Appointment

From: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Sent: 1/6/2021 3:20:35 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Meadowcroft, Micah [Meadowcroft.Micah@epa.gov]

Subject: Exit Conversation
Location: WJCN-3402

Start: 1/12/2021 9:00:00 PM
End: 1/12/2021 9:45:00 PM
Show Time As: Busy

Recurrence: (none)

Required Attendees: Gunasekara, Mandy; Meadowcroft, Micah

Message

From: Molina, Michael [molina.michael@epa.gov]
Sent: 1/6/2021 11:53:17 AM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
CC: Johnson, Taylor [Johnson.Taylor.C@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Block, Molly [block.molly@epa.gov]; McFaul, Jessica [mcfaul.jessica@epa.gov]; Grantham, Nancy [Grantham.Nancy@epa.gov]; Rodriguez, Alejandra (Allie) [rodriguez.alejandra@epa.gov]; Murray, William [Murray.William@epa.gov]
Subject: Re: FOR APPROVAL: Storage Tanks Release

Ok by me. MM

Sent from my iPhone

On Jan 5, 2021, at 5:15 PM, Gunasekara, Mandy <Gunasekara.Mandy@epa.gov> wrote:

Edits for quote included below.

From: Johnson, Taylor <Johnson.Taylor.C@epa.gov>
Sent: Tuesday, January 5, 2021 4:17 PM
To: Molina, Michael <molina.michael@epa.gov>; Gunasekara, Mandy <gunasekara.Mandy@epa.gov>
Cc: Hewitt, James <hewitt.james@epa.gov>; Block, Molly <block.molly@epa.gov>; McFaul, Jessica <mcfaul.jessica@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Rodriguez, Alejandra (Allie) <rodriguez.alejandra@epa.gov>; Murray, William <Murray.William@epa.gov>
Subject: FOR APPROVAL: Storage Tanks Release

Hi Michael and Mandy, this is slated to be signed tomorrow:

EPA REDUCES REGULATORY BURDEN AND EMISSIONS FROM LARGE STORAGE TANKS BY ALLOWING ALTERNATIVE INSPECTION METHOD

<<DATE>>
Contact Information:
EPA Press Office (press@epa.gov)
WASHINGTON (Date) –

Today, the U.S. Environmental Protection Agency (EPA) expanded the availability of a proven, modern inspection method for finding and correcting air pollution leaks at large liquid storage tanks. EPA's final action offers regulatory flexibility to more than 3,500 petroleum, chemical, and coal products manufacturing facilities and petroleum bulk stations and terminals by allowing an alternate, less cumbersome mode of inspection of liquid storage tanks to show compliance with Clean Air Act regulations.

These amendments offer flexibility to conduct "in-service" rather than out-of-service inspections – potentially saving industry between $768,000 and $1,091,000 per year and reducing emissions of volatile organic compounds by as much as 83-tons per year.

"The Trump Administration is delivering on its promise to cut unnecessary regulatory costs while retaining important emissions reductions," **said EPA Administrator Andrew Wheeler.**

"This action shows that environmental protection and a strong domestic energy industry go hand-in-hand."

These amendments will allow owner/operators of certain large tanks known as Volatile Organic Liquid Storage Vessels to conduct less cumbersome "in-service" inspections of the tanks, without emptying and degassing the storage tank. Since 2018, EPA has received more than 300 requests from facilities seeking permission to conduct roof-top, also known as in-service, inspections to demonstrate compliance with a 1987 Clean Air Act regulation. These one-off requests are time consuming and burdensome for both tank owners and operators and for EPA. The current inspection methods can also be expensive, labor intensive and results in volatile organic compound air emissions and other pollutants from venting and flaring.

Further, EPA understands that in recent months inspecting these large tanks from the inside has become more challenging because there is a significant increase in the need for liquid storage capacity (particularly crude and petroleum products), due to slower consumer demand.

Background

In 1987, EPA promulgated New Source Performance Standards (NSPS) subpart Kb which applies to large storage tanks that store volatile organic liquids across a variety of industries, such as petroleum refineries, chemical plants, and portions of the oil and gas industry. To reduce volatile organic compound emissions from storage vessels, NSPS subpart Kb specifies, for certain tanks in certain circumstances, out of service inspections for holes and tears at least every 10 years, as well as monitoring, recordkeeping, reporting, and other requirements and to ensure compliance with the standards. In 1999, EPA finalized the National Emission Standards for Hazardous Air Pollutants (NESHAP) subpart WW for storage vessels (tanks) that, in certain circumstances, allow for less cumbersome in-service inspections, without emptying and degassing the storage tank.

