPA's proposed EEF is based upon a fundamental chemical property – K_{ow}. This property helps determine certain aspects of environmental fate such as uptake into fish, beef and dairy, but there are numerous other fate behaviors which it does not predict such as metabolism, biodegradation, environmental half-life and several types of phase transitions and partitioning. Thus, it is perhaps overly optimistic to expect K_{ow} by itself to have high concordance with exposure dose.

EPA's empirical correlation between K_{ow} and LADD for chemicals with sufficient data (RTR methods report Figure 3.2. U.S. EPA 2017) is a logical step in creating the read-across approach. However, as suggested above, K_{ow} is an imperfect predictor of LADD. Figure 3.2 shows the relationship between K_{ow} and LADD for 14 POM analytes for which there are more complete data. There is considerable variability around the regression line in Fig 3.2; this variability is currently unexplored but may arise from uncertainty and variability in the underlying parameters that influence the LADD including not only K_{ow} but also intermedia partition coefficients, molecular weight, half-life, potential for biodegradation, etc. The variability around the regression line is up to two orders of magnitude and thus the calculated EEF may substantially underestimate the LADD for some undefined members of data-poor chemical classes.

The SAB finds this read-across extrapolation of environmental fate could benefit from a refined approach and has identified two options for improving the EEF estimate as follows.

- Conduct further statistical evaluation of the relationship between K_{ow} and LADD to generate an upper bound on the regression slope and then apply this to derive EEFs for data poor chemicals.
- Conduct further evaluation of the underlying transport and fate parameters to develop distributions for each influential parameter and then perform a probabilistic analysis that replaces the Fig 3.2 regression slope; EPA can then make a transparent choice of which percentile of the distribution of LADDs for a given K_{ow} (and/or additional parameters) will be used in evaluating exposure and risk for data-poor POMs.

The SAB also finds the current documentation of key parameter inputs to the fate, transport and bioaccumulation model for PB-HAPs is not adequately described. The range of potential values and key citations should be presented in an appendix for all the modeled PB-HAPs. The document states that the EEF will change based upon environmental and geospatial conditions (e.g., Page 19, paragraph 1) but examples of this dynamic relationship are not provided, which further precludes a full review. For example, how are the effects of age/weathering incorporated to account for the loss of lighter dioxin congeners over time or with distance?

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The SAB notes that in Table 3.4, the products of the EEF and TEF values do not always equal the corresponding REF. Perhaps rounding prior to the multiplication causes these differences. Whatever the reason, the product of column multiplication should be mathematically consistent to avoid the impression that the table contains incorrect values.

In summary, the SAB finds that the REF would benefit from better explanation, documentation and statistical analysis in terms of: (a) documentation of TEFs (Table 3.4), including consideration of whether the TEF for carcinogenic activity is appropriate for certain PAHs not traditionally considered as carcinogens; and (b) documentation of the methods for EEF derivation, especially with respect to better analysis of the relationship between EEF and key environmental fate characteristics of each chemical (K_{ow}, environmental persistence, molecular weight, etc.) potentially including a probabilistic analysis and, at a minimum, more complete statistical treatment of the relationship between K_{ow} and LADD.

3.3 Fishing, lake and pond assumptions

Charge Question 3: Does the SAB find that the assumptions for human fishing behavior used in the refined fisher scenario, the assumptions about PB-HAP deposition to lakes, and the assumptions on the ability of ponds and lakes to sustain populations of fish are appropriate?

The Tier 2 multipathway screening scenario replaces some of the assumptions in the Tier 1 screen and is considered more realistic than Tier 1. Specifically, site-specific information is used for the locations of potentially fishable lakes and for meteorology. In addition, the Tier 2 assessment includes: a screening configuration that assesses the fisher and farmer exposure scenarios separately; and an estimation of lake productivity and fish population dynamics. The consideration is that a fisher might catch and consume fish from more than one nearby contaminated lake because more than one lake might be needed to catch enough fish for subsistence living. The approach at this level of screening analysis also attempts to account for PB-HAP deposition into a lake from multiple facilities in the same RTR source category.

3.3.1 Human fishing behavior and sustainability of fish populations in ponds and lakes

The SAB finds the assumptions used for human fishing behavior in the refined fishing scenario to be appropriate with caveats as noted below, while the assumptions concerning sustainability of fish populations in ponds and lakes may be inappropriately conservative. Assuming all parameters (such as size of the lake needed to support fish of a given size, assumptions about fish populations, etc.) are correct, the approach used seems reasonable. The equations seem appropriate and the assumptions appear to be properly managed. However, the SAB finds that most of the assumptions/parameters are possibly too conservative to achieve the objective of effective risk screening and suggests that more realistic ingestion rates and other model parameters be considered. For example, the Tier 2 method limits the fish consumption rate from a local water body due to potential depletion of fish by a single subsistence fisherman. The end result of a number of assumptions and productivity calculations is that no more than 1 gram fish/acre of waterbody can be sustainably removed per day (page 40, lines 7-9). In comparison, in one study the productivity of lakes was 82 kg/hectare/year (N=22 lakes, Randall et al. 1995) which converts to 90 g/acre/day. This 90-fold difference indicates the EPA should reconsider lake

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productivity and how to relate it to fish consumption estimates for a specific lake. Furthermore, with some of the contaminants examined, fish will not take up 100% of the chemical. Also, the chemicals considered will have different toxicodynamic and toxicokinetic properties in the fish, making the half-life of some chemicals (PABs/dioxins) much shorter than values assumed. These issues will affect exposure estimates in the fisher population.

There is considerable heterogeneity across lakes and the SAB has concerns with the presumed universality of some of the assumptions invoked for the analysis. For example, the analysis assumes: 21% of the fish biomass are piscivores; benthic fish account for 17.5% and pelagic fish account for 3.5% of total fish biomass; humans consume 50:50% from benthic and pelagic piscivores (note some people consume pan fish); and total fish biomass is 40 g fish ww/m^2. It seems likely that rather than fixed values these parameters have a wide range of occurrence in actual lakes. Also, as explained in the appendix of the Agency's draft RTR methods document, benthic fish collection is usually higher than pelagic species (although pelagic are preferred by consumers) due to the general species abundance. The SAB recommends that the EPA document and justify these assumptions.

The SAB encourages the EPA to consider other data available to make more realistic assumptions such as using the most recent NHANES data to estimate fish consumption. Additionally, the EPA might be able to refine the assumptions on chemical runoff and erosion from the watershed by using relevant U.S. Geological Survey (USGS) data that are available for the region of interest (U.S.G.S. 2018). As another example, the EPA Risk-Screening Environmental Indicators (RSEI) Model is part of the Toxics Release Inventory (TRI) program and is primarily used as a transport and fate model to estimate concentrations, hazard level and risk of air pollutants covered by the TRI. However, RSEI also has a model that estimates transport and fate of TRI releases to water bodies including both direct releases and transfers between wastewater plants. The primary data product is toxicity-weighted concentrations downstream of TRI discharges. These data are available by stream segment. The Office of Pollution Prevention and Toxics could presumably prepare data specific to the modeler's needs. Alternatively, the RSEI Water Microdata can also be accessed online (U.S. EPA 2018i).

The SAB struggled with understanding some of the RTR modeling inputs/assumptions. This process may become more transparent if the data are presented with information about how studies were included or excluded, how data were prioritized and selected for use, how the evidence was weighted, etc. The appendices to the EPA report achieve this goal to a certain extent but are incomplete.

3.3.2 PB-HAP deposition to lakes

The SAB could not determine whether the assumptions for PB-HAP deposition to lakes are appropriate for the following reasons. Regarding PB-HAP transport and deposition, air dispersion models recommended by EPA, such as AERMOD, have been continuously improved and updated many times over the years (as recently as January 2017). Such models have been used by many users in a variety of regulatory applications and have been subject to rigorous performance evaluation by EPA and the scientific community to test and demonstrate their accuracy. The SAB recommends clarification of the extent to which TRIM.FaTE has been updated since 2002, when its technical support document was released. Assuming AERMOD is valid for the use cases of interest, the reliability of TRIM.FaTE's air

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dispersion component should be assessed by comparing to AERMOD for a variety of scenarios. Also, the EPA may seek to consult with EPA Office of Pesticide Programs (OPP) Environmental Fate and Effects Division (EFED) since they have developed models with different tiered assumptions about runoff into ponds.

It is unclear how accurately PB-HAP deposition is calculated by TRIM.FaTE. Additional information is needed to demonstrate the accuracy (or for a screening methodology, to evaluate how conservative the assumptions are) of such deposition estimates and their implications to the reliability of fish consumption exposure estimates. EPA should test and demonstrate for a range of representative scenarios the reliability of TRIM.FaTE air concentration and deposition estimates.

Finally, the SAB recommends conducting a sensitivity analysis of the distribution of critical parameters at higher tiers. The use of multiple health-protective assumptions/parameters is likely to overestimate the actual risks, probably by a substantial margin. Furthermore, a probabilistic analysis should provide a more accurate and transparent estimate regarding uncertainty of the risks and may be appropriate at higher tiers.

3.4 Lake data, plume rise, and meteorological data

> *Charge Question 4: Does the SAB find the methods used for evaluations of (1) lake data, (2) plume rise, and (3) time-series meteorological and time-series plume-rise data are appropriate?*

When the Tier 2 screening analysis indicates that further evaluation is warranted, the EPA applies the Tier 3 screening approach described in Section 3.3 of the Agency's draft RTR methods document. The method includes three individual refinements to the Tier 2 methods that are conducted in a step-wise fashion. The refinements include: further analysis of the affected lakes identified in the Tier 2 screen; analysis of plume rise resulting in PB-HAPs lost to the upper atmosphere; and the use of time-series meteorology from meteorological data stations and modeled effective chemical release heights.

3.4.1 Lake data

The SAB finds the method to evaluate lake data to be generally appropriate and indicates items for refinement. The SAB supports the use of up-to-date land-use data to more accurately represent exposures that occur through lake media. EPA should consider relying less on analyses that are time-intensive and that depend on analysts' subjective judgments. Web or GIS searches, as described in the Agency's draft RTR methods document, may be useful to produce input data. A guiding principle should be "documented and reproducible" such that independent experts can understand the data and methods applied by EPA analysts and can reproduce the results.

EPA should consider the use of data streams that can be automated so that ongoing land use changes can be incorporated. Widely available data sets include the National Land Cover Database (NLCD) and USGS Digital Elevation Model (DEM). The SAB cautions EPA against *a priori* exclusion of wetland influenced lakes, which may host fish.

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3.4.2 Plume rise

The SAB believes the plume rise methodology may be inappropriate in some cases EPA should evaluate the use of plume-rise models other than those described in the Agency's draft RTR methods document screening procedure. An example is Briggs (1984) and the documentation of AERMOD (Cimorelli *et al.* 2004) which thoroughly discusses plume rise and contains other citations.

For this and other dispersion and transport modeling, the SAB recommends that EPA consider the use of meteorological reanalysis data for both surface-air and upper-air wind speeds. These data can overcome some uncertainties when weather stations are far from the modeled site.

3.4.3 Time series meteorological and plume-rise data

The SAB believes that the hour-by-hour response treatment is not yet justified. Furthermore, the corresponding time-series meteorological and time-series plume-rise data used in the hour-by-hour treatment may be inappropriate in some cases.

First, EPA should be cautious about undue oversimplification of complex atmospheric processes. Full or partial penetration of a plume through the top of the mixed layer depends on many complex factors including plume momentum, plume buoyancy, stack release height and exit conditions, depth of the mixed layer, inversion strength, and atmospheric stability. These processes may vary with time, as meteorological factors evolve over the course of a day, possibly causing plume re-entrainment or rapid fumigation. Atmospheric processes governing plume penetration are more complex than can be adequately represented by a simple comparison of inversion height with effective plume height (which includes plume rise).

Second, the Agency's draft RTR methods document indicates that hour-by-hour data from the closest meteorological station should be used. These data may not reflect specific microclimatic conditions at the site, including topography, directional valley orientations, and specific inversion conditions that can differ from those at the station. For accurate screening, these local conditions should be considered.

EPA should test and demonstrate the reliability of the proposed adjustment by comparing screening results as implemented using TRIM.FaTE to those calculated by a more physically realistic model, such as AERMOD. Indeed, the SAB suggests EPA evaluate the additional accuracy perceived to result from implementing hour-by-hour adjustments. The suggested procedure requires extensive data manipulation yet has not been validated, whereas with a moderate additional investment the screening could be done with a validated and accepted model such as AERMOD.

The SAB also has two overarching recommendations addressing issues which were not specifically called out in the charge questions.

- EPA should consider that the quantity of emissions in the National Emission Inventory (NEI) may differ from reality, either because of upset conditions, or because self-reporting does not always suffice. The location of emissions may also be different than

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reported. These inaccuracies may have important effects on predicted exposures and should be assessed to the extent practicable.

- The SAB recommends that EPA consider sensitivity analysis to determine the parameters and assumptions that have the greatest effect on predicted exposures, especially at the higher tiers. Identification of factors that dominate risk and uncertainty could guide future screening analyses by providing justification to obtain detailed input data for those factors. Furthermore, probabilistic analysis would provide a framework to estimate confidence bounds.

3.5 The gardener scenario

Charge Question 5: Does the SAB find the assumptions and approaches laid out for application in the gardener scenario to be appropriate? Does the SAB find that adding the gardener scenario to Tier 3 would improve our ability to characterize ingestion risks for urban and rural environments?

The Agency's draft RTR methods document includes a new exposure pathway added to the EPA methods (Section 3.4) – a gardening exposure scenario added to the multipathway screen. This scenario is intended to better characterize multipathway risk and the EPA suggested it will significantly improve the screening for locations where the presence of a subsistence farm is either unlikely (in urban areas) or difficult to confirm based on the characterization of land use surrounding a facility.

The gardener scenario is described on pages 59-62 of the Agency's draft RTR methods document. EPA is proposing to implement this scenario as part of Tiers 2 and 3 in locations where at least some individuals are likely to consume homegrown produce. The SAB was asked to comment on the assumptions used and whether the addition of the scenario would improve characterization of ingestion risk in both urban and rural environments. In general, the SAB finds that the gardener scenario is an appropriate addition to both Tier 2 and Tier 3 evaluation thereby developing a more useful model system for screening.

Regarding the first component of the charge question – the appropriateness of assumptions and approaches in the scenario – the SAB's response focuses on the media ingested by the gardener. EPA has selected ingestion routes like those experienced by subsistence farmers. These categories include direct ingestion of soil, ingestion of protected fruits and vegetables, ingestion of root vegetables, and ingestion of breastmilk (although intake rates for the latter are not presented in Tables 3-18 and 3-19). These appear to be appropriate and sufficiently distinct to provide coverage of the appropriate sources of soil ingestion and contaminants contained in soil. EPA distinguishes intake of gardeners from farmers by noting that meat products and dairy products are not likely to be sources for the gardeners (Table 3-17).

The SAB suggests including chicken eggs in the gardener scenario as many gardeners also keep egg-laying chickens. The SAB also notes that the gardening scenario appears to use many of the same assumptions about diet as the subsistence farmer, suggesting that the gardening scenario does not add much value to the tiered approach. The SAB therefore suggests that it is especially important to distinguish between the gardener and the subsistence farmer.

EPA has separated gardeners into two categories – rural and urban. The approach seems reasonable, especially given differing intake rates for urban and rural gardeners. The

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assumptions that a rural gardener would have enough land to develop a subsistence, or near-subsistence, garden while the urban gardener would not seem, on face value, to be valid. Following this reasoning, EPA uses an upper (90th) percentile estimate for intake rate of home-grown vegetables for the rural gardener but a central tendency home-grown vegetables intake rate for urban gardeners (See Table 3-19 for the intake rates). Both intake rates are taken from the Exposure Factors Handbook and appear to be justified as EPA's best assessment of such rates.

Regarding soil intake rates, gardener soil intake rates were matched to those of farmers, consistent with the notion that gardens in both rural and urban settings must be tended, affording gardeners with intimate soil contact and thus intake. Further, in the rural setting, the farmer-specific rates for surface runoff-related contamination would be used while this term would not be used in urban settings. The farmer-specific rates are less health-protective in the sense that it focuses only on agricultural runoff. In urban settings, runoff may occur from other sources (e.g., industrial facilities and roadways) and might well be considered important. The SAB suggests that these additional urban sources be considered and matched with those of the rural settings.

Except for the surface runoff component, the assumptions made above are health-protective but not unreasonably so even when compared to earlier assumptions (e.g., Charge Question 3). The SAB notes that including the same assumptions for multiple tiers likely results in little effective screening. Further, the assumptions may offer too much health protection and thereby reduce the screening utility of the tool. In addition, the SAB suggests alternative- and higher- soil intake rates for the adult gardener.

Regarding the second component of this charge question, inclusion of the gardener scenario is appropriate because it improves the characterization of the potential risk in both rural and urban environments for those who take part in this activity.

3.6 Environmental risk screening methodology

> *Charge Question 6. Does the SAB find that the environmental risk screening approach is appropriate for identifying facilities whose PB-HAP emissions may have the potential to cause adverse environmental effects? Specifically, does the SAB find that the pollutants (Section 4.2.1), ecological assessment endpoints (Section 4.2.2), and benchmarks (Section 4.3) that are included in the environmental risk screen are appropriate? Does the SAB have specific suggestions for improvement with regard to any aspect of this environmental risk screening methodology?*

Charge Question 6 addresses the information provided in Chapter 4 of the Agency's draft RTR methods document (and supporting appendices) that describes the environmental risk screen that was developed to provide a systematic, scientifically defensible, and efficient approach that EPA can use to screen for potential adverse environmental effects associated with emissions of HAPs from facilities in RTR source categories. It is designed so that the screen can be run quickly and with minimal additional data gathering by drawing on existing data, models, and modeling results, including those developed for the human health multipathway risk screen. The overall methodology was reviewed by the SAB in 2009. The material in Chapter 4 of the Agency's draft RTR methods document focused on

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those aspects that have been refined/revised since the last review. The revised aspects include:

- Modeled environmental concentrations are compared to ecological benchmarks, not human health thresholds, for all pollutants included in the screen;
- An evaluation of HAPs for potential inclusion in the screen was conducted;
- The environmental risk screen was expanded to include the following additional environmental HAPs: cadmium, hydrogen fluoride, lead, arsenic, and additional POMs;
- The number of ecological endpoints and effect levels that are evaluated was expanded;
- A literature review was conducted to identify the most up-to-date ecological benchmarks; and
- Tiers were added to the environmental risk screen for PB-HAP that are parallel to the tiers in the multipathway human exposure screen.

The SAB finds that the overall methodology and specifically the revisions since 2009 are appropriate and improve the ecological assessment capabilities. It represents a comprehensive approach that builds upon, and uses, the screening tools used in the health assessment/screening (i.e., TRIM.FaTE, AERMOD). As noted below, the SAB offers several recommendations and comments towards refining the approach.

The methodology for identifying the pollutants to be included in the screening activities are clearly stated and the criteria used to prioritize the chemicals are judged to be appropriate with the following considerations to be taken into account. The SAB is concerned that selenium is not included as a chemical to screen. Selenium is an essential trace element which is toxic at elevated concentrations. Elevated exposure can lead to selenosis. Selenates and selenites are particularly toxic forms of selenium (Hamilton, 2004). Given selenium's potentially important role in ecological impacts, the SAB recommends it be considered. In addition, it is not clear that BaP is the most appropriate POM chemical to use in the ecological analysis. There may be more important POM molecules (lower molecular weights) to use in this screening and further analysis is recommended. Furthermore, the emission rates presented in Table 4.1 are for base year 2005, and they need to be updated to reflect recent emissions data. Also, on page 67 line 21 there is reference to "99.9% of national emissions" but the basis is not clear (mass, toxicity or some other basis).

The SAB finds the expansion of ecological assessment endpoints appropriate and that the benchmarks, and the use of a tier system, are justified. The Agency's draft RTR methods report and appendices document the processes and assumptions used to identify the endpoints and benchmarks. Overall, the calculation of potential risks is robust and follows current scientific methodologies. As the amount and diversity of information analyzed in identifying the endpoints and benchmarks is vast, it would be helpful to clarify when most sensitive or most exposed species are used. In addition, the SAB notes that the overall approach would be strengthened by allowing site-specific variables to be added during the assessments, as some sites may have very specific sensitive species. Using a less sensitive receptor in a screening methodology runs the risk of underestimating the impact to the environment in those regions.

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Tables 4.2 (endpoints) and 4.3 (benchmarks) are critical to the screening process. Values in these tables are likely to change over time as new information becomes available so it is important that they be viewed as tables requiring continuous development and a process should be identified by the EPA to continuously review and update them. Furthermore, many of the studies listed are from the 1980s-1990s and are compilation reviews from earlier publications. Notations should be made in the table or the text as to why the benchmark value was chosen. Many of the benchmarks have multiple studies (chronic / acute) with varying methodologies and results. The SAB recommends the EPA consider grading studies based on Klimisch score, a method of assessing the reliability of toxicological studies, mainly for regulatory purposes.

The SAB finds that the general methodology of the tiered approach and the use of TRIM.FaTE and AERMOD are appropriate. The SAB notes the simplicity of the air dispersion treatment in TRIM.FaTE and encourages the advancement of incorporating AERMOD analysis within the TRIM.FaTE framework. The use of reanalysis meteorological data is recommended to improve the meteorological fields used in the analysis. As stated elsewhere in this report, the analysis would also benefit from considering the implementation of a probabilistic approach.

The SAB recommends that analysis elements performed under the environmental risk screen be incorporated in the farmer screen (e.g., utilizing the deposition to soils).

The following additional specific recommendations regarding endpoints and benchmarks are provided:

- The SAB suggests EPA consider indirect HCl effects by evaluating the concentrations of chloride from a facility relative to background chloride concentrations contributing to loss of surface water acid neutralizing capacity or soil base saturation. Critical loads of acidity have been developed (NADP 2018) for the U.S. and the acidity associated with estimated chloride deposition could be compared to these critical load values.
- Mercury targets may need to be updated or expanded to protect communities of predator animals associated with bioaccumulation of methylmercury and to reflect broader wildlife impacts[4] (e.g., song birds.)
- The water quality and soil criteria (Table 4-1) for mercury are very high. This is particularly true for water where concentrations are typically on the order of nanograms per liter (ng/L). For example, the sediment clean-up values for Onondaga Lake, NY– a mercury contaminated site – are 2.2 μg/g for probable effective concentration based on macroinvertebrate toxicity testing and 0.8 μg/g for bioaccumulation-based sediment quality. The SAB suggests EPA consider criteria values for water and sediment/soil for contaminants that have been established for hazardous waste clean-up at sites around the U.S. for several contaminants.

3.7 Inhalation risk assessment enhancements

[4] http://www.briloon.org/uploads/Library/item/265/file/Hidden%20Risk.pdf https://www.crcpress.com/Environmental-Contaminants-in-Biota-Interpreting-Tissue-Concentrations/Beyer-Meador/p/book/9781420084054https://www.niehs.nih.gov/research/supported/assets/docs/a_c/bioscience_508.pdf

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Charge Question 7: Does the SAB find that the Urban/Rural Dispersion Selection Enhancement Tool is an appropriate procedure for identifying facilities to be modeled using the urban option in AERMOD?

In previous chronic inhalation risk assessments, the EPA assumed the land surrounding each facility was rural. The 2009 SAB review (U.S. EPA SAB 2010) indicated additional development was appropriate. Chapter 5 of the Agency's draft RTR methods document is an enhancement to the chronic inhalation risk assessment that the EPA contends accounts for the variation in urban to rural characteristics of the land surrounding each evaluated facility. The goal of the improvement is to better characterize pollutant dispersion near sources.

The urban/rural dispersion selection enhancement tool provides a way to specify atmospheric turbulence within a model domain to allow AERMOD to more accurately model pollution dispersion. The tool currently provides two options. The Agency's draft RTR methods document evaluates the differences in model results using these two methods and proposes using the census (population density)-based designation of "urban" ("HEM default procedure") as the preferred method.

The SAB agrees that incorporating the effects of turbulence as a model input is appropriate and of significant value because it avoids the overly conservative assumption of applying the "rural" assumption to all facilities. However, the SAB disagrees with the Agency's draft RTR methods document on the procedure of choice and recommends the land use procedure which uses the National Land Cover Database (NLCD). This procedure directly measures the feature that controls turbulence, unlike the HEM default procedure which relies on a secondary effect – an aggregated population density metric – that may not correlate well in highly industrialized areas with dense concentrations of buildings, pavement and other structures yet little residential land. The land use procedure provides a more accurate assessment for the selection, and the Agency's draft RTR methods document does not offer a compelling explanation of the benefits from using the HEM default procedure. The land use procedure also more directly aligns with EPA's 2005 Guidelines on Air Quality Models as stated on page 121 (last paragraph) in the Agency's draft RTR methods document; the guidelines list specific land use types to be considered, rather than population density.

Using the land use procedure is not significantly more difficult or time/resource intensive than the HEM default procedure, so any logistical advantage of the HEM default procedure is minimal. Analysis can be automated using Model Builder or Python scripting in ArcGIS. Problems described in the Agency's draft RTR methods document associated with the land use procedure misclassifying facilities with significant coverage by water bodies inside the model domain can be addressed in the GIS procedures, and the SAB recommends that this be included in the procedure to avoid misclassifying heavily developed areas near large water bodies as "rural."

Because the inhalation risk assessment is a location-based estimate using modeled ambient concentrations and is not population-weighted, the use of population density via the HEM default procedure is less appropriate than using land use. In addition, the land use procedure finds fewer urban areas than the HEM default procedure, indicating the latter misclassifies turbulence in some cases.

The SAB also notes that the quality of the NLCD data makes it possible to express the "urban

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nature" of the model domain as a continuous variable, rather than a binary "yes/no" value. Such a calculation adds little to the time and difficulty of the GIS procedures used to calculate the variable. It provides a measure of the intensity of "urban" character for each area considered and could also be used to characterize the geographic variation of turbulence within a given model domain. There are different ways to use this type of metric in modeling; it is not certain whether EPA modeling tools can use that variation, but it might be useful in future versions of the modeling and represents a "best practices" approach for gathering input data, particularly if it is only a little more difficult or expensive to do so. Using this approach with successive versions of the NLCD, which is updated every four years, allows for tracking land cover change over time.

If EPA adopts this more nuanced use of the NLCD, the SAB suggests the EPA consider including NLCD class 22 (low intensity developed) in identifying "urban" in this context. This class is defined as 20-44% impervious surfaces and it correlates very well with residential land use when compared to other high-resolution datasets. Class 22 is used in screening methods in California and has been shown to be of value in characterizing or measuring fine scale heterogeneity in other contexts (Chabaeva and Civco 2004; Smith et al. 2010).

Another alternative is the use of a regular NLCD derivative product – the percent impervious surface data layer which is produced for each NLCD generation, as is a measure of the net change in imperviousness between NLCD generations. Use of these metrics are generally as cost effective as using population density and have the advantage of being updated more often than the census. The SAB looks forward to reviewing and commenting on the approach eventually adopted.

Regardless of the urban/rural dispersion selection procedure that is used, the automatically-generated designation should be manually evaluated with the final choice of urban/rural dispersion a matter of professional judgment based on 'facts on the ground.' In cases where a material difference in estimated potential risk exists between urban and rural dispersion and professional judgement is used to overrule the selection tool's designation, EPA should document and justify this decision.

3.8 The census block receptor check tool

> *Charge Question 8: Does the SAB find that the Census Block Receptor Check Tool and associated enhancements are an appropriate method for identifying and adjusting model receptors to ensure the receptors are representative of residential locations?*

Section 5.2 of the Agency's draft methods document describes an enhancement made to the chronic inhalation risk assessment – the addition of the Census Block Receptor Check Tool. The rationale for the new tool is that the block centroid does not always represent residential locations. The HEM-3 model calculates ambient air concentrations at census block centroid locations as surrogates for population exposure. If the centroid is located outside of the block polygon, then the U.S. Census Bureau provides the longitude and latitude of an internal point near the geometric centroid that falls inside the block polygon. The points are not weighted or reflective of the population distribution. Census blocks vary in size depending on population density. In urban areas, a census block may be equivalent to a city block bounded on all sides by a street. In sparsely populated areas, a census block is often irregularly shaped with streams, property lines, and rural roads as boundaries. In the 2009 review conducted by the

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SAB (U.S. EPA SAB 2010) it was noted that census block centroids might not always be an appropriate surrogate for residential locations. The Census Block Receptor Check Tool was developed to address this concern. This new tool identifies two examples when internal centroid points may not be a good surrogate for where populations reside and provides options to address this.

The first scenario is for block centroids located within 300 meters of emission points, which may be within the facility grounds and not where there are residents. The tool user would be able to view these receptors and delete them if they are on the facility property. The second scenario focuses on large and irregularly shaped census blocks, where the centroid may be farther away from population centers. If blocks with an area greater than 2.6 km^2 are identified within 1 km of a facility, aerial images of the blocks can be examined using the tool to determine if the centroid receptor needs to be relocated and other receptors added to represent multiple residential locations.

The SAB finds the Census Block Receptor Check Tool to be an appropriate framework, but the precise methodology underlying the tool may be unreliable in some cases. The SAB offers recommendations for improving the method, but also encourages the Agency to consider an alternative approach.

The EPA report does not provide enough information about the tool, especially regarding criteria that would be used to determine the number and placement of new receptors. For example, the statement "If residential locations cannot be represented by a single receptor (that is, the residences are spread over the block), additional receptors are added for residences nearer to the facility than the centroid" (page 140, lines 15-17) is vague and the method appears to be *ad hoc*. The SAB is concerned that the process would not be reproducible if another risk assessor were to subsequently model that facility. The choice of a 300-meter buffer from an emission source is also somewhat arbitrary. Furthermore, the impact of these changes is not obvious. The Agency's draft RTR methods report should include more detailed examples of how risk estimates change based on these enhancements compared to the default block centroid method.

Overall, the SAB believes that methods predominantly relying on census block centroid locations – including cases where the enhancement tool is applied – can in some cases be reliable, but additional effort is needed to verify that receptors are representative of residential areas near the facilities. One approach would be to review satellite imagery within 1 km of all facilities, not just those in identified large census blocks, and manually add receptors as needed to appropriately represent population centers. However, any manual placement would be subjective and likely not reproducible between risk assessors. The SAB recommends the Agency evaluate an alternative approach that uses the same 2011 National Land Cover data used for the Urban/Rural Dispersion Selection Enhancement tool to automate the process of identifying population centers. The NLCD data is available at a high spatial resolution (30 m) and receptors could be placed in areas of developed land use classes 22-24. Aerial photos (e.g. Google Earth™) can then be used to check that the land use-based placement of receptors is appropriate. If professional judgement is used to select the location then the RTR screening analysis documentation should include sufficient information such that another expert could follow the reasoning and reproduce the selection.

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If the EPA prefers to continue using census block centroids as nearby exposure receptors, then the SAB recommends additional enhancements to make the tool less *ad hoc*. For example, facilities are better represented as polygons than points. Satellite imagery can be used to estimate the facility boundary and then GIS procedures could be used to exclude centroids located within the boundary. In such cases, satellite imagery could then be used to add alternative receptors to replace the deleted centroid and ensure nearby residences are represented. It is noted that this procedure would not be needed if receptors were placed at actual population locations using land use data as recommended.

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4. REFERENCES

ATSDR 2018. Agency for Toxic Substances and Disease Registry. Available at http://www.atsdr.cdc.gov/mrls. Last accessed April 24, 2018.

Briggs, G. A. 1984. Plume rise and buoyancy effects, in *Atmospheric Science and Power Production*, edited by D. Randerson, pp. 327-366, Department of Energy.

CalEPA 2018. California Environmental Protection Agency. Toxic Air Contaminants. Available at https://oehha.ca.gov/air/toxic-air-contaminants. Last accessed April 24, 2018.

CDC 2018. National Health and Nutrition Examination Survey. Centers for Disease Control and Prevention. Available at https://www.cdc.gov/nchs/nhanes/nhanes_products.htm. Last accessed April 24, 2018.

Chabaeva, A. A., D.L. Civco, S. Prisloe 2004. Development of a population density and land use based regression model to calculate the amount of imperviousness ASPRS Annual Conference Proceedings, Denver, Colorado, May 2004 (2004) (from Unpaginated CD ROM paper available at http://clear.uconn.edu/publications/research/tech_papers/Chabaeva_et_al_ASPRS2004.pdf)

Cimorelli, A. J., S. G. Perry, A. Venkatram, J. C. Weil, R. J. Paine, R. B. Wilson, R. F. Lee, W. D. Peters, R. W. Brode, and J. O. Paumier. 2004. *AERMOD: Description of Model*. EPA-454/R-03-004. U.S. Environmental Protection Agency, Washington, DC.

Hamilton, S. 2004. Review of selenium toxicity in the aquatic food chain. *Science of the Total Environment*. 326:1-31.

Morrison G.C., Weschler C.J., Bekö G, Koch HM, Salthammer T, Schripp T, Toftum J, Clausen G. 2016. Role of clothing in both accelerating and impeding dermal absorption of airborne SVOCs. *J Expo Sci Environ Epidemiol*. 2016 Jan-Feb;26(1):113-8.

NADP 2018. CLAD – Critical Loads of Atmospheric Deposition Science Committee. National Atmospheric Deposition Program, Madison, WI. Available at http://nadp.sws.uiuc.edu/committees/clad/. Last accessed April 24, 2018.

Nisbet ICT, LaGoy PK. Toxic equivalency factors (TEFs) for polycyclic aromatic hydrocarbons (PAHs). *Reg. Toxicol. Pharmacol.* 1992. 16:290-300.

Randall R.G., Minns C.K., Kelso J.R.M. 1995. Fish production in freshwaters: Are rivers more productive than lakes? *Can. J. Fish. Aquat. Sci.*, 1995, 52(3):631-643.

Smith, M. L., W. Zhou, M. Cadenasso, M. Grove, and L. E. Band 2010. Evaluation of the National Land Cover Database for hydrologic applications in urban and suburban Baltimore, Maryland. *J. Am. Water Resour. Assoc.* 2010 **46**: 429–442.