More information, including a pre-publication version of the *Federal Register* notice and related fact sheet, is available at https://www.epa.gov/stationary-sources-air-pollution/volatile-organic-liquid-storage-vessels-including-petroleum-storage.

Message

From: Molina, Michael [molina.michael@epa.gov]
Sent: 1/6/2021 1:07:47 PM
To: Rodriguez, Alejandra (Allie) [rodriguez.alejandra@epa.gov]
CC: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Block, Molly [block.molly@epa.gov]; Johnson, Taylor [Johnson.Taylor.C@epa.gov]
Subject: Re: FOR REVIEW: Prevent Lung Cancer by Testing your Home for Radon, EPA Recommends

Good to go.

Sent from my iPhone

On Jan 5, 2021, at 10:56 AM, Rodriguez, Alejandra (Allie) <rodriguez.alejandra@epa.gov> wrote:

Circling back on this – slated to go out today as well. Thank you ☺

From: Rodriguez, Alejandra (Allie)
Sent: Monday, January 4, 2021 2:57 PM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Molina, Michael <molina.michael@epa.gov>
Cc: hewitt.james@epa.gov; 'block.molly@epa.gov' <block.molly@epa.gov>; 'Johnson.Taylor.C@epa.gov' <Johnson.Taylor.C@epa.gov>
Subject: FOR REVIEW: Prevent Lung Cancer by Testing your Home for Radon, EPA Recommends

Mandy and Molina,
Please review the below AAW quote for this release slated to go out ASAP. Thank you! ☺

Prevent Lung Cancer by Testing your Home for Radon, EPA Recommends

WASHINGTON (January X, 2021) – This week marks the beginning of National Radon Action Month. Every January, the U.S. Environmental Protection Agency (EPA) urges everyone across the United States to test their homes for radon gas. Radon is a naturally occuring radioactive gas that that can seep into homes from the ground and, in some cases, well water supply.

"Radon is the second leading cause of lung cancer in the United States, and is both colorless and odorless, so I encourage everyone to take time this January to test and prevent radon exposure in your homes," said EPA Administrator Andrew Wheeler. "Millions of homes have been tested for radon and repaired, but millions more homes with high levels of this radioactive gas remain."

Each year we lose over 21,000 American lives due to radon-induced lung cancer. Testing for radon can be as simple as stopping by your local home improvement store to pick up a do-it-yourself testing kit, often found for less than $20. Test kits can also be purchased online, or individuals can hire a qualified professional to conduct a radon test. Contact your state or tribal radon program for advice.

To date, tens of millions of homes have been tested for radon, and nearly two million with high radon levels have been fixed through the efforts of state and local radon programs, radon service providers, non-profit health organizations, and federal agencies. However, EPA estimates that millions of homes with high levels of radon remain. Take the simple step today to protect your loved ones: Test. Fix. Save a Life.

Radon Hero Award

During this year's National Radon Action Month, EPA is honoring long-time employee Lou Witt, who was posthumously awarded the "Radon Hero Award" by the Conference of Radiation Control Program Directors for his lifelong work and commitment to preventing lung cancer risks from radon.

Appointment

From: Adm15Wheeler.Calendar [Adm15Wheeler.Calendar@epa.gov]
Sent: 1/6/2021 1:38:39 PM
To: Molina, Michael [molina.michael@epa.gov]; Bolen, Brittany [bolen.brittany@epa.gov]; Brazauskas, Joseph [brazauskas.joseph@epa.gov]; Terwilleger, Brock [terwilleger.brock@epa.gov]; Benevento, Douglas [benevento.douglas@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Murray, William [Murray.William@epa.gov]; Fotouhi, David [Fotouhi.David@epa.gov]; Bodine, Susan [bodine.susan@epa.gov]; Etheridge, George [Etheridge.George@epa.gov]; Hoverman, Taylor [hoverman.taylor@epa.gov]

Subject: Canceled: Daily Briefing
Location: Administrator's Office/ Conference Call: Ex. 6 ; dial-in: Ex. 6