ED_002496_00003261-00037

U.S. EPA 1993. *Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons*. EPA/600/R-93/089. U.S. Environmental Protection Agency, Cincinnati, OH. Available at: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=49732

U.S. EPA. 1999. *Residual Risk Report to Congress*. EPA-453/R-99-001. U.S. Environmental Protection Agency, Research Triangle Park, NC. Available at https://www.epa.gov/sites/production/files/2013-08/documents/risk_rep.pdf

U.S. EPA. 2017. *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*. U.S. Environmental Protection Agency, Research Triangle Park, NC. Availabe at https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html last accessed April 24, 2017.

U.S. EPA 2018a. Clean Air Act Standards and Guidelines for the Metals Production Industry. U.S. Environmental Protection Agency, Research Triangle Park, NC. Available under "Iron and Steel Production" at https://www.epa.gov/stationary-sources-air-pollution/clean-air-act-standards-and-guidelines-metals-production-industry. Last accessed April 24, 2018.

U.S. EPA 2018b. Clean Air Act Standards and Guidelines for the Solvent Use and Surface Coating Industry. U.S. Environmental Protection Agency, Research Triangle Park, NC. Available under "Dry Cleaning" at https://www.epa.gov/stationary-sources-air-pollution/clean-air-act-guidelines-and-standards-solvent-use-and-surface. Last accessed April 24, 2018.

U.S. EPA 2018c. Clean Air Act Standards and Guidelines for the Solvent Use and Surface Coating Industry. U.S. Environmental Protection Agency, Research Triangle Park, NC. Available under "Solvent Use and Cleaning" at https://www.epa.gov/stationary-sources-air-pollution/clean-air-act-guidelines-and-standards-solvent-use-and-surface. Last accessed April 24, 2018.

U.S. EPA 2018d. Air Quality Dispersion Modeling – Preferred and Recommended Models. U.S. Environmental Protection Agency, Research Triangle Park, NC. Available under "AERMOD" at https://www.epa.gov/scram/air-quality-dispersion-modeling-preferred-and-recommended-models#aermod. Last accessed April 24, 2018.

U.S. EPA 2018e. Integrated Risk Information System. U.S. Environmental Protection Agency, Washington, DC. Available at https://www.epa.gov/iris. Last accessed April 24, 2018.

U.S. EPA 2018f. Risk and Technology Review (RTR) Methods Panel Draft Report Discussion. U.S. Environmental Protection Agency, Washington, DC. Available at https://yosemite.epa.gov/sab/SABPRODUCT.NSF/MeetingCal/64CE76E2636EBDC3852581A00065CCA3?OpenDocument. Last Accessed April 24, 2018.

U.S. EPA 2018g. Benzo[a]pyrene (BaP). Integrated Risk Information System. U.S. Environmental Protection Agency, Washington, DC. Available at

https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=136. Last accessed April 24, 2018.

U.S. EPA 2018h. Toxicological Review of Benzo[a]pyrene (BaP). Integrated Risk Information System. U.S. Environmental Protection Agency, Washington, DC. Available at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0136tr.pdf. Last accessed April 24, 2018.

U.S. EPA 2018i. RSEI Data Dictionary: Water Microdata. U.S. Environmental Protection Agency, Washington, DC. Available at https://www.epa.gov/rsei/rsei-data-dictionary-water-microdata. Last accessed April 24, 2018.

U.S. EPA SAB (U.S. Environmental Protection Agency Science Advisory Board). May 7, 2010. *Letter to Lisa P. Jackson.* U.S. Environmental Protection Agency, Science Advisory Board, Washington, DC. Available at https://yosemite.epa.gov/sab/sabproduct.nsf/0/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf

U.S. EPA SAB (U.S. Environmental Protection Agency Science Advisory Board). June 20, 2007. *Letter to Stephen L. Johnson.* U.S. Environmental Protection Agency, Science Advisory Board, Washington, DC. Available at https://yosemite.epa.gov/sab%5Csabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf

U.S. EPA SAB (U.S. Environmental Protection Agency Science Advisory Board. 2001. *NATA – Evaluating the National Scale Air Toxics Assessment 1996 Data-An SAB Advisory.* U.S. Environmental Protection Agency, Science Advisory Board, Washington, DC. Available at https://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/$File/ecadv02001.pdf

U.S. EPA SAB (U.S. Environmental Protection Agency Science Advisory Board). 2000. *An SAB Advisory on the USEPA's Draft Case Study Analysis of the Residual Risk of Secondary Lead Smelters.* U.S. Environmental Protection Agency, Science Advisory Board, Washington, DC. Available at http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf

U.S.G.S. 2018. Welcome to StreamStats. U.S. Geological Survey, Washington, DC. Available at https://water.usgs.gov/osw/streamstats/. Last accessed April 24, 2018.

Weschler CJ, and W.W. Nazaroff. 2012. SVOC exposure indoors: fresh look at dermal pathways. *Indoor Air* 2012 Oct;22(5):356-77.

Weschler CJ, and W.W. Nazaroff. 2014. Dermal uptake of organic vapors commonly found in indoor air. *Environ Sci Technol.* 2014 Jan 21;48(2):1230-7.

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5. APPENDIX A: CHARGE TO THE SAB

May 26, 2017

MEMORANDUM

SUBJECT: Request for SAB Peer Review of the document: "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis"

FROM: Erika N. Sasser, Director /s/
Health and Environmental Impacts Division
Office of Air Quality Planning and Standards (C504-02)

TO: Christopher Zarba, Director
EPA Science Advisory Board Staff Office (1400F)

EPA's Office of Air Quality Planning and Standards is requesting a peer review by the Science Advisory Board (SAB) on the document: "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis." This report describes specific screening methodologies that have evolved since the SAB last reviewed the RTR risk assessment methods in 2009. The screening methodologies are used to quickly identify those facilities in particular RTR source categories that have little potential for human health multipathway or environmental risk, while also identifying those facilities where a refined multipathway or environmental risk assessment may be needed. This report also describes the potential addition of a new multipathway exposure scenario that can estimate ingestion risk for members of urban or rural households who consume contaminated homegrown fruits and vegetables, as well as several improvements to EPA's chronic inhalation risk assessment methodology. The application of the updated risk assessment screens and methodologies is highlighted in this report through the presentation of example facilities emitting hazardous air pollutants.

The case study analysis and accompanying documentation were prepared by staff in the EPA's Office of Air Quality Planning and Standards. The document is being made publicly available on the Agency's website at the following address:
https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.

Attached is the charge to the Science Advisory Board. It includes background information on the screening methodologies and identifies the questions and issues we would like the Science Advisory Board to address in their peer review of the methods.

Attachment:
Peer Review Charge

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Attachment

Charge to the Science Advisory Board for their review of the "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis"

Office of Air Quality Planning and Standards
Office of Air and Radiation

Background:

The Clean Air Act (CAA) establishes a two-stage regulatory process for addressing emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, the CAA requires the EPA to develop technology-based standards for categories of industrial sources. We have largely completed the required Maximum Achievable Control Technology (MACT) standards with about 112 MACT standards being issued to date for stationary major sources of HAP. In the second stage of the regulatory process, EPA must review each MACT standard at least every eight years and revise them as necessary, "taking into account developments in practices, processes and control technologies." We call this requirement the "technology review." EPA is also required to complete a one-time assessment of the human health and environmental risks that remain after sources come into compliance with MACT. If additional risk reductions are deemed necessary to protect public health with an ample margin of safety or to prevent adverse environmental effects that are judged to be "significant and widespread", EPA must develop standards to address these remaining risks. For each source category for which EPA issued MACT standards, the residual risk stage must be completed within eight years of promulgation of the initial MACT standard. Since the initial technology review requirement coincides in deadline with the risk review requirement, EPA generally combines these two requirements into one rulemaking activity, calling this the "risk and technology review" process, or simply RTR. In this way, the results of the risk review can be potentially informative to the technology review process, and vice versa.

Because RTR assessments are used for regulatory purposes, and because components of our screening analyses have evolved over time, EPA periodically seeks the Science Advisory Board's (SAB) review (see below). For the current review, we seek the SAB's input on the specific enhancements made to our risk assessment methodologies, particularly with respect to multipathway and environmental screening methodologies, since the last SAB review was completed in 2009. Facilities that do not screen out may be the subject of refined multipathway risk assessments, which 1) are conducted for a single facility at a time; 2) are very costly; 3) and can take several months to complete. Thus, we consider these screens to be an important step in the RTR risk assessment process that helps the agency to maximize the use of its resources and, when appropriate, to facilitate its communication with stakeholders.

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Previous Relevant Peer Reviews

Previous peer reviews have covered various elements associated with the RTR process. A brief summary of each peer review is provided:

1) The *Residual Risk Report to Congress*, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methodology were described in this report, although individual elements have been improved over time. The final SAB advisory is available at http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf).

2) A peer review of multipathway risk assessment methodologies for RTR was conducted by the EPA's SAB in 2000. The final SAB advisory is available at http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$Fi le/ecadv05.pdf.

3) A consultation on EPA's updated methods for developing emissions inventories and characterizing human exposure was conducted by SAB in 2006. The final SAB advisory is available at https://yosemite.epa.gov/sab%5Csabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf.

4) A review of the updated and expanded risk assessment approaches and methods used in the RTR program was completed in 2009. This methodology was highlighted to the SAB utilizing two RTR source categories: Petroleum Refining Sources MACT I and Portland Cement Manufacturing. The final SAB advisory is available at https://yosemite.epa.gov/sab/sabproduct.nsf/0/b031ddf79cffded38525734f00649caf!Ope nDocument&TableRow=2.3#2.

5) The individual dose-response assessment values used in the RTR assessment have themselves been the subject of peer reviews through the agencies that developed them (including EPA, through its Integrated Risk Information System, or IRIS; the California Environmental Protection Agency, or CalEPA; and the Agency for Toxic Substances and Disease Registry, or ATSDR).

We are not asking the SAB panel to duplicate or comment on previously reviewed methodologies, but rather to evaluate whether the specific enhancements to previously reviewed methodologies as described below are appropriate and scientifically credible.

Goals of This Review

We are seeking a scientific peer review of the updated screening methodologies. We are also seeking a scientific peer review of several specific enhancements to our chronic inhalation risk assessment that serve to reduce some of the uncertainties identified by EPA in the last SAB review. These updates and enhancements are outlined in the report: "Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis" (the report).

The most important revisions and enhancements to our methodologies since the last SAB review include the following:

ED_002496_00003261-00042

1) A tiered multipathway screening methodology that determines whether the potential for multipathway risk from persistent and bioaccumulative HAP (PB-HAP)[5]1 emitted from RTR source categories is low or whether more analysis is needed.

2) A tiered environmental screening methodology that determines whether the potential exists for adverse environmental effects from PB-HAP and the acid gases hydrogen chloride (HCl) and hydrogen fluoride (HF) emitted from RTR source categories.

3) The potential use of a new multipathway exposure scenario that can be used to estimate ingestion risk for members of urban or rural households who consume contaminated homegrown fruits and vegetables.

4) Enhancements to our previously reviewed inhalation risk assessment that allow us to more accurately model air concentrations where populations actually reside and to better characterize the dispersion of the air in the vicinity of sources.

ED_002496_00003261-00043

Charge questions for the Panel's consideration:

There are eight charge questions for this peer review, each of which has been placed in a box below. These eight questions concern three topic areas that cover the most important revisions and enhancements to our methodology since the last SAB review.

Multipathway Human Health Risk Screening Methodology (Chapters 2 and 3):

In RTR assessments, EPA considers ingestion risks using a multipathway approach, in which we model the dispersion, transport, and fate of HAPs emitted from facilities in specific source categories in the environment and estimate human health risks resulting from the ingestion of HAPs from food products, such as vegetables, fruit, meat, and fish.

Since the 2009 SAB review of RTR methods, we refined our original one-tier multipathway screen to include a three-tiered multipathway screening approach that progressively replaces health-protective default assumptions with location-specific data. Since full-scale facility-specific multipathway assessments are time consuming and expensive, the tiered screening approach "screens out" low-risk facilities for which no additional analysis is needed, so that only facilities with potentially higher risk remain in the pool for further analysis.

Chapter 2 of the report provides an overview of the tiered multipathway screening methodology, including a brief description of each multipathway screening tier. The technical detail on each tier of the multipathway screen is laid out in Chapter 3 of the report.

Charge Question 1: Does the SAB find that the three-tiered multipathway risk screening approach appropriately eliminates from further consideration those facilities unlikely to emit PB-HAP in concentrations resulting in appreciable multipathway risk and identifies those facilities where additional multipathway analysis may be warranted? Does the SAB have specific suggestions for improvement of the risk screening methodology?

Tier 1

The multipathway screen previously reviewed by SAB did not account for differences in environmental fate and transport among POM or dioxin congeners (i.e., all POM congeners were assumed to move, partition, and degrade in the environment as BaP does, and all dioxins were assumed to exhibit the same fate and transport as 2,3,7,8-TCDD). Section 3.1.2 of the Report describes the new risk equivalency factor (REF) approach that includes an exposure-equivalency factor (EEF) that reflects an individual chemical's fate and transport relative to the index chemical for each group (BaP for POM and 2,3,7,8-TCDD for dioxin).

Charge Question 2: Does the SAB find that the risk equivalency factor methodology appropriately accounts for differences in the environmental fate and transport among polycyclic organic matter (POM) and dioxin congeners?

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Tier 2
Section 3.2 of the report describes the Tier 2 multipathway screening scenario, in which some of the health-protective assumptions in the Tier 1 screen are replaced with more site- specific information. Specifically, in the Tier 2 assessment, site-specific information is used for the locations of potentially fishable lakes and meteorology. In addition, the Tier 2 assessment includes:

- A screening configuration that assesses the fisher and farmer exposure scenarios separately (see Sections 3.2.1.2 and 3.2.1.3).
- An estimation of lake productivity (see Section 3.2.2.2).
- The consideration that a fisher might catch and consume fish from more than one nearby contaminated lake, because more than one lake might be needed to catch enough fish for subsistence living (see Section 3.2.2.3).
- An approach that accounts for PB-HAP deposition into a lake from multiple facilities in the same RTR source category (see Section 3.2.2.3).

Charge Question 3: Does the SAB find that the assumptions for human fishing behavior used in the refined fisher scenario, the assumptions about PB-HAP deposition to lakes, and the assumptions on the ability of ponds and lakes to sustain populations of fish are appropriate?

Tier 3
The Tier 3 screening approach described in Section 3.3 of the report consists of three individual refinements to Tier 2 that are conducted in a step-wise fashion. These refinements include:

- Further analysis of the affected lakes identified in the Tier 2 screen (Section 3.3.1).
- Analysis of plume rise resulting in PB-HAPs lost to the upper atmosphere (Section 3.3.2).
- The use of time-series meteorology and effective release heights (Section 3.3.3).

Section 3.4 of the report describes a gardening exposure scenario we are considering adding to the Tier 3 multipathway screen. The gardening exposure scenario could help us to better characterize multipathway risk in some instances, especially in locations where the presence of a subsistence farm is either unlikely (e.g., in urban areas) or difficult to confirm based on the characterization of land use surrounding a facility.

Charge Question 4: Does the SAB find the methods used for evaluations of (1) lake data, (2) plume rise, and (3) time-series meteorological and time-series plume-rise data are appropriate?

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Charge Question 5: Does the SAB find the assumptions and approaches laid out for application in the gardener scenario to be appropriate? Does the SAB find that adding the gardener scenario to Tier 3 would improve our ability to characterize ingestion risks for urban and rural environments?

Environmental Risk Screening Methodology (Chapter 4):

Chapter 4 of the report describes the environmental risk screen that was developed to provide a systematic, scientifically defensible, and efficient approach that EPA can use to screen for potential adverse environmental effects associated with emissions of HAPs from facilities in RTR source categories. The screen can be run quickly and with minimal additional data gathering by drawing on existing data, models, and modeling results, including those developed for the human health multipathway risk screen.

The revised environmental risk screen presented in the report builds on and enhances the methods the SAB reviewed in 2009 as follows:

- Modeled environmental concentrations are compared to ecological benchmarks, not human health thresholds, for all pollutants included in the screen.
- A systematic evaluation of HAPs for potential inclusion in the screen was conducted.
- The environmental risk screen was expanded to include the following additional environmental HAPs: cadmium, hydrogen fluoride, lead, arsenic, and additional POMs.
- The number of ecological endpoints and effect levels that we evaluate was expanded.
- A comprehensive literature review was conducted to identify the most up-to-date ecological benchmarks.
- Tiers were added to the environmental risk screen for PB-HAP that are parallel to the tiers in the multipathway screen.

Charge Question 6: Does the SAB find that the environmental risk screening approach is appropriate for identifying facilities whose PB-HAP emissions may have the potential to cause adverse environmental effects? Specifically, does the SAB find that the pollutants (Section 4.2.1), ecological assessment endpoints (Section 4.2.2), and benchmarks (Section 4.3) that are included in the environmental risk screen are appropriate? Does the SAB have specific suggestions for improvement with regard to any aspect of this environmental risk screening methodology?