Start: 1/6/2021 1:30:00 PM
End: 1/6/2021 2:00:00 PM
Show Time As: Free

Required Attendees: Michael Molina; Bolen, Brittany; Brazauskas, Joseph; Terwilleger, Brock; Benevento, Douglas; Gunasekara, Mandy; Hewitt, James; Bill Murray; Fotouhi, David; Bodine, Susan; Etheridge, George; Taylor Hoverman Meredith

Message

From: Molina, Michael [molina.michael@epa.gov]
Sent: 1/6/2021 1:08:13 PM
To: Rodriguez, Alejandra (Allie) [rodriguez.alejandra@epa.gov]
CC: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Block, Molly [block.molly@epa.gov]; Johnson, Taylor [Johnson.Taylor.C@epa.gov]
Subject: Re: FOR REVIEW: Prevent Lung Cancer by Testing your Home for Radon, EPA Recommends

I'm sorry. I realized that I replied to myself in this on Monday. My bad.

Sent from my iPhone

On Jan 5, 2021, at 10:56 AM, Rodriguez, Alejandra (Allie) <rodriguez.alejandra@epa.gov> wrote:

Circling back on this – slated to go out today as well. Thank you ☺

From: Rodriguez, Alejandra (Allie)
Sent: Monday, January 4, 2021 2:57 PM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Molina, Michael <molina.michael@epa.gov>
Cc: hewitt.james@epa.gov; 'block.molly@epa.gov' <block.molly@epa.gov>; 'Johnson.Taylor.C@epa.gov' <Johnson.Taylor.C@epa.gov>
Subject: FOR REVIEW: Prevent Lung Cancer by Testing your Home for Radon, EPA Recommends

Mandy and Molina,
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Radon Hero Award

During this year's National Radon Action Month, EPA is honoring long-time employee Lou Witt, who was posthumously awarded the "Radon Hero Award" by the Conference of Radiation Control Program Directors for his lifelong work and commitment to preventing lung cancer risks from radon.

Message

From: Barker, Kendal [Barker.Kendal@epa.gov]
Sent: 1/6/2021 1:38:47 PM
To: Dunn, Alexandra [dunn.alexandra@epa.gov]
CC: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Benevento, Douglas [benevento.douglas@epa.gov]
Subject: Re: AA Meeting Topic

Hi Alex,

No problem. I've added both agenda items. Thank you!

Best,
Kendal Barker
Special Advisor to the Chief of Staff
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, D.C. 20004
O: (202) 564-6624
C: (202) 834-6447
barker.kendal@epa.gov

On Jan 6, 2021, at 6:57 AM, Dunn, Alexandra <dunn.alexandra@epa.gov> wrote:

Also can you add "Succession Announcements" (Mandy this goes to what I raised about coordinating)

Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, DC

Sent from my iPhone

On Jan 5, 2021, at 2:50 PM, Barker, Kendal <Barker.Kendal@epa.gov> wrote:

Hi Alex,

Thank you so much for your submission. I've added it to Thursday's agenda.

Best,
Kendal Barker
Special Advisor to the Chief of Staff
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, D.C. 20004
O: (202) 564-6624
C: (202) 834-6447

barker.kendal@epa.gov

On Jan 5, 2021, at 2:39 PM, Dunn, Alexandra
<dunn.alexandra@epa.gov> wrote:

Gringard - air disinfectant FIFRA.

Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, DC

Sent from my iPhone

Message

From: Johnson, Taylor [Johnson.Taylor.C@epa.gov]
Sent: 1/6/2021 2:32:07 PM
To: Molina, Michael [molina.michael@epa.gov]
CC: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Block, Molly [block.molly@epa.gov]; Rodriguez, Alejandra (Allie) [rodriguez.alejandra@epa.gov]; McFaul, Jessica [mcfaul.jessica@epa.gov]; Murray, William [Murray.William@epa.gov]
Subject: RE: FOR APPROVAL: Auto Trends Report

Hey Mandy, just following up on the below if you have any additional input. Thanks!

From: Johnson, Taylor
Sent: Tuesday, January 5, 2021 8:28 AM
To: Molina, Michael <molina.michael@epa.gov>
Cc: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Hewitt, James <Hewitt.James@epa.gov>; Block, Molly <block.molly@epa.gov>; Rodriguez, Alejandra (Allie) <Rodriguez.Alejandra@epa.gov>; McFaul, Jessica <mcfaul.jessica@epa.gov>; Murray, William <Murray.William@epa.gov>
Subject: RE: FOR APPROVAL: Auto Trends Report

Thanks, Michael! Updated that below. Mandy, please let me know if you have any additional edits.