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Inhalation Risk Assessment Enhancements (Chapter 5):

Urban/Rural Dispersion Selection Tool
In previous chronic inhalation risk assessments, we assumed the land surrounding each facility was rural. Since the most recent SAB review in 2009, we developed an urban/rural enhancement to the chronic inhalation risk assessment that allows us to account for the urban/rural characteristics of the land surrounding each evaluated facility, and therefore, to better characterize the dispersion of pollutants near sources (Section 5.1).

Charge Question 7: Does the SAB find that the Urban/Rural Dispersion Selection Enhancement Tool is an appropriate procedure for identifying facilities to be modeled using the urban option in AERMOD?

Census Block Receptor Check Tool
In its 2009 review, the SAB noted that census block centroids might not always be an appropriate surrogate for residential locations. For example, when the census block centroid is located on industrial property ("on-site"), or when a census block is large and the centroid is far from where populations actually reside, using the centroid may not be appropriate. Since 2009, we developed the census block receptor enhancement (Section 5.2) that allows us to model air concentrations more accurately where populations actually reside. Specifically, the new enhancement automatically identifies census block centroids that might be located on facility, and census blocks that are very large. When onsite or large blocks are identified, we add new receptors, delete census block centroids, or move census block centroids to represent residential locations more accurately.

Charge Question 8: Does the SAB find that the Census Block Receptor Check Tool and associated enhancements are an appropriate method for identifying and adjusting model receptors to ensure the receptors are representative of residential locations?

ED_002496_00003261-00047

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 3/29/2019 5:38:52 PM
To: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
Subject: AIR POLLUTION: EPA advisory panel urges Wheeler to bring back fired experts -- Friday, March 29, 2019 -- www.eenews.net

https://www.eenews.net/greenwire/2019/03/29/stories/1060134247

EPA advisory panel urges Wheeler to bring back fired experts

Sean Reilly, E&E News reporter
Published: Friday, March 29, 2019

AIR POLLUTION

EPA headquarters in Washington. EPA/Flickr

A divided EPA advisory panel is asking for help as its ability to handle a high-stakes review of particulate matter standards is under harsh scrutiny.

At a public teleconference yesterday, the seven-member Clean Air Scientific Advisory Committee agreed to recommend that EPA Administrator Andrew Wheeler reconvene an

auxiliary panel of experts he abruptly fired last October — or name a new panel made up of members with similar know-how.

There's no assurance, however, the EPA chief will honor the request. A former contract lobbyist whose clients had included the nation's largest privately owned coal company, Wheeler has given little explanation for his decision to disband the auxiliary panel, which was charged with helping the main committee in its review of the existing national limits on airborne particulate pollution (*Greenwire*, Oct. 12, 2018).

EPA press aides had no immediate comment when asked in an email late yesterday whether Wheeler will accept the clean air committee's recommendation. Tony Cox, a Denver-based consultant who chairs the committee, said in an email that members have not discussed how to proceed if Wheeler rejects their request. Also unclear is whether revival of the auxiliary panel would serve as a drag on completing the review by EPA's self-imposed deadline of December 2020.

The committee, usually known by its acronym of CASAC, is charged with offering independent advice to EPA during the review of the particulate standards, which were last revised in 2012. But its members' fitness to do their jobs again came under biting attack yesterday from former CASAC members and other critics.

"This process is a travesty," Lianne Sheppard, an ex-member who is on the University of Washington's public health faculty, said during one of two sessions allotted for public feedback during the teleconference. Sheppard was one of more than a dozen people to speak, most of whom were similarly cutting.

For the committee, the call's primary purpose was to hammer out a final version of its report on a draft EPA roundup of scientific research on particulate matter's health and ecological effects. That draft roundup, released last fall and formally known as an integrated science assessment (ISA), cited evidence the existing standards are too weak.

The CASAC's preliminary report, made public early this month, had slammed the EPA document for employing "unverifiable opinions" to draw its conclusions and a litany of other alleged flaws. For the committee's detractors, the scathing tone and tentative findings fueled suspicions the panel has no intention of conducting an impartial review.

In a paper published last week, two of those critics accused Cox of pursuing an approach that would make it far more difficult for EPA to strengthen air quality standards to protect public health. Underlying calls for the revival of the auxiliary panel, which was made up mostly of scientists and researchers from academia, is the fact that the CASAC's current members mostly lack a deep background in air pollution research.

Cox, who has previously done work for the oil and chemical industries, had previously described the preliminary report as a CASAC document and accused opponents of distorting his views. Yesterday, however, he took responsibility for the language that has drawn the most attention and offered a partial mea culpa.

While Cox did not disavow the views underlying his earlier broadside, he said he "made a bad mistake by holding out this ideal of what science should be and then criticizing the ISA for not adhering to that ideal." A more useful approach, he said, would be to make specific recommendations for what the ISA should do "that it doesn't do now."

The bulk of the call was dedicated to hashing out a final version of the preliminary report the committee could then send to Wheeler with its blessing. All of the committee's seven members are rookies to EPA's intricate process for reviewing air quality standards. During the call, there were occasional struggles to follow Cox as he proposed major changes to the preliminary report.

"Where are we? What page are you on?" Steve Packham, a Utah state air official, asked at one point. The call, which had been scheduled to last four hours, ran closer to six. Citing a previous commitment, Corey Masuca, another member based in Alabama, dropped out early but left instructions with the EPA employee running the teleconference that he would go along with whatever the committee agreed on.

Dominating the remaining discussions were Cox and Mark Frampton, a retired professor of medicine from the University of Rochester; the two politely but repeatedly clashed over specific "wordsmithing" changes to the preliminary assessment. One of the lengthier debates involved whether to recommend that the research underpinning the ISA's conclusions should be "independently reproducible and verifiable."

"This could be read as indicating that all studies should be thrown out unless somebody has gone in and reproduced them," Frampton said. The wording, he indicated, reminded him of former EPA chief Scott Pruitt's controversial proposal to more broadly bar the use of studies in drafting new regulations for which the underlying data were not transparent and reproducible.

"The thing is, it should be independently reproducible — otherwise it's not science," Cox later replied, shortly before broaching a compromise that appeared to win Frampton's assent. At the call's conclusion, committee members verbally signed off on some significant changes to the original draft. Those changes will now be incorporated into a final version that will go to Wheeler; besides urging revival of the auxiliary panel, the committee is also calling on EPA to do a second draft of the ISA.

Under the Clean Air Act, particulate matter is one of a half-dozen "criteria" pollutants for which EPA is supposed to periodically review and, if needed, tighten National Ambient Air Quality Standards.

The use of auxiliary panels to augment the main CASAC's expertise dates back decades. In defending Wheeler's decision to fire the particulate matter review panel last fall, a spokesman said it was consistent with the Clean Air Act and the CASAC's charter, neither of which mentions such panels.

In response to a congressional query preceding his Senate confirmation earlier this year, Wheeler said he believed that the main committee "has the experience and expertise needed to serve in this capacity." He added that EPA can also tap advice from other experts to assist the CASAC as needed.

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 12/11/2018 10:27:32 PM
To: Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]
Subject: CASAC

Deliberative Process / Ex. 5

the policy decisions the CAA requires the Administrator to make."

More background:

Deliberative Process / Ex. 5

1. Deliberative Process / Ex. 5

participated in previous NAAQS reviews for ozone and particulate matter. The full line up: Dr. Anthony (Tony) Cox, Cox Associates (Chair); Dr. James Boylan; Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/18/2018 11:08:50 AM
To: Sasser, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=477638fe84004800bfdf8e62fe3cafc8-ESASSER]
Subject: Re: Charge questions -- PM ISA

An email would be great - Unclear to me if there were any changes in version that went to the Chair. Thanks!

On Oct 18, 2018, at 7:03 AM, Sasser, Erika <Sasser.Erika@epa.gov> wrote:

Deliberative Process / Ex. 5

It's also out for review with Tony Cox so he may ask for some specificity too.

From: Woods, Clint
Sent: Thursday, October 18, 2018 6:56 AM
To: Sasser, Erika <Sasser.Erika@epa.gov>
Subject: Fwd: Charge questions -- PM ISA

Erika,

Did we have any targeted additions? Thanks!

Begin forwarded message:

From: "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>
Date: October 12, 2018 at 12:11:28 PM EDT
To: "Woods, Clint" <woods.clint@epa.gov>, "Dunlap, David" <dunlap.david@epa.gov>
Subject: FW: Charge questions -- PM ISA

Clint, to follow up on the latest, attached are the draft charge questions. Note a copy also shared w Erika. Have a good wkend!

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
Office of Research and Development
US Environmental Protection Agency
Cell
DC **Cell Phone / Ex. 6**

RT Cell Phone / Ex. 6

From: Bahadori, Tina
Sent: Friday, October 12, 2018 10:47 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Vandenberg, John <Vandenberg.John@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>
Subject: Charge questions -- PM ISA
Importance: High

Hi Jennifer,

Deliberative Process / Ex. 5

Thanks,
Tina

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 4/3/2019 7:48:31 PM
To: Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]
CC: Jones, Lindsey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e1ca93678b0469eb3943c9612a2b7ff-Jones, Lind]
Subject: Re: CASAC nominations list of ecologists

+ Lindsey

On Apr 3, 2019, at 3:41 PM, Dunlap, David <dunlap.david@epa.gov> wrote:

> Yes final list as far as I aware. Plane racing for takeoff. You did no copy Lindsey.
>
> David D. Dunlap
> Deputy Assistant Administrator
> EPA Office of Research & Development
> Office Cell Phone / Ex. 6
>
> On Apr 3, 2019, at 3:40 PM, Woods, Clint <woods.clint@epa.gov> wrote:
>
>> Thanks – That was final list? Lindsey, you, and I should talk about some CASAC stuff in the next week or so.
>>
>> **From:** Dunlap, David
>> **Sent:** Wednesday, April 3, 2019 3:39 PM
>> **To:** Woods, Clint <woods.clint@epa.gov>
>> **Subject:** Fwd: CASAC nominations list of ecologists
>>
>> FYI - These names are ready to post for public comment Deliberative Process / Ex. 5
>> Deliberative Process / Ex. 5
>>
>> DDD
>>
>> David D. Dunlap
>> Deputy Assistant Administrator
>> EPA Office of Research & Development
>> Offic Cell Phone / Ex. 6
>>
>> Begin forwarded message:
>>
>>> **From:** "Brennan, Thomas" <Brennan.Thomas@epa.gov>
>>> **Date:** March 25, 2019 at 10:38:50 AM EDT
>>> **To:** "Dunlap, David" <dunlap.david@epa.gov>, "Woods, Clint" <woods.clint@epa.gov>
>>> **Cc:** "Fitzmorris, Amanda" <fitzmorris.amanda@epa.gov>
>>> **Subject: CASAC nominations list of ecologists**
>>>
>>> Hi Clint and David,

Just as a reminder, the CASAC nomination period for ecologists closes on Thursday 3/28.

Here is what I have so far:

Person	City	State	Organization	Address Affiliation	Who Referred
Deliberative Process / Ex. 5					
Deliberative Process / Ex. 5			Western		Dr. Tony Cox, CASAC Chair
Deliberative Process / Ex. 5			National		
Deliberative Process / Ex. 5					Dr. Tony Cox, CASAC Chair

Tom Brennan
Acting Director, Science Advisory Board Staff Office
US Environmental Protection Agency

Desk # 202 564 6953
Mobile # 703 581 9300

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/23/2018 12:13:02 PM
To: Sasser, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=477638fe84004800bfdf8e62fe3cafc8-ESASSER]
CC: Tsirigotis, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d19c179f3ccb4fadb48e3ae85563f132-PTSIRIGO]; Koerber, Mike [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c513901d4fd49f9ab101a6f7a7a863e-Koerber, Mike]
Subject: Re: Revised Charge questions -- PM ISA

I agree - Thanks! Hoping to get feedback on ozone IRP draft back today

On Oct 22, 2018, at 6:20 PM, Sasser, Erika <Sasser.Erika@epa.gov> wrote:

Deliberative Process / Ex. 5

From: Woods, Clint
Sent: Monday, October 22, 2018 6:36 AM
To: Sasser, Erika <Sasser.Erika@epa.gov>; Tsirigotis, Peter <Tsirigotis.Peter@epa.gov>; Koerber, Mike <Koerber.Mike@epa.gov>
Subject: Fwd: Revised Charge questions -- PM ISA

FYI - Thanks!

Begin forwarded message:

From: "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>
Date: October 22, 2018 at 4:56:57 AM EDT
To: "Woods, Clint" <woods.clint@epa.gov>
Cc: "Dunlap, David" <dunlap.david@epa.gov>
Subject: Fwd: Revised Charge questions -- PM ISA

Updated. Thanks Clint

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
Office of Research and Development
US EPA
Cell
DC Personal Phone / Ex. 6
RTP

Begin forwarded message:

From: "Vandenberg, John" <Vandenberg.John@epa.gov>
Date: October 22, 2018 at 1:25:06 AM EDT

To: "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>
Cc: "Bahadori, Tina" <Bahadori.Tina@epa.gov>, "Dunlap, David" <dunlap.david@epa.gov>, "Rodan, Bruce" <rodan.bruce@epa.gov>
Subject: Revised Charge questions -- PM ISA

Jennifer,

Attached is a revised draft Charge to CASAC for review of the PM ISA.

Deliberative Process / Ex. 5

Tony Cox, CASAC Chair, Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Please let me know if you'd like to see a Track Changes version.

Deliberative Process / Ex. 5

Thank you,

John

From: Orme-Zavaleta, Jennifer
Sent: Thursday, October 18, 2018 11:27 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: RE: Charge questions -- PM ISA

Helpful, thanks Tina

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
Office of Research and Development
US Environmental Protection Agency
Ce
DC Personal Phone / Ex. 6
RT

From: Bahadori, Tina
Sent: Thursday, October 18, 2018 10:58 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: RE: Charge questions -- PM ISA

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

We will send a revised version to you soon.

Thanks,
Tina

From: Orme-Zavaleta, Jennifer
Sent: Thursday, October 18, 2018 10:24 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>
Subject: FW: Charge questions -- PM ISA

See below from Clint. Send an updated charge. thanks

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
Office of Research and Development
US Environmental Protection Agency
Cell Personal Phone / Ex. 6
DC
RTP

From: Woods, Clint
Sent: Thursday, October 18, 2018 9:43 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>
Subject: Re: Charge questions -- PM ISA

Jennifer,

Thanks for the chance to look at these charge questions. Realizing a version went to CASAC leadership for their response, I wanted to share a bit of feedback from conversations with OAQPS.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks again!

Clint

On Oct 12, 2018, at 12:11 PM, Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov> wrote:

> Clint, to follow up on the latest, attached are the draft charge questions. Note a copy also shared w Erika. Have a good wkend!
>
> Jennifer Orme-Zavaleta, PhD
> Principal Deputy Assistant Administrator for Science
> Office of Research and Development
> US Environmental Protection Agency
> Cel Personal Phone / Ex. 6
> DC
> RTP
>
> ---
>
> **From:** Bahadori, Tina
> **Sent:** Friday, October 12, 2018 10:47 AM
> **To:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
> **Cc:** Vandenberg, John <Vandenberg.John@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>

Subject: Charge questions -- PM ISA
Importance: High

Hi Jennifer,

Deliberative Process / Ex. 5

Thanks,
Tina

<PM ISA Charge to CASAC unsigned 10-12-18.docx>

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 4/2/2019 6:30:57 PM
To: Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]
CC: Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]
Subject: RE: "If I were still working at the EPA, I would resign"

Fact check below – Copied Schwab to review yellow highlighting on 10/2017 FACA memo

1. "Last week, the Environmental Protection Agency's Clean Air Scientific Advisory Committee met via teleconference to devise a new standard for airborne particle pollution."

Deliberative Process / Ex. 5

2. "Congress established this committee in 1977 to provide unbiased external scientific advice on air-pollutant standards, which are revisited every five years. Congress requires the committee to have seven members, including one from a state agency. But it soon became clear that a seven-member committee would not have sufficient in-depth expertise to make a science-based recommendation. Accordingly, for more than 40 years, the committee has drawn on the expertise of external advisory subcommittees established for each pollutant of concern."

Deliberative Process / Ex. 5

3. "That is how it is supposed to work. But last October, Wheeler suddenly and highhandedly terminated the subcommittees working to develop recommendations for the particulate standard, as well as the standard for ozone pollution (which CASAC will review next)."

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

4. "Wheeler has appointed four state agency members to CASAC, an unprecedented majority. All work for Republican governors."

Deliberative Process / Ex. 5

5. "Moreover, Wheeler promulgated a new rule that prohibits scientists funded by the EPA from providing the agency with advice."

Deliberative Process / Ex. 5

6. "I cannot ask President Trump's EPA assistant administrator for research and development to resign. That position remains unfilled."

Deliberative Process / Ex. 5

From: Konkus, John
Sent: Tuesday, April 2, 2019 12:20 PM
To: Woods, Clint <woods.clint@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>
Subject: RE: "If I were still working at the EPA, I would resign"

Yes. Let's consider a fact check. Since the Washington Post opinion editors only selectively fact check.

From: Woods, Clint
Sent: Tuesday, April 2, 2019 12:18 PM
To: Konkus, John <konkus.john@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>
Subject: "If I were still working at the EPA, I would resign"

RE: CASAC PM Panel. This op-ed has multiple factual errors – Let me know if you all want them catalogued.

https://www.washingtonpost.com/opinions/if-i-were-still-working-at-the-epa-i-would-resign/2019/04/02/88e6e2b8-519a-11e9-88a1-ed346f0ec94f_story.html?noredirect=on&utm_term=.769efe69650d

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 9/26/2018 12:35:48 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Attachments: EPA-SAB-18-002+.pdf; ATT00001.htm

https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/E7CB10891C8CAD8F852582B3006EFAF7/$File/EPA-SAB-18-002+.pdf

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

June 21, 2018

EPA-SAB-18-001

The Honorable E. Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Subject: Science Advisory Board (SAB) Consideration of EPA Planned Actions in the Spring 2017 Unified Agenda of Regulatory and Deregulatory Actions and their Supporting Science

Dear Administrator Pruitt:

As part of its statutory duties, the EPA's Science Advisory Board recently concluded discussions about possible review of the science supporting major EPA planned actions associated with the Spring 2017 Unified Agenda of Regulatory and Deregulatory Actions. The EPA Office of Policy provided notice of the release of this information on July 20, 2017. The SAB discussed whether to review the science supporting any of the planned regulatory actions in that agenda in order to provide advice and comment on the adequacy of the science, as authorized by section (c) of the Environmental Research, Development and Demonstration Authorization Act, during a public meeting held on May 31, 2018.

The SAB focused its attention on 12 major planned actions identified by the EPA Office of Policy and published in the *Federal Register*. The SAB convened a Work Group to review the planned actions, conduct fact-finding, and develop recommendations for further consideration by the chartered SAB[1]. At the public meeting, the SAB discussed the Work Group's findings and decided to undertake review of the science supporting three of the actions in the semi-annual regulatory agenda at this time. The SAB also identified two actions for which insufficient information was available and deferred a determination until such information is available. The list of actions considered is enclosed.

[1] Memorandum: Preparations for Chartered Science Advisory Board (SAB) Discussions of EPA Planned Agency Actions and their Supporting Science in the Spring 2017 Regulatory Agenda https://yosemite.epa.gov/sab/sabproduct.nsf/A4070377D540D61B8525827F0075E673/$File/SABWkGrpSpring2017Att+ABC.pdf

The SAB notes that nine of the planned actions were listed as long-term actions. The Office of Management and Budget defines long term actions as planned actions "under development but for which the Agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda" and notes that some long-term actions may only have abbreviated information. The SAB considered the stage of rulemaking of the planned actions and notes that the Board has the option to defer a decision on whether the planned action merits further review until sufficient information is available.

EPA Planned Actions that Merit SAB Review

Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed, and Modified Sources (RIN 2060-AT54): This planned action merits review by the SAB. The SAB has considered two previous actions regarding Oil and Gas New Source Performance Standards: 1) *Oil and Natural Gas Sector: Reconsideration of Remaining Provisions of New Source Performance Standards (RIN 2060-AS30);* and 2) *Guidelines for the Existing Oil and Natural Gas Sector (RIN 2060–AT29).* The SAB found that the EPA sought out expert review and public input and determined that the *Remaining Provisions to the NSPS (RIN 2060-AS30)* did not merit further review[2] stating that further SAB input was likely to provide marginal benefits to the Agency's expert input processes. The SAB deferred consideration of a related rule, the *Emission Guidelines for the Existing Oil and Natural Gas Sector (RIN 2060–AT29)* noting there was insufficient information to review the planned action and the SAB requested the agency provide more information about the scientific and technical basis. The Agency informed the SAB that the Guideline rule (2060-AT29) withdraws the 2016 Information Collection Request (ICR) from the oil and gas industry and no further activity is anticipated. Thus, this action is currently listed as completed in the Spring 2017 Regulatory agenda.

The EPA has made a broad commitment to reviewing the information in the original rule setting the NSPS promulgated in 2016[3] and evaluating the information submitted by commenters on the current action (RIN 2060-AT54). The EPA states that, at this time, they do not anticipate using new Influential Scientific Information (ISI) during the reconsideration of additional requirements. However, the scientific and technical basis for identifying and evaluating measures being reconsidered for methods to reduce emissions of greenhouse gases, including methane, and volatile organic compounds (VOCs) in the oil and natural gas industry was not provided. Given that some time has elapsed since the rule-making processes for the 2016 Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources was finalized, information regarding the scientific and technical basis for identifying alternative measures applicable to individual power plants may have changed. Therefore, the SAB recommends a review of any new ISI that would change the prior justification for the rule.

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[2] Preparations for Chartered SAB Discussions of EPA Planned Actions and Their Supporting Science in the Fall 2014 Regulatory Agenda (Attachment B and C) available at: https://yosemite.epa.gov/sab/sabproduct.nsf/8D67738EFAF3C69385257E3500532AF6/$File/Work+Group+Memorandum+Fall+2014+Reg+Rev+posted.pdf

[3] Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources (Federal Register 81 35824-35942) 40 CFR part 60, subpart OOOOa

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Review of the Clean Power Plan (RIN 2060-AT55): This action also merits review by the SAB. The review of the Clean Power Plan (CPP) pertains to a scope of scientific and technical issues that should be considered and subjected to peer review. Limited information was available to the SAB about this planned action. The scientific and technical basis for identifying and evaluating measures including heat rate improvement, and other options that are applicable to individual plants, is not specified in the announcements of the planned action. The identification and use of ISI or Highly Influential Scientific Information (HISI) is not explained or defined. In the SAB Work Group's fact-finding, the EPA was asked to provide further details regarding what specific sources of new information will be used and how ISI or HISI will be properly vetted through a rigorous peer review process (See Attachment C of the Work Group memorandum[4]). The Agency replied that public comments were being solicited on "whether there are additional control measures and information beyond what was included in the original Clean Power Plan." The response did not address whether the EPA would seek updated information on measures that were included in the original CPP, or whether such information would be considered ISI or HISI, or, the nature of peer review procedures planned for any ISI or HISI.

In the absence of information from the EPA, a presumption could be made that there have been updates to scientific and technical information for control measures that were included in the original CPP. Given the potential significance of the CPP with regard to addressing GHG emissions that endanger public health and welfare, and the myriad of potential best systems of emissions reductions, further SAB review of this matter is warranted to ensure the soundness of the scientific and technical basis for the action.

Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units (RIN 2060-AT56): This planned action merits review by the SAB. In its *Federal Register* notice the EPA stated that the Agency "will review whether this Rule or alternative approaches appropriately maintain the diversity of reliable energy resources and encourage the production of domestic energy sources to achieve energy independence and security." This statement implies that scientific questions and new analyses may arise regarding diversity of energy sources, reliability of energy sources, or capabilities to recover or utilize energy resources domestically. These analyses may be novel and require review or development of methodology and collection and evaluation of data. The specific scope of technical issues to be addressed is not provided, such as regarding what fuels, co-firing, firing, gasification, control, steam cycle, sequestration, and other options might form the basis of determination of best systems of emissions reduction. There is further complexity since this rule covers new, modified, and reconstructed facilities. The applicable range of options may differ depending on these stages of the plant life cycle. Based on a fact-finding query, the EPA indicated that it "plans to issue a proposed revision to the final NSPS and will consider comments it receives on that proposal." However, no further details were provided. (See Attachment C of the Work Group Memorandum[5]).

Given the potential significance of the Rule with regard to addressing GHG emissions that endanger public health and welfare, and the myriad of potential best systems of emissions

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[4] Ibid.
[5] Ibid.

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reductions, further SAB review of this matter is warranted to ensure the soundness of the scientific and technical basis for the action.

The full SAB overwhelmingly voted to categorize these three activities as meriting further review, rather than deferring them until additional information is available, in part for expediency. If the EPA ultimately provides the SAB with supporting scientific and technical information demonstrating that the activities do not use new ISI or HISI, the SAB will not review them.

EPA Planned Actions Awaiting Further Information for SAB Review

Two separate planned actions consider the recodification of the Waters of the United States. *Definition of "Waters of the United States" – Recodification of Preexisting Rules (RIN 2040-AF74)*: This planned action does not merit further SAB consideration. It redefines WOTUS from the current 2015 rule to the definition in place before 2015. The goal of this first step is to provide stability in the regulation of the Clean Water Act pursuant to a decision issued by the U.S. Court of Appeals for the Sixth Circuit staying the 2015 WOTUS definition, a decision that is under review by the Supreme Court.

Second Action: Definition of "Waters of the U.S." (RIN 2040-AF75): The SAB will defer a decision on reviewing this planned action until reviewable supporting documents or draft rule language are available. A significant amount of time and effort has gone into determining the connectivity of different water bodies to downstream navigable waters. The science related to that connectivity has been well documented by well over hundreds of journal articles and technical reports. The SAB has reviewed EPA's September 2013 scientific report and synthesis that documented this extensive literature.

In 2014, the SAB provided a report to the EPA Administrator and recommended that the interpretation of connectivity be revised from a binary, categorical distinction (connected versus not connected) to a gradient that is a function of the frequency, duration, magnitude, predictability, and consequences of physical, chemical, and biological connections. The SAB also commented on approaches to measuring or otherwise quantifying connectivity.

The SAB reviewed the proposed rule "Definition of 'Waters of the United States' Under the Clean Water Act[6]" and provided advice and comments[7] related to that proposal. The SAB found that the available science provides an adequate scientific basis for the key components of the proposed rule.

EPA's Office of Water stated it does not intend to develop any new work products to support *Definition of "Waters of the U.S." (RIN 2040-AF75*), yet it is unclear how any development of new boundaries can be justified without new scientific analysis and further review by the SAB.

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[6] Definition of ''Waters of the United States'' Under the Clean Water Act RIN 2040–AF30 (FR 79 22188-22274)
[7] Science Advisory Board (SAB) Consideration of the Adequacy of the Scientific and Technical Basis of the EPA's Proposed Rule titled "Definition of Waters of the United States under the Clean Water Act" available at: https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/518D4909D94CB6E585257D6300767DD6/$File/EPA-SAB-14-007+unsigned.pdf

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The SAB should evaluate the science that would support any decision about bright-line boundaries for WOTUS jurisdiction. The SAB requests that the EPA provide briefings on the science that would underlie the Agency's selection of these boundaries and justify what is and is not jurisdictional under the revised WOTUS rule.

The SAB found that at present there is insufficient information to make a determination as to whether a review of *Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK34)* will be warranted. At this time, it is not known what information base is available for the five chemical compounds, the particulars of the peer review process, or whether the individual chemical assessments will be brought back to the SAB or the Scientific Advisory Committee on Chemicals. The EPA is developing a plan and has indicated that letter peer review will be used. Due to the timeframes established by the statute, and the need to determine the likelihood of exposure, the EPA plans to use reasonably available information to complete exposure and use assessments. Depending on the available information base, these assessments may be qualitative or quantitative. The assessments are intended to support rulemaking under TSCA section 6(h) in order to reduce exposure to the extent practicable. The SAB has previously reviewed planned actions for specific TSCA chemical assessments and urged the EPA to continue this level of robust transparent peer review. A final recommendation on further SAB review will await the provision of updated information about these scientific and technical issues.

EPA Planned Actions Not Meriting Further SAB Review

National Primary Drinking Water Regulations: Finished Water Storage Facility Inspection Requirements Addendum to the Revised Total Coliform Rule (RIN2040-AF37): This action does not merit further SAB consideration. The SAB notes that the Safe Drinking Water Act requires EPA to request comments from the Board prior to proposal of a maximum contaminant level goal and national primary drinking water regulation. Thus, EPA may bring this action to the SAB in the future.

Clean Water Act Hazardous Substances Spill Prevention (RIN2050-AG87): This action does not merit further SAB consideration. EPA states that no scientific work products are being developed and standard methods for regulatory impact and economic analyses are being used. Data from the National Response Center will be surveyed from 2007 through 2016, and impacts will be assessed with information from National Toxic Substance Incident Program. While the environmental risks are high and uncertainties growing, especially given the recent decision to open more off shore drilling across the US Coasts, there is no scientific work to be analyzed and evaluated by SAB.

Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide (RIN2060-AR57): This action does not merit further SAB consideration. This action will undergo a multi-year detailed review process by the EPA Clean Air Scientific Advisory Committee and its Nitrogen Oxides Review Panel. CASAC is a FACA committee. The NOx Review Panel will be specifically constituted, in terms of independent scientific expertise, to review this proposed action. CASAC has a statutory mandate under the Clean Air Act to advise the Administrator regarding National Ambient Air Quality Standards (NAAQS).

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The SAB finds that two actions regarding the eight-year review of National Emissions Standards for Hazardous Air Pollutants (NESHAPs) do not merit further SAB consideration. They are the risk and technology review (RTR) for the *National Emission Standards for Hazardous Air Pollutants for Iron and Steel Foundries (RIN 2060-AT30)* and *National Emission Standards for Hazardous Air Pollutants: Asphalt Processing and Asphalt Roofing Manufacturing Residual Risk and Technology Review (RIN 2060-AT34*) While the details of each RTR are unique to the sources and pollutants being evaluated, the general approaches and methodologies employed in EPA RTRs have become standardized, have been employed in numerous previous RTRs, and have been subject to multiple peer reviews over the past 17 years. As EPA's RTR methodologies are refined and revised over time, there is a need for periodic peer reviews of the changing methods. In addition, the SAB just completed the review of recent revisions to the screening methodologies used to support RTR reviews. Given the extensive past and currently ongoing peer reviews that have been conducted on RTR methodologies, the SAB finds that review is not warranted for these specific RTRs at this time.

Review of Pesticides; Certification of Pesticide Applicators (RIN 2070-AK37) In the current context this action does not merit further SAB consideration. If EPA identifies a need for changes to the certification rule, SAB review may be warranted. In a related planned action (RIN 2070-AJ20), EPA's FIFRA Science Advisory Panel considered whether to review certification for pesticide applicators and waived its review of the proposed rule on September 4, 2014, and the final rule on August 15, 2016, because the proposed revisions were administrative in nature and did not contain scientific issues that required the SAP's consideration.

SAB Requests Improvements in the Descriptions of EPA Planned Actions

The SAB thanks the EPA for providing information for consideration but emphasizes that more complete and timely information is required from the Agency to make recommendations and decisions regarding the science supporting planned actions. To improve the process for future review of the semi-annual regulatory agenda, the SAB strongly recommends that the EPA enhance descriptions of future planned actions by providing specific information on the peer review associated with the science basis for actions and more robust descriptions of the scientific and technical bases for the actions. In reviewing the Spring 2017 Regulatory Agenda, there were several cases where key information about the planned action, its supporting science and peer review were provided only after specific SAB Work Group requests. The SAB finds that the EPA's written responses to fact finding questions were not comprehensive and participation in the fact-finding teleconference was limited.

Effective SAB evaluation of planned actions requires the Agency to characterize the following elements in the initial descriptions provided to the work group:

- All relevant key information associated with the planned action.
- The science supporting the regulatory action. If there is new science to be used, provide a description of what is being developed. If the EPA is relying on existing science, provide a short description.

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- The nature of planned or completed peer review. To the extent possible, provide information about the type of peer review, the charge questions provided to the reviewers, how relevant peer review comments were integrated into the planned action, and information about the qualifications of the reviewer(s).

Despite the SAB making several of these recommendations in previous reviews, less information is being provided. We request that the Agency provide more complete information to support future SAB decisions about the adequacy of the science supporting actions in future regulatory agendas.

On behalf of the SAB, I thank you for the opportunity to support EPA through consideration of the science supporting actions in the Agency's regulatory agenda.

Sincerely,

/S/

Dr. Michael Honeycutt, Chair
Science Advisory Board

Enclosure
(1) Summary of Proposed Actions Considered
(2) Roster of SAB Members

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NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to 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 Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA Web site at http://www.epa.gov/sab.

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Summary of Proposed Actions Considered

Proposed actions in the Spring 2017 Unified (Regulatory) Agenda and Regulatory Plan considered by the Science Advisory Board and whether to provide advice and comment on the adequacy of the science supporting the action		
RIN[1]	**Planned Action Title**	**Recommendation**
2060-AT54	Review of the 2016 Oil and Gas New Source Performance Standards for New, Reconstructed, and Modified Sources	Merits review by the SAB.
2060-AT55	Review of the Clean Power Plan	Merits review by the SAB
2060-AT56	Review of the Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Generating Units	Merits review by the SAB
2040-AF75	Second Action: Definition of "Waters of the U.S."	Defer a determination until sufficient information is available
2070-AK34	Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)	Defer a determination until sufficient information is available
2040-AF37	National Primary Drinking Water Regulations: Finished Water Storage Facility Inspection Requirements Addendum to the Revised Total Coliform Rule	No further SAB consideration is merited.
2040-AF74	Definition of "Waters of the United States" – Recodification of Preexisting Rules	No further SAB consideration is merited.
2050-AG87	Clean Water Act Hazardous Substances Spill Prevention	No further SAB consideration is merited.
2060-AR57	Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide	No further SAB consideration is merited.