From: Molina, Michael <molina.michael@epa.gov>
Sent: Tuesday, January 5, 2021 7:36 AM
To: Johnson, Taylor <Johnson.Taylor.C@epa.gov>
Cc: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Block, Molly <block.molly@epa.gov>; Rodriguez, Alejandra (Allie) <rodriguez.alejandra@epa.gov>; McFaul, Jessica <mcfaul.jessica@epa.gov>; Murray, William <Murray.William@epa.gov>
Subject: Re: FOR APPROVAL: Auto Trends Report

"We have set realistic standards in 2020 that will reduce emissions as well as vehicle costs and maintain consumer choice going forward."

Sent from my iPhone

On Jan 4, 2021, at 3:27 PM, Johnson, Taylor <Johnson.Taylor.C@epa.gov> wrote:

Hi Michael and Mandy, please see below for the Auto Trends release planned for Wednesday. Thanks!

Agency Releases Annual Automotive Trends Report Showing Manufacturers Still Struggling to Comply with Obama Era Standards without Use of Credits

01/06/2021

Contact Information:
(press@epa.gov)

WASHINGTON (January 6, 2020) – Today, the U.S. Environmental Protection Agency (EPA) released its annual *Automotive Trends Report*, which provides the public with a single source of information about new light-duty vehicle greenhouse gas (GHG) emissions, fuel economy,

technology data, and auto manufacturers' performance in meeting the agency's GHG emissions standards. The report shows that fuel economy remains high but has slipped slightly from the record pace set in previous years and that reducing emissions through innovation remains a priority for automotive manufacturers.

"This report shows in detail how few auto manufactures were able to meet the unrealistic emissions standards set by the Obama Administration without resorting to purchasing emission credits," **said EPA Administrator Andrew Wheeler**. "We have set realistic standards in 2020 that will reduce emissions as well as vehicle costs and maintain consumer choice going forward."

Fuel economy for Model Year (MY) 2019 was 24.9 miles per gallon, lower than MY 2018 by only 0.2 mpg. Since MY 2004, when the fleet averaged 19.3 mpg, fuel economy, and CO_2 emissions have improved in twelve out of fifteen years.

The report also assesses compliance performance for individual automakers, and for the U.S. fleet, with the GHG emissions standards for light-duty vehicles. This year's report once again shows that only 3 large manufacturers complied with MY 2019 standard based on technology factors of their vehicles alone. When accounting for credits, however, the report shows all large manufacturers are in compliance. Eleven out of 14 large manufacturers used a combination of technology improvements, banked credits, and purchased credits to maintain compliance in MY 2019.

Key Highlights

- Due to a combination of technology, innovation and regulatory flexibility, the average new MY 2019 vehicle sold in the U.S. was near record low GHG emissions and near record high fuel economy.
- New vehicles continue to make progress on GHG emissions while providing consumer choice for Americans. For example, sport utility vehicles reached record high market share, while also achieving record high fuel economy and record low CO_2 emissions.
- Manufacturers continue to have a large bank of credits to use toward compliance in future model years, however, about two-thirds of the current credits will expire after model year 2021.

To read the full Automotive Trends Report, please visit: https://www.epa.gov/automotive-trends

Background

Each manufacturer fleet generates credits if the fleet average emissions performance is below the standards, or deficits if it is above the standards. Credits, or deficits, that manufacturers have accrued in previous model years, credits earned as part of the early credit program, credit trades, credit forfeitures, and credit expirations are also important components in determining the final compliance status of each manufacturer. Manufacturers that maintain a positive, or zero, credit balance are considered in compliance with the GHG program. Manufacturers that end any model year with a deficit have up to three years to offset that deficit to avoid non-compliance.

About the Report

This annual report is part of the EPA's commitment in providing the public with transparent information about new light-duty vehicle GHG emissions, fuel economy, technology data, and

auto manufacturers' performance in meeting the agency's GHG emissions standards. EPA has collected data on every new light-duty vehicle model sold in the United States since 1975. Data is collected to support several national programs, including EPA criteria pollutant and GHG standards, the U.S. Department of Transportation's National Highway Traffic Safety Administration (NHTSA) Corporate Average Fuel Economy (CAFE) standards, and vehicle Fuel Economy and Environment labels.