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Proposed actions in the Spring 2017 Unified (Regulatory) Agenda and Regulatory Plan considered by the Science Advisory Board and whether to provide advice and comment on the adequacy of the science supporting the action		
RIN[1]	**Planned Action Title**	**Recommendation**
2060-AT30	National Emission Standards for Hazardous Air Pollutants for Iron and Steel Foundries	No further SAB consideration is merited.
2060-AT34	National Emission Standards for Hazardous Air Pollutants: Asphalt Processing and Asphalt Roofing Manufacturing Residual Risk and Technology Review	No further SAB consideration is merited.
2070-AK37	Review of Pesticides; Certification of Pesticide Applicators	No further SAB consideration is merited.

[1]The Regulatory Identification Number provides a hyperlink to the Office of Management and Budget's webpage and information on the planned action provided in the Unified Regulatory Agenda on the OMB website http://www.reginfo.gov/

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U.S. Environmental Protection Agency
Science Advisory Board

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Also Member: CASAC

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Dr. Otto C. Doering III, Professor, Department of Agricultural Economics, Purdue University, W. Lafayette, IN

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Dr. Joel J. Ducoste, Professor, Department of Civil, Construction, and Environmental Engineering, College of Engineering, North Carolina State University, Raleigh, NC

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Dr. John D. Graham, Dean, School of Public and Environmental Affairs, Indiana University, Bloomington, IN

Dr. Steven P. Hamburg, Chief Scientist, Environmental Defense Fund, Boston, MA

Dr. Cynthia M. Harris, Director and Professor, Institute of Public Health, Florida A&M University, Tallahassee, FL

Dr. Merlin R. Lindstrom, Vice President Technology, Phillips 66 Research Center, Bartlesville, OK

Dr. Robert E. Mace, The Meadows Center for Water and the Environment, Texas State University, San Marcos, TX

Dr. Clyde F. Martin, Horn Professor of Mathematics, Emeritus, Department of Mathematics and Statistics, Texas Tech University, Crofton, MD

Dr. Sue Marty, Senior Toxicology Leader, Toxicology & Environmental Research, The Dow Chemical Company, Midland, MI

Dr. Kristina D. Mena, Associate Professor, Epidemiology, Human Genetics and Environmental Sciences, School of Public Health, University of Texas Health Science Center at Houston, El Paso, TX

Dr. Surabi Menon, Director of Research, ClimateWorks Foundation, San Francisco, CA

Mr. Robert W. Merritt, Independent Consultant, Houston, TX

Dr. Larry Monroe, Independent Consultant, Braselton, GA

Dr. Thomas F. Parkerton, Senior Environmental Associate, Toxicology & Environmental Science Division, ExxonMobil Biomedical Science, Houston, TX

Dr. Robert Phalen, Professor, Air Pollution Health Effects Laboratory, Medicine, Department of

ED_002496_00004378-00012

Medicine, University of California-Irvine, Irvine, CA

Mr. Richard L. Poirot, Independent Consultant, Burlington, VT

Dr. Kenneth M. Portier, Independent Consultant, Athens, GA

Dr. Robert Puls, Owner/Principal, Robert Puls Environmental Consulting, Hilton Head Island, SC

Dr. Kenneth Ramos, Associate Vice-President of Precision Health Sciences and Professor of Medicine, Arizona Health Sciences Center, University of Arizona, Tucson, AZ

Dr. Tara L. Sabo-Attwood, Associate Professor and Chair, Department of Environmental and Global Health, College of Public Health and Health Professionals, University of Florida, Gainesville, FL

Dr. William Schlesinger, President Emeritus, Cary Institute of Ecosystem Studies, Millbrook, NY

Dr. Anne Smith, Managing Director, NERA Economic Consulting, Washington, DC

Dr. Richard Smith, Professor, Department of Statistics and Operations Research, University of North Carolina, Chapel Hill, NC

Dr. Jay Turner, Associate Professor and Vice Dean for Education, Department of Energy, Environmental and Chemical Engineering, School of Engineering & Applied Science, Washington University, St. Louis, MO

Dr. Jeanne M. VanBriesen, Duquesne Light Company Professor of Civil and Environmental Engineering, and Director, Center for Water Quality in Urban Environmental Systems (Water-QUEST), Department of Civil and Environmental Engineering, Carnegie Mellon University, Pittsburgh, PA

Dr. Donald vanderVaart, Independent Consultant, Raleigh, NC

Dr. Kimberly White, Senior Director, Chemical Products and Technology Division, American Chemistry Council, Washington, DC

Dr. Peter J. Wilcoxen, Laura J. and L. Douglas Meredith Professor for Teaching Excellence, Director, Center for Environmental Policy and Administration, The Maxwell School, Syracuse University, Syracuse, NY

Dr. S. Stanley Young, Chief Executive Officer, CGStat, Raleigh, NC

SCIENCE ADVISORY BOARD STAFF

Mr. Thomas Carpenter, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board Washington, DC

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Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/16/2018 7:48:55 PM
To: Dickerson, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0440d9f06994021827e0d0119126799-Dickerson,]; Molina, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d19c1d68da1a4587866e1850f22a6ae5-Molina, Mic]
Subject: FW: Clean Air Advisory Committees
Attachments: CASAC Details 10-16-18.docx

FYI - Attached is briefing material. Not sure if our folks have been in touch on timing.

-----Original Message-----
From: adm15.arwheeler.email
Sent: Tuesday, October 16, 2018 2:20 PM
To: Wehrum, Bill <Wehrum.Bill@epa.gov>; Woods, Clint <woods.clint@epa.gov>
Subject: Clean Air Advisory Committees

I would like a briefing on the two committees disbanded last week, sometime tomorrow. Thanks.

- Andrew

Sent from my iPhone

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/16/2018 7:05:00 PM
To: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
Subject: FW: CASAC Talking Points

Suggested briefing material:

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/10/2018 10:10:50 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
BCC: jsloan@csg.org; mkeogh@4cleanair.org; Kelly Poole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user5e432e30]; bbeckstead@westgov.org; Elizabeth_Horner@epw.senate.gov; Andrew_Zach@epw.senate.gov; peter.spencer@mail.house.gov
Subject: Fwd: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee

FYI - Thanks!

Begin forwarded message:

> **From:** "EPA Press Office" <press@epa.gov>
> **Date:** October 10, 2018 at 5:07:53 PM EDT
> **To:** "woods.Clint@epa.gov" <woods.Clint@epa.gov>
> **Subject: Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee**
> **Reply-To:** press@epa.gov

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

---

WASHINGTON (October 10, 2018) – Today, U.S. Environmental Protection Agency (EPA) Acting Administrator Andrew Wheeler announced the appointment of five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). This seven-member panel, required under Section 109 of the Clean Air Act, provides critical advice related to National Ambient Air Quality Standards (NAAQS), including about how to set standards that protect public health with an adequate margin of safety, the role of background pollution, research needs, and potential adverse effects from strategies to meet these standards. Consistent with the Clean Air Act and CASAC's charter, Acting

Administrator Wheeler also tasked this panel with leading the review of science for any necessary changes to the NAAQS for ozone or particulate matter. As outlined in the May 2018 "Back-to-Basics Process for Reviewing NAAQS" memorandum these changes would be finalized by late 2020.

"These experts will provide critical scientific advice to EPA as it evaluates where to set national standards for key pollutants like ozone and particulate matter," said Acting Administrator Wheeler. **"They are highly qualified and have a diverse set of backgrounds in fields like toxicology, engineering, medicine, ecology, and atmospheric science. These individuals, including five panelists who work in state, local, or federal environmental agencies, will work hard over the next two years to advise EPA in a manner consistent with the Clean Air Act and the protection of public health."**

The seven-member chartered CASAC:

- Dr. Anthony (Tony) Cox, Cox Associates (Chair)
- Dr. James Boylan, Georgia Department of Natural Resources
- Dr. Mark Frampton, University of Rochester Medical Center
- Dr. Sabine Lange, Texas Commission on Environmental Quality
- Dr. Timothy Lewis, U.S. Army Corps of Engineers
- Dr. Corey Masuca, Jefferson County (AL) Department of Health
- Dr. Steven Packham, Utah Department of Environmental Quality

Under the Clean Air Act, CASAC is to provide advice on air quality criteria, recommending any new NAAQS or revisions of existing criteria or standards as may be appropriate as well as advising the Administrator of: areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS; research efforts necessary to provide the required information; the relative contribution to air pollution concentrations of natural as well as anthropogenic activity; and any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS.

Following the April 2018 Presidential Memorandum on Job Creation and Domestic Manufacturing, EPA issued a memorandum laying out the following principles to reform the process for setting NAAQS:

- Meet statutory deadlines;
- Address all Clean Air Act provisions for NAAQS reviews;
- Streamline and standardize the process for development and review of key policy-relevant information;
- Differentiate science and policy considerations in the NAAQS review process; and
- Issue timely implementation rules or guidance following the revision of a NAAQS.

CASAC operates pursuant to the Clean Air Act, the Federal Advisory Committee Act, and its charter, which is renewed every two years. Consistent with these authorities, the seven-member chartered CASAC will serve as the body to review key science assessments for the ongoing reviews of the ozone and particulate matter NAAQS (last revised in 2015 and 2012, respectively). In the next two weeks, EPA's Office of Research and Development (ORD) intends to make public the draft Integrated Science Assessment for particulate matter for review and comment by CASAC and the public ahead of an in-person meeting in December. ORD also intends to hold a webinar regarding the Integrated Science Assessment for ozone in late October. EPA will also be releasing a draft Integrated Review Plan to outline the expected ozone NAAQS review process. These steps will kick off the scientific review process which will result in EPA finalizing any necessary changes to the ozone or particulate matter NAAQS by the end of 2020.

For more information, visit EPA's NAAQS review and CASAC websites.

<!--[if !mso]-->Visit The EPA's Newsroom<!--[endif]-->

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Washington, D.C. 20004

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Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/26/2018 5:12:44 PM
To: Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]
Subject: Fwd: Charge to CASAC for review of the draft PM ISA

David - Per your vm, just wanted to follow up. These appear to include our feedback. Thanks again!

Begin forwarded message:

> **From:** "Woods, Clint" <woods.clint@epa.gov>
> **Date:** October 25, 2018 at 12:32:38 PM EDT
> **To:** "Dunlap, David" <dunlap.david@epa.gov>
> **Subject: Re: Charge to CASAC for review of the draft PM ISA**
>
> Yes - Thanks so much!
>
> On Oct 24, 2018, at 10:00 PM, Dunlap, David <dunlap.david@epa.gov> wrote:
>
>> Clint,
>>
>> Are you good with these changes to the charge questions? Do the changes align with the input you provided?
>>
>> DDD
>>
>> ---
>>
>> **From:** Vandenberg, John
>> **Sent:** Tuesday, October 23, 2018 4:18 PM
>> **To:** Yeow, Aaron <Yeow.Aaron@epa.gov>
>> **Cc:** Bahadori, Tina <Bahadori.Tina@epa.gov>; Brennan, Thomas <Brennan.Thomas@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>; Greaver, Tara <Greaver.Tara@epa.gov>; Hagerthey, Scot <Hagerthey.Scot@epa.gov>; Jarabek, Annie <Jarabek.Annie@epa.gov>; Jenkins, Scott <Jenkins.Scott@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Johnston, Khanna <Johnston.Khanna@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Robbins, Chris <Robbins.Chris@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Sacks, Jason <Sacks.Jason@epa.gov>; Sasser, Erika <Sasser.Erika@epa.gov>; Vette, Alan <Vette.Alan@epa.gov>; Wayland, Robertj <Wayland.Robertj@epa.gov>; Wesson, Karen <Wesson.Karen@epa.gov>
>> **Subject:** Charge to CASAC for review of the draft PM ISA
>> **Importance:** High
>>
>> Aaron,
>>
>> Attached please find the charge for the CASAC review of the draft PM ISA, and the Preamble for the ISAs. (I will send you a signed version when I return to my office on Thursday).

We reviewed and considered comments from Dr. Cox and from ORD and OAR management while developing this final Charge.
Please let me know if you have any questions.
Thank you
John

John Vandenberg, PhD
Director, Research Triangle Park Division
National Center for Environmental Assessment/ORD
U.S. Environmental Protection Agency/B243-01
Research Triangle Park, NC 27711
(919) 541-4527

<ISA_PREAMBLE_FINAL2015 (1).pdf>
<Charge to CASAC_PM ISA 10-23-18.docx>

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 10/16/2018 5:44:52 PM
To: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Harlow, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a9a34e31fc4fe6b2beaddda2affa44-Harlow, Dav]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]
Subject: PM ISA Story

https://www.eenews.net/greenwire/2018/10/16/stories/1060102671

AIR POLLUTION: Standards too weak — evidence in draft EPA report

Sean Reilly, E&E News reporter
Published: Tuesday, October 16, 2018

EPA issued a new draft report acknowledging evidence that its current standards for airborne fine particulates are not tight enough to adequately protect public health.

A "causal relationship" exists between short-term exposure to fine particulates and the risk of premature death, according to the draft report, formally known as an integrated science assessment.

EPA's current annual standard, set in 2012, is 12 micrograms per cubic meter of air. But the report notes that U.S. studies "indicate a linear relationship at levels as low as" 5 micrograms per cubic meter. Particularly vulnerable are children, based on "strong evidence of impaired lung function growth," and minorities, the draft adds.

Spanning almost 1,900 pages, the draft appears to have been posted online yesterday, but EPA press aides did not reply to an emailed request for confirmation. Its release marks a milestone in EPA's latest review of the national air quality standards for particulate matter, which are associated with an array of heart and lung ailments. While the draft stops short of making policy recommendations, it in effect offers a roundup of the scientific research to be considered in the review.

That review, required under the Clean Air Act, was launched with a workshop in 2015 and was originally supposed to conclude in 2021. But it has already fallen well behind that schedule; the draft report, for example, was originally scheduled for release in spring of last year.

In addition, EPA officials and an outside review panel known as the Clean Air Scientific Advisory Committee are now proceeding under new ground rules put in place in May by Scott Pruitt, then the agency's administrator. Those rules call for the review's completion late 2020; they also require the committee, usually known by its acronym as CASAC, to examine potential "adverse" economic and energy effects that could result from changes to the standards (Greenwire, May 10).

Environmental and public health groups say that requirement could undercut effects to strengthen air pollution limits. They also reacted with alarm last week when acting EPA Administrator Andrew Wheeler fired what was in effect a CASAC subcommittee intended to add more scientific expertise to the review of the particulate matter standards.

An EPA spokesman has said that Wheeler's decision was consistent with the Clean Air Act and CASAC's charter. Wheeler last week also named five new members to the committee, the bulk of them from state and local regulatory agencies as opposed to the scientific research community.

The committee has tentatively scheduled a meeting for Dec. 12-13 in Washington, D.C., to consider the draft report, Chairman Tony Cox said in an email this morning.

Under the Clean Air Act, EPA is supposed to review the standards for particulate matter, ozone and four other common pollutants every five years, although the agency has hitherto rarely met that deadline.

The last review of the particulate matter thresholds wrapped up in 2012. At that time, EPA decided to cut the annual standard for fine particulates from 15 micrograms per cubic meter of air to 12 but left the 24-hour standard unchanged at 35 micrograms per cubic meter of air.

In the latest review, "any recommendations and advice for revisions will be developed through this and other meetings and discussions," Cox, a Denver-based consultant, said in the email, "and no decisions on them have yet been made."

Twitter: @SeanatGreenwire Email: sreilly@eenews.net

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Appointment

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 7/2/2018 4:12:50 PM
To: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]

Subject: Accepted: Pre discussion re: Follow-up call with CASAC chair Dr. Tony Cox
Location: WJC - N 5400

Start: 7/2/2018 4:15:00 PM
End: 7/2/2018 4:30:00 PM

Recurrence: (none)

Appointment

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 7/2/2018 1:30:27 PM
To: Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]

Subject: FW: Follow-up call with CASAC chair Dr. Tony Cox (confirmed)
Attachments: CASAC follow-up call/mtg
Location: WJC - N 5400 + 202-991-0477 + 311-0813

Start: 7/2/2018 4:30:00 PM
End: 7/2/2018 5:00:00 PM
Show Time As: Tentative

From: Wehrum, Bill
Sent: Thursday, June 28, 2018 2:02:37 PM UTC
To: Wehrum, Bill; Woods, Clint; Brennan, Thomas; Yeow, Aaron; Hockstad, Leif; Mazza, Carl; Shoaff, John
Subject: Follow-up call with CASAC chair Dr. Tony Cox (confirmed)
When: Monday, July 2, 2018 4:30 PM-5:00 PM.
Where: WJC - N 5400 + 202-991-0477 + 311-0813

TO: Bill Wehrum, Clint Woods, Tom Brennan, Aaron Yeow, Leif Hockstad, Carl Mazza, John Shoaff

Message

From: Shoaff, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC16FB09CF2C44ADB34A7405DC331532-JSHOAFF]
Sent: 6/27/2018 8:15:57 PM
To: Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]; Rakosnik, Delaney [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=274573739a9f446883072599086ededd-Rakosnik, D]; Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]
CC: Hockstad, Leif [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a4fb1f8930645efa34fdfa7485bc6da-LHOCKSTA]
Subject: CASAC follow-up call/mtg

Emily,

We had a call with Dr. Tony Cox, the CASAC chair, today and need to schedule a follow up mtg/call to complete our discussion in the near future, e.g., next week. Participants include:

Tony Cox
Bill and Clint
Tom Brennan
Aaron Yeow
Leif Hockstad
Carl Mazza
John Shoaff

Think today's call/mtg entry has the email for Tony, rest are EPA.

A half hour should do it.

Thank you!

John

Appointment

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 7/2/2018 1:22:52 PM
To: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]

Subject: Accepted: Follow-up call with CASAC chair Dr. Tony Cox (confirmed)
Location: WJC - N 5400 Personal Phone / Ex. 6

Start: 7/2/2018 4:30:00 PM
End: 7/2/2018 5:00:00 PM

Recurrence: (none)

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 3/27/2019 2:25:58 PM
To: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
Subject: CASAC Research Scientist Attacks Panel Chairman's NAAQS Review Shift | InsideEPA.com

https://insideepa.com/daily-news/casac-research-scientist-attacks-panel-chairman%e2%80%99s-naaqs-review-shift

CASAC Research Scientist Attacks Panel Chairman's NAAQS Review Shift

Mark Frampton, the sole research scientist on EPA's Clean Air Scientific Advisory committee (CASAC), is lambasting panel Chairman Tony Cox's controversial new approach to assessing air pollution science for reviewing the agency's particulate matter (PM) air standards, saying it undermines and misstates the latest data on PM.

Conclusions about the uncertainty on PM and its adverse health effects that Cox outlined in a March 7 draft letter to EPA do not represent a consensus of the panel, and in some cases Cox has misrepresented the panel's prior discussions, Frampton warns in comments on the letter. Cox's letter "does not accurately reflect the results of that discussion or represent a consensus among CASAC members," writes Frampton.

The comments show the high-profile split within the independent CASAC over Cox's new approach to reviewing science underpinning EPA's national ambient air quality standards (NAAQS). Cox is proposing that the panel use the new approach for its ongoing review of the agency's PM NAAQS.

And they reflect the lone CASAC research scientist's input on the new approach, with other panelists such as toxicologists either not addressing Cox's approach or offering some support for it.

The split could dominate a slated March 28 teleconference where panel members will review Cox's draft letter, in which the committee gives its input on the agency's integrated science assessment (ISA) for the PM NAAQS.

The ISA a key step in the Clean Air Act-mandated five-year NAAQS review process, summarizing the most policy-relevant science on the health and environmental impacts of

PM air pollution. The ISA will inform the agency's ultimate decision on whether to tighten its fine PM (PM2.5) and large "coarse" PM standards. The ISA under review by CASAC supports findings from prior reviews about the harmful effects of the pollutant, but also adds some new conclusions about the likely causal relationship between various forms of PM and neurological effects.

Cox's draft letter broadly condemns the method used by agency staff to determine whether air pollutants cause specific adverse health effects. His attacks go well beyond questions specific to PM, calling for a wholesale change in EPA's approach to NAAQS reviews. Cox is an industry consultant and longstanding skeptic of the agency's conclusions on health effects, and considered something of a fringe voice by some scientists.

Perhaps most provocatively, Cox in his draft letter to the agency accuses EPA of ignoring evidence that PM2.5 air pollution does not, in fact, cause death as many scientists believe it does.

Cox also says the ISA "does not provide a comprehensive or systematic assessment of the available science relevant to understanding the health impacts of exposure to fine particulate matter, nor does it follow widely accepted scientific methods for deriving sound, independently verifiable, scientific conclusions from available data."

Cox offers a scathing critique of EPA's "causality framework," and advocates for a new, narrower approach to determining causation of health effects than the weight-of-evidence approach used so far.

Frampton's Push-Back

But Frampton says the "framework used by the EPA for determining causality was extensively discussed in the comments of individual CASAC members" in a public meeting in December. Yet Cox's conclusion "does not accurately reflect the results of that discussion or represent a consensus among CASAC members."

Frampton writes, "The causal determination categories as used in this as well as previous ISAs, provide clear and workable descriptions of the level of certainty for potentially causal relationships."

Cox's criteria "essentially eliminate determination that a PM effect is causal because such a requirement is unachievable in accountability studies," he writes. Accountability study is a nascent field that seeks to verify whether air rules produced not only cuts in pollution but also the projected improvements in public health.

Cox doubts EPA's conclusion, accepted by many in the scientific community, that PM2.5 exposure can cause death, saying EPA ignores some scientific studies that do not find increased mortality rates from exposure to elevated PM2.5.

But Frampton in his written comments counters that, "Overall the ISA presents a reasonably balanced view of the convincing evidence linking long-term PM2.5 exposure and mortality."

Cox in the draft letter says, "the Draft ISA does not clearly communicate what science has revealed about the real-world effects of changing PM exposures on human health and welfare -- and hence about whether or under what conditions changes in PM are needed to protect human health. Substantial discordant and conflicting evidence remains ignored or unresolved." But Frampton says this criticism is too broad.

Frampton says, "This is not an accurate assessment of most of the draft ISA, and such sweeping statements are inappropriate," arguing the draft letter departs from CASAC's task of reviewing the assessment.

However, CASAC panelist and Texas state toxicologist Sabine Lange in her comments posted to EPA's website largely backs Cox's draft letter. And there appears to be consensus on the panel that EPA has not justified its findings on neurological effects of PM2.5 air pollution and the even smaller "ultrafine" PM.

Other CASAC panelists have few observations on Cox's comments. However, Janes Boylan, a Georgia air regulator, says in his comments that, "There is substantial controversy over CASAC's recommendations with regards to the causal framework approach used by EPA. Since this subject is outside my area of expertise, I do not feel comfortable providing consensus on a controversial subject that I am not intimately familiar with."

'Delays And Paralysis'

Meanwhile, others continue to strongly criticize Cox's approach, including former CASAC Chairman H. Christopher Frey who warns the new method would significantly slow the NAAQS review process.

In public comments prepared for the March 28 meeting, Frey -- a professor of environmental engineering at North Carolina State University -- says Cox "is attempting to redefine the policy and decision context of the science review. The policy and decision context of the science review is set forth by Congress in the Clean Air Act, as interpreted by Federal courts, and is not amenable to ad hoc redefinition by CASAC or its chair." Cox's approach contradicts the 2016 review plan already approved by CASAC, Frey says.

Frey echoes Frampton's criticisms that Cox has ignored contrary opinions to his own in his draft letter, such as Frampton's prior assertion that Cox's attempt to redefine key terms in the ISA related to causation will merely "obfuscate" and lead to confusion. Cox's approach risks "delays and paralysis," Frey warns. -- *Stuart Parker* (sparker@iwpnews.com)

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Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 8/3/2018 9:14:55 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Attachments: drp-10-209.pdf; ATT00001.txt

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3375488/pdf/drp-10-209.pdf

Dose-Response, 10:209–218, 2012
Formerly Nonlinearity in Biology, Toxicology, and Medicine
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ISSN: 1559-3258
DOI: 10.2203/dose-response.11-040.Cox

International Dose-Response Society
www.Dose-Response.org

HORMESIS FOR FINE PARTICULATE MATTER (PM 2.5)

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□ The hypothesis of hormesis – that substances that harm health at high exposures can reduce risks below background at low exposures, e.g., if they activate defenses without overwhelming them – becomes important for practical policy making if it holds for regulated substances. Recently, the U.S. EPA concluded that reductions in ambient concentrations of fine particulate matter (PM2.5) in air caused trillions of dollars worth of human health benefits for a compliance cost of only about $65 billion per year. This conclusion depends on an unverified assumption of a positive, causal, straight-line relation between PM2.5 concentrations and mortality risks. We review empirical data on PM2.5 and mortality risks (and their precursors, inflammatory responses) and conclude that the PM2.5 concentration-response relation may be J-shaped, rather than linear. This possibility implies that the 1990 Clean Air Act Amendment may well have produced no (or negative) human health benefits, rather than the trillions of dollars worth of reduced mortalities ascribed to it by EPA; and that attempts to achieve further risk-reduction benefits by further reducing PM2.5 concentrations may be counterproductive. This creates a very high value for scientific information that better reveals the true shape of the PM2.5 concentration-response function at and below current ambient levels.

Key words: PM2.5, hormesis, Clean Air Act, air pollution health effects, uncertainty analysis, risk-cost-benefit analysis, Weibull uncertainty distribution

INTRODUCTION

A strong form of the hypothesis of hormesis in toxicology and disease biology states that exposures to sufficiently small concentrations or exposure rates of agents that cause harm at higher levels are typically beneficial, reducing rates of disease or adverse effects below their background levels. A commonly postulated and observed general mechanism for hormesis is that low levels of exposure activate defensive mechanisms without overwhelming them, while higher levels saturate, deplete, or down-regulate the defenses, causing injury. For example, studies of the etiology of lung injury and diseases resulting from exposures to particulates in air have shown that high, prolonged exposures to a variety of particulates induce a non-specific inflammatory response, characterized by an increase in production of reactive oxygen species (ROS) by alveolar macrophages and other lung cells (Janssen *et al.* 1992, Comhair and Erzurum 2002, Azad *et al.* 2008). Low levels of exposure stimulate a compensating production of antioxidants (Janssen *et al.* 1992, Comhair and

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Erzurum 2002) that may compensate – or, if hormesis is correct, more than compensate – for increased ROS production, but experiments in rats show that higher levels of exposure overwhelm and down-regulate this limited defensive capacity, shifting the balance of oxidants and antioxidants toward an abnormally high-ROS environment that may then increase the risks of a variety of lung diseases, from emphysema to lung cancer (Azad *et al.* 2008). Such a mechanistic account naturally suggests that the concentration-response (C-R) function for particulate matter (PM) may have an effective threshold, or a hormetic (U-shaped or J-shaped) shape with a nadir, below which further reductions in exposure concentration, C, do not produce further reductions (and may even increase) the rates of adverse health responses, R.

If the hypothesis of hormesis is to play an important role in informing and improving national science-policy decisions about risk management of low-concentration exposures, it must be evaluated in the context of important real-world risk assessments and risk management decisions. A recent assessment by the United States Environmental Protection Agency (EPA) concluded that further reductions in fine particulate matter (PM2.5) in air are certain to produce further reductions in mortality risks (EPA, 2011) – more specifically, by an amount described by a Weibull uncertainty distribution, which puts zero probability mass on zero and negative values for the slope of the concentration-response relation at low exposure concentrations. This assessment provides an ideal opportunity to examine the plausibility of hormesis for PM2.5. EPA's analysis assumes that the C-R relation between PM2.5 concentrations (C) and mortality risks (R) is well described at low (e.g., present and future) ambient exposure levels by a straight-line, no-threshold function all the way down to the lowest measurable levels. According to this assumption, the C-R relation can be characterized by a single number, the slope of this line, called the C-R coefficient. EPA's uncertainty analysis puts a subjective probability of 100% on positive values for the C-R coefficient, implying that hormesis has zero probability of correctly describing the C-R function for PM2.5. The purpose of this paper is to re-examine this assumption in light of available data, and to re-evaluate whether hormesis might after all give a correct description of the PM2.5 C-R data.

If hormesis turns out to provide a correct description, or even a plausible possibility, for PM2.5, it has crucially important policy implications. Instead of accepting EPA's assumption that further reductions in PM2.5 concentrations will necessarily produce (proportionate) reductions in mortality risks and gains in life expectancy, hormesis would imply that there is an optimal exposure level (which we might have already passed) below which further reductions in PM2.5 concentrations produce no additional gains in public health – let alone the trillions of dollars of health benefits per year projected by EPA. Indeed, at sufficiently low

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ambient concentrations, further reductions in PM2.5 could even be associated with modest increases in mortality rates, implying a negative C-R relation. This would require rethinking the wisdom and prudence of continuing to spend resources (estimated by EPA as about $65 billion per year in compliance costs) to reduce PM2.5 concentrations in order to seek hypothesized health benefits that may only become more remote as they are pursued.

META-ANALYSIS OF PM2.5-MORTALITY STUDIES SHOWS BOTH POSITIVE AND NEGATIVE ASSOCIATIONS, SUGGESTING A POSSIBLE J-SHAPED RELATION

Over 100 epidemiological studies have now estimated the concentration-response (C-R) coefficient in regression models of all-cause and cause-specific mortality rates regressed against ambient PM2.5 concentrations and other covariates. A puzzling feature of these studies has been that a sizable minority of them report statistically significant *negative* C-R coefficients, i.e., higher concentrations of PM2.5 are associated with significantly lower mortality rates, even though more report statistically significant positive coefficients. Nearly a decade ago, Dominici *et al.* (2002) found 20 non-significant negative C-R coefficients among 88 cities, although most coefficients in that study (positive and negative) were not statistically significant, due to limitations in sample sizes. Thus, the negative coefficients might have been due to sampling error. However, a more recent review (Franklin *et al.* 2007) found negative C-R coefficients for all-cause mortality and PM2.5 in one third (9 of 27) U.S. communities, with several being statistically significant (including Birmingham, Dallas, and Houston). Although it has been common practice to simply pool results across locations, and to conclude that the pooled mean C-R coefficient is significantly positive (since the 2/3 majority of positive coefficients outweighs the 1/3 of negative ones), this does not resolve the puzzle of why so many locations report negative coefficients.

If the statistical models being used are even approximately correct, then finding multiple statistically significant negative coefficients among 27 locations suggests that negative associations between PM2.5 and mortality rates really do occur. The same logic suggests that the multiple significant positive coefficients are also real. To reconcile these opposing conclusions, it is natural to assume that they are two parts of a larger, nonmonotonic relation, e.g., a J-shaped or U-shaped function, with ascending and descending segments. In this case, locations with a high proportion of exposures on the descending part of the C-R relation will have negative average C-R coefficients, while locations with a high proportion of exposures on the ascending portion will have positive average C-R coefficients. Averaging the C-R coefficients across locations is not sensible, however, if the response to changes in concentrations is highly location-spe-

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cific – as, indeed, appears to be the case. For example, an examination of C-R curves (rather than assumed constant C-R slope coefficients) for PM10 data in the twenty largest U.S. cities identified U-shaped curves in some cities, although this information was lost when the curved were averaged across cities (Daniels *et al.* 2000).

EPIDEMIOLOGICAL DATA ARE AMBIGUOUS, BUT NOT INCONSISTENT WITH HORMESIS

Evidence for negative, as well as positive, association between PM2.5 concentrations and mortality rates also arises from analyses that take into account model uncertainty by considering *multiple plausible models*, rather than selecting any single model (which would almost certainly be incorrect, given the large number of alternative statistical models that fit the data approximately equally well). Bayesian Model-Averaging (BMA) is one of the best-developed of such "ensemble" methods for using multiple models to reduce model-selection biases and to make more accurate risk predictions and uncertainty characterizations than any single regression model is likely to achieve. Applied to data from 11 Canadian cities, BMA indicates that both total suspended particulate (TSP) and ozone have statistically significant *negative* associations with mortality rates (Koop *et al.* 2007). Similar findings of negative associations for ozone have been reported in the United States (Joseph 2008).

To independently check the validity of such previously published reports of negative C-R relations, one may examine the iHAPSS (internet-based Health and Air Pollution Surveillance System) data base of pollutant levels and mortality rates for U.S. cities made available on-line by Johns Hopkins at www.ihapss.jhsph.edu/. Figure 1 shows plots of cause-specific mortality rate vs. deciles of estimated PM2.5 concentrations. (The data are reconstructed from preprocessed NMMAPS data posted at the website, which documents the smoothing procedure used to preprocess the raw data and the resulting possibility of negative values when data are reconstructed by adding back the smoothed mean. The NMMAPS documentation defines all-cause mortality (*death*) as excluding accidents.) The plots pool data across time (daily data from 1987 to 2000, although different cities started reporting in different years) and across the ten largest metropolitan area in the data base (Chicago, Dallas/Fortworth, Detroit, Houston, LA, Miami, New York, Phoenix, San Diego, and Santa Ana/Anaheim.)