Message

From: Meadowcroft, Micah [Meadowcroft.Micah@epa.gov]
Sent: 1/6/2021 2:22:22 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Molina, Michael [molina.michael@epa.gov]
Subject: FW: Termination of detail for Schedule C employee, Sean Donahue_21 0021058

Good morning,

I wasn't actually aware Sean was on a detail. Please advise regarding below.

Thank you,
Micah Meadowcroft

White House Liaison
U.S. Environmental Protection Agency
William Jefferson Clinton Building North, Room 2402A
1200 Pennsylvania Ave, NW
Washington, DC 20460
Office Phone: (202) 564-0015
Work Cell: (202) 768-4924

From: Carr, Dorothy <Carr.Dorothy@epa.gov>
Sent: Wednesday, January 6, 2021 7:50 AM
To: Meadowcroft, Micah <Meadowcroft.Micah@epa.gov>
Cc: Timpy, Sarah <timpy.sarah@epa.gov>
Subject: FW: Termination of detail for Schedule C employee, Sean Donahue_21 0021058

Good morning Micah,

Will Sean's detail end as scheduled, or are you submitting an action to extend it?

Dorothy Carr
Lead Human Resources Specialist, Executive Resources
Human Resources Management Division, OARM-RTP
U.S. Environmental Protection Agency
Research Triangle Park, NC
(919) 541-4356 (office)
(252) 301-4784 (cell)

CONFIDENTIALITY: This communication may contain privileged or other confidential information. If you are not the intended addressee, or believe you have received this communication in error, you may neither copy, disseminate, nor distribute it to anyone else or use it in any unauthorized manner; to do so is strictly prohibited and may be unlawful. If you receive this email by mistake, please advise the sender immediately by using the reply facility in your mail software and delete it from your computer. Information in this message may be subject to the Privacy Act (5 USC 552a) and should be treated accordingly.

From: Timpy, Sarah <timpy.sarah@epa.gov>
Sent: Tuesday, January 5, 2021 4:37 PM
To: Carr, Dorothy <Carr.Dorothy@epa.gov>
Subject: Termination of detail for Schedule C employee, Sean Donahue_21 0021058

Hi Dorothy,

A detail termination generated for Schedule C employee, Sean Donahue. Would you like me to process this termination?

DONAHUE, SEAN M.	932	TERM OF DETAIL	A0000000	01/15/21	21 0021058

Thank you,
Sarah Timpy
Human Resources Specialist
Executive Resources, OARM-RTP
U.S. Environmental Protection Agency
Research Triangle Park, NC
919-541-3916

OFFICE OF ADMINISTRATION AND RESOURCES MANAGEMENT
RESEARCH TRIANGLE PARK

Message

From: Grantham, Nancy [Grantham.Nancy@epa.gov]
Sent: 1/6/2021 1:53:02 PM
Subject: january 6 issues
Attachments: january 6 issues .docx

Nancy Grantham
Principal Deputy Associate Administrator
Environmental Protection Agency
Office of Public Affairs
202-564-6879 (desk)
202-253-7056 (cell)
grantham.nancy@epa.gov

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Message

From: OIG News [OIG.News@epa.gov]
Sent: 1/6/2021 2:30:15 PM
To: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]
CC: Wheeler, Andrew [wheeler.andrew@epa.gov]; Darwin, Henry [darwin.henry@epa.gov]; Benevento, Douglas [benevento.douglas@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Carpenter, Wesley [Carpenter.Wesley@epa.gov]; Bloom, David [Bloom.David@epa.gov]; LeBlanc, Andrew [LeBlanc.Andrew@epa.gov]; Atcherson, Aileen [Atcherson.Aileen@epa.gov]; Kercado Deleon, Jose [KercadoDeleon.Jose@epa.gov]; OCFO Agency AFC [OCFO_Agency_AFC@epa.gov]; Fotouhi, David [Fotouhi.David@epa.gov]; Willey, Katharine [willey.katharine@epa.gov]; Brazauskas, Joseph [brazauskas.joseph@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Martiyan, Stefan [MARTIYAN.STEFAN@EPA.GOV]; Benton, Michael [benton.michael@epa.gov]; Brennan, Thomas [Brennan.Thomas@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Robbins, Chris [Robbins.Chris@epa.gov]; Dunlap, David [dunlap.david@epa.gov]; Rodan, Bruce [rodan.bruce@epa.gov]; Steenbock, John [Steenbock.John@epa.gov]; VanDrunick, Suzanne [vanDrunick.Suzanne@epa.gov]; Goodin, John [Goodin.John@epa.gov]; Hingeley, Maureen [Hingeley.Maureen@epa.gov]; Crawford, Tiffany [Crawford.Tiffany@epa.gov]; Sinks, Thomas (Tom) [Sinks.Tom@epa.gov]
Subject: OIG Report: "Office of Research and Development Initiatives to Address Threats and Risks to Public Health and the Environment from Plastic Pollution Within the Waters of the United States"
Attachments: _epaoig_20210106-21-N-0052_cert.pdf

Attached is the EPA Office of Inspector General report, *Office of Research and Development Initiatives to Address Threats and Risks to Public Health and the Environment from Plastic Pollution Within the Waters of the United States* (Report No. 21-N-0052). This report will be available to the public on the OIG's website at www.epa.gov/oig.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

January 6, 2021

MEMORANDUM

SUBJECT: Office of Research and Development Initiatives to Address Threats and Risks to Public Health and the Environment from Plastic Pollution Within the Waters of the United States
Report No. 21-N-0052

FROM: Sean W. O'Donnell

TO: Jennifer Orme-Zavaleta, Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development

The U.S. Environmental Protection Agency's Office of Inspector General initiated an audit to identify the extent to which the EPA's existing Clean Water Act programs and Office of Research and Development research initiatives address threats and risks to public health and the environment from plastic pollution within the waters of the United States. The project number for this audit is OA&E-FY19-0086. We performed our work within two EPA offices: the Office of Water, or OW, and the Office of Research and Development, or ORD.

This report contains our conclusions related to the ORD and closes our work on this aspect of the audit with no recommendations. We will issue a separate report on our findings related to the OW.

Background

Microplastics

Plastic debris in the aquatic environment presents a persistent and growing environmental problem. Worldwide, more than 29 million metric tons of plastic enter the environment each year.[1] Over time, in some cases over hundreds of years, plastic objects fragment into progressively smaller and more numerous particles without substantial chemical degredation. Particles smaller than 5 millimeters are defined as *microplastics* and account for approximately 90 percent of plastic in the ocean.

In 2017, the EPA convened a Microplastics Expert Workshop to identify and prioritize the scientific information needed to understand the risks posed by microplastics to human and ecological health.

[1] Palardy, Jim, "Science Study Shows That Nearly 80% of the Annual Plastic Flow Into the Environment Can Be Stopped Using Existing Technology," PEW Charitable Trusts, July 23, 2020.

EPA's ORD

The ORD primarily focuses on providing a scientific and technical foundation for the EPA to fulfill its statutory obligations and help Agency, state, and other partners address environmental and public health challenges. The ORD is composed of six national research programs, which aim to deliver a cleaner, safer, and healthier environment for all Americans. One of those research programs is the Safe and Sustainable Water Resources program, or SSWR.

By collaborating with EPA program offices, such as the OW, the ORD develops Strategic Research Action Plans, or StRAPs, for each national research program. Each program's StRAP outlines a four-year research strategy to advance the program's goals and the cross-Agency priorities identified in the EPA's Strategic Plan.

The 2019–2022 SSWR StRAP organizes the SSWR's activities into three interrelated research areas:

- Watersheds.
- Nutrients and harmful algal blooms.
- Water treatment and infrastructure.

Plastics research occurs under the "Watersheds" research area, specifically under StRAP Output 1.4:

> *Methods to identify and quantify micro/nanoplastics in environmental matrices*. Research will address plastic pollution in the aquatic environment by establishing reliable and reproducible methods for micro/nanoplastics collection, extraction, characterization, and quantification in sediment and surface water.

Scope and Methodology

We conducted this work from November 2019 to October 2020. While our overall audit, which is still ongoing, is being conducted in accordance with generally accepted government auditing standards, the work related to this report does not constitute an audit done in accordance with these standards. However, we did follow the OIG's quality control procedures