The plots do not suggest any significant positive relations between PM2.5 and excess mortality risk at the lowest exposure concentrations (except possibly for COPD, which is a relatively small contributor to death rates); if anything, they are consistent with a weak negative or U-shaped association between exposures and cause-specific mortality risks for cardiovascular disease (CVD) and pneumonia/influenza mortality risks at the

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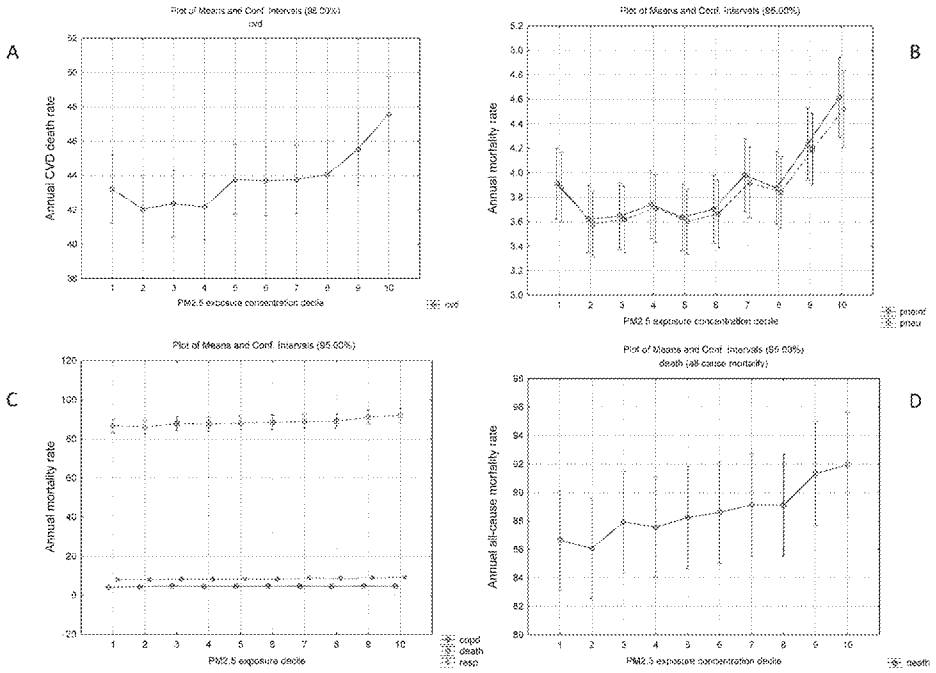

FIGURE 1. PM2.5 and Mortality Rate C-R Relations in Ten U.S. Cities. C-R relations for annual mortality rates: A = cardiovascular disease (CVD); B = pneumonia (pne) and pneumonia/influenza (pneuinf); C = all-case (death), chronic obstructive pulmonary disease (COPD), and respiratory (resp); D = all-cause mortality (expanded from C).

low (left) end of the PM2.5 exposure concentration distribution. The highest (right-most) deciles of the PM2.5 exposure concentration distribution do show increased risks, but it would be inappropriate to extrapolate these linearly down to zero, given the U-shapes of the empirical C-R relations between exposure concentrations (C) and mortality rates (R).

In multivariate regression analyses, other explanatory variables in the date set (especially year, month of year (with the winter months of December-February being high-risk months as well as high-pollution months), and minimum temperature) are all highly statistically significant predictors of all-cause and cardiovascular disease mortality rates in different age categories. PM2.5, too, is a strong predictor of all-cause and CVD mortality rates. After conditioning on other variables, however, no positive statistical effect of PM2.5 on mortality rates remains. For example, Table 1 shows the results of a multiple linear regression model fit to the data (using the commercial statistical software environment *Statistica 9.0.* The *b* coefficients are the ordinary least squares regression coefficients, and the *b** coefficient are their standardized values. The variable *Dec-Feb* is a binary variable with value 1 for these three months and 0 for other months.) Both estimated PM2.5 exposure (*pm25Reconstruct*) and all-cause mortality rates are highest in the winter months: the variable Dec-Feb is a con-

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TABLE 1. Multiple Linear Regression Model for All-Cause Mortality Rates in 10 Cities

Regression Summary for Dependent Variable: death (all causes)
R= .41 R?= .17 Adjusted R?= .17

N=22242	b*	Std.Err. of b*	b	Std.Err. of b	t(22235)	p-value
Dec-Feb	0.16	0.007	31.66	1.50	21.2	0.000000
tmin	0.15	0.008	0.83	0.04	20.0	0.000000
Year	0.02	0.006	0.35	0.14	2.6	0.009320
Month	-0.02	0.006	-0.47	0.16	-3.0	0.002524
pm25Reconstruct	-0.02	0.006	-0.18	0.05	-3.4	0.000589
pHisp	-0.43	0.007	-226.40	3.47	-65.3	0.000000
Intercept			-619.44	270.48	-2.3	0.022023

founder that explains a positive univariate association between them, as shown in Figure 1D. However, in the multivariate model in Table 1, the coefficient of PM2.5 exposure is significantly *negative*, suggesting that, apart from such confounding, PM2.5 exposure does not increase mortality rates. Although, any such ecological regression (with unknown individual exposures) must be interpreted with caution, it is noteworthy that the apparent positive association between PM2.5 and mortality in Figure 1D is entirely removed by controlling for other variables in multivariate analysis, leaving a negative association at sufficiently low exposure concentration (and hence hormesis, overall) as a viable possibility.

Table 2 shows analogous results specifically for CVD mortality rates. Although both all-cause and CVD mortality rates are significantly predicted by month of year, as well as year (as mortality rates fall and life expectancies rise over time), minimum temperature (tmin), and proportion of Hispanics in the population, it is conspicuous that PM2.5 (the *pm25reconstruct* variable) has no significant positive relation with either mortality rate. The same is true in non-linear (e.g., polynomial regression and classification tree) models with interaction effects, for lagged values of PM2.5, and for other health end points, including respiratory mortality rate: *PM2.5 at ambient levels is not significantly positively associated with any adverse health outcomes.* This observation for ten U.S. cities is generally consistent with the results of Koop and Tole (2004) for Toronto.

Although reports of mixed positive and negative associations of PM2.5 concentrations with mortality rates are common in the literature (Daniels *et al.* 2000, Franklin *et al.* 2007, Koop *et al.* 2007, Joseph 2008), and although they may suggest a possible U-shaped or J-shaped relation between exposure concentrations and mortality rates, epidemiological studies are generally too weak and ambiguous to decisively reveal the true shape of the concentration-response function. Principal reasons include the lack of reliable measurements of individual exposures and lack of complete identification and control of confounders, both of which cast

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TABLE 2. Multiple Linear Regression Model for Cardiovascular Mortality Rate

Regression Summary for Dependent Variable: cvd
R= .37 R?= .14 Adjusted R?= .14

N=22242	b*	Std.Err. of b*	b	Std.Err. of b	t(22235)	p-value
Dec-Feb	0.14	0.01	15.53	0.85	18.2	0.000000
tmin	0.12	0.01	0.36	0.02	15.0	0.000000
pm25Reconstruct	-0.01	0.01	-0.06	0.03	-1.8	0.068621
Month	-0.02	0.01	-0.22	0.09	-2.4	0.016366
Year	-0.05	0.01	-0.56	0.08	-7.3	0.000000
pHisp	-0.38	0.01	-110.64	1.98	-55.8	0.000000
Intercept			1170.99	154.60	7.6	0.000000

severe doubt on statistical estimates and inferences obtained by plugging estimated city-level exposures into regression or time series models as presumed explanatory variables (Sheppard *et al.* 2011). In addition, statistical associations (of any sign) need not necessarily reflect causality. Therefore, is desirable to consider toxicological dose-response data, to see whether a J-shaped relation is consistent with experimental data.

EXPERIMENTAL DATA SHOW J-SHAPED CONCENTRATION-RESPONSE RELATIONS

Experimental studies in human volunteers, including asthmatics, have led some commentators to conclude that, "[T]he weight of the evidence from controlled studies with animals and human volunteers suggests that PM is unlikely to cause premature death or other serious health effects at levels found in real-world air" (Schwartz 2007). This is consistent with earlier conclusions that, "It remains the case that no form of ambient PM — other than viruses, bacteria, and biochemical antigens — has been shown, experimentally or clinically, to cause disease or death at concentrations remotely close to US ambient levels" (Green and Armstrong 2003). To test such reassuring-looking conclusions more carefully, it is instructive to examine the concentration-response relations for particulate matter in animals, where concentrations have been varied systematically from low levels, at which no adverse effects are observed, to much higher levels at which inflammation in mice and rats, and fibrosis and lung tumors in rats, can be induced.

Figure 2 summarizes two sets of experimental data. The left panel shows lung tumor responses in rats (the only species that develops them) in response to varying concentrations of different types of particulates. The mechanism of tumor induction involves overwhelming of antioxidant and clearance defenses, unresolved chronic inflammation, repetitive injury to lung tissue, and fibrosis, scarring, and proliferation leading to tumors (Azad *et al.* 2008, Oberdörster 1997). The three right panels

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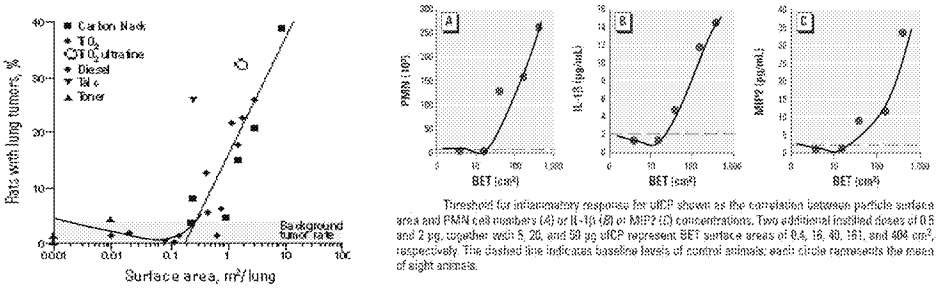

Rat tumors (adapted from Oberdorster 1997) Mouse inflammation markers (adapted from Stoeger et al. 2006)

FIGURE 2. Rat tumor (left-most) and mouse inflammation (right) responses to PM. Original figures reproduced with permission from *Environmental Health Perspectives,* www.ncbi.nlm.nih.gov/pmc/articles/PMC1392224/figure/f3-ehp0114-000328/, doi: 10.1289/ehp.8266 and www.ncbi.nlm.nih.gov/pmc/articles/PMC1470142/?tool=pubmed. J-shaped curves have been superimposed on the original figures.

show the responses of three inflammatory markers in mice, to different concentrations of ultrafine carbon particulates (ufCP).

In both experiments, the surface area of particles in the lung is used as a dose metric, since it is the best predictor of response (better than mass or volume of PM. The "BET" protocol referred to on the right side provides a way to quantify this surface area.) The original authors of these experimental studies interpreted their findings as showing a threshold exposure level, below which exposure did not increase risk of adverse responses (inflammation in mice, on the right; tumors in rats, resulting from unresolved inflammation and associated other effects, on the left). However, as indicated by the J-shaped cuves that we have superimposed on the data points, the data are actually more consistent with hormesis, i.e., a positive baseline level at zero exposure that is reduced by very low levels of exposure, but that increases above background at higher exposure concentrations. Thus, while there may indeed be an exposure concentration level below which risk of adverse effects is not greater than background, it is more accurate to interpret the J-shaped curves as indicating hormesis, rather than thresholds.

DISCUSSION AND CONCLUSIONS

EPA's assumption that the concentration-response (C-R) function relating changes in ambient exposure concentrations of fine particulate matter (PM2.5) is well-described by a straight line with a positive slope (with 100% confidence, based on a subjective Weibull uncertainty analysis that precludes zero and negative slopes from having positive subjective probabilities), poses a direct challenge to the hypothesis of hormesis. We have reexamined empirical evidence on the shape of the C-R function, and find that such certainty that a positive linear C-R relation provides a

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better description that alternative, hormetic (J-shaped) relations is unjustified. A J-shaped relation provides one possible explanation for common reports in the literature of statistically significant negative, as well as positive, C-R coefficients. However, in the absence of more accurate and detailed information about individual exposures, as opposed to ambient exposures at monitoring locations, epidemiological data alone cannot decisively establish the true shape of the C-R function (Sheppard *et al.* 2011). In our own analysis of a data set made available for public analysis, there is no clear positive relation between PM2.5 and all-cause or cause-specific mortality rates, although cause-specific mortality rates are significantly correlated with each other.

Turning to toxicological data, the results are clearer: in animal studies with accurate exposure measurements for individual animals, it is clear that inflammatory responses (and tumors in rat lungs) are not increased by sufficiently low exposures, contrary to the low-dose linear no-threshold assumption. As shown in Figure 2, hormesis (J-shaped dose-response relations) provides a description of such data.

In conclusion, available evidence supports the hypothesis of hormesis more strongly than the hypothesis of a positive linear no-threshold model for PM2.5 and mortality risks. Experimental evidence (Figure 2) indicates hormesis as the hypothesis that best fits the data. Epidemiological data, although more ambiguous (Figure 1), is consistent with hormesis in meta-analyses, as evidenced by mixed positive and negative C-R coefficients.

However, it is not necessary to settle conclusively whether hormesis holds for PM2.5 in order for it to have major policy implications. Recent EPA estimates of the human health benefits from the 1990 Clean Air Act Amendment (EPA, 2011) are crucially dependent on the unverified assumption of a positive linear no-threshold C-R function for PM2.5. As soon as it is acknowledged that hormesis is at least a plausible possibility – so that assigning it a subjective probability of zero, as in EPA's benefit assessment, is not warranted by data – it follows that the true incremental human health benefits of the 1990 Clean Air Act Amendment could also be zero or negative in many locations. This changes the nature of the cost-benefit comparison presented to the public from an apparent certainty of large positive return, in which compliance costs of $65 billion per year are said to produce lower mortality risks among the elderly, valued by EPA at about two trillion dollars per year, to a revised comparison in which the expenditure of $65 billion per year in compliance costs may instead – with probability of greater than 50%, if hormesis is more plausible than low-dose linearity – produce zero or negative net health benefits in reducing mortality risks. Many policy-makers who would embrace the former description might reject the latter, or at least request much more information about the uncertainties and evidence on the shape of the C-R function for PM2.5 at and below current ambient levels.

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Thus, the hypothesis of hormesis, which appears to be supported by experimental data and consistent with (but not decisively proved or refuted by) current epidemiological data, changes the policy evaluation of claimed marginal health benefits of the 1990 Clean Air Act Amendment from a clear win for the public to a possible loss. More careful evaluation of the true shape of the C-R function is needed to determine which is correct. However, that the hypothesis of hormesis is plausible for a major air pollutant such as PM2.5 already provides sufficient grounds to question regulatory benefits assessments, evaluations, and policies that assume that cleaner air necessarily reduces mortality risks, even at and below current ambient concentrations.

REFERENCES

Azad N, Rojanasakul Y, Vallyathan V. 2008. Inflammation and lung cancer: roles of reactive oxygen/nitrogen species. J Toxicol Environ Health B Crit Rev. Jan;11(1):1-15. http://pdfserve.informaworld.com/643704__789269849.pdf

Comhair SA, Erzurum SC. 2002. Antioxidant responses to oxidant-mediated lung diseases. Am J Physiol Lung Cell Mol Physiol. Aug; 283(2):L246-55.

Daniels MJ, Dominici F, Samet JM, Zeger SL. 2000. Estimating particulate matter-mortality dose-response curves and threshold levels: an analysis of daily time-series for the 20 largest US cities. Am J Epidemiol. Sep 1;152(5):397-406.

Dominici F, Daniels MJ, Zeger SL, Samet JM. 2002. Air Pollution and Mortality: Estimating Regional and. National Dose-Response Relationships. Journal of the American Statistical Association. 97(457): 100-111

EPA (U.S. Environmental Protection Agency). 2011. The Benefits and Costs of the Clean Air Act from 1990 to 2020. Final Report – Rev. A. Office of Air and Radiation, Washington D.C.

Franklin M, Zeka A, Schwartz J. 2007. Association between PM2.5 and all-cause and specific-cause mortality in 27 US communities. J Expo Sci Environ Epidemiol. May;17(3):279-87.

Green LC, Armstrong SR. 2003. Particulate matter in ambient air and mortality: Toxicologic perspectives. Regul Toxicol Pharmacol. Dec;38(3):32

Janssen YM, Marsh JP, Absher MP, Hemenway D, Vacek PM, Leslie KO, Borm PJ, Mossman BT. 1992. Expression of antioxidant enzymes in rat lungs after inhalation of asbestos or silica. J Biol Chem. May 25;267(15):10625-30.

Joseph PM. Can fine particulate matter explain the paradoxical ozone associations? Environ Int. 2008 Nov;34(8):1185-91.

Koop G, McKitrick R, Tole L. 2007. Does air pollution cause respiratory illness? A new look at Canadian cities. Available at http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.164.6048

Koop G, Tole L. 2004. Measuring the health effects of air pollution: To what extent can we really say that people are dying from bad air? Journal of Environmental Economics and Management 47:30-54. See also: http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.164.6048

Oberdörster G. 1997. Pulmonary carcinogenicity of inhaled particles and the maximum tolerated dose. Environ Health Perspect. Sep;105 Suppl 5:1347-55

Schwartz J. 2007. Burying evidence: The Union of Concerned Scientists' Unscientific Claims About Air Pollution and Health. Available at http://joelschwartz.net/pdfs/BuryingEvidence011707.pdf

Sheppard L, Burnett RT, Szpiro AA, Kim S-Y, Jerrett M, Pope CA, Brunekreef B. 2011. Confounding and exposure measurement error in air pollution. Air Quality, Atmosphere & Health. Available at http://www.springerlink.com/content/dn32w61163232063/.

Stoeger T, Reinhard C, Takenaka S, Schroeppel A, Karg E, Ritter B, Heyder J, Schulz H. 2006. Instillation of six different ultrafine carbon particles indicates a surface area threshold dose for acute lung inflammation in mice. Environ Health Perspect Mar;114(3):328-33.

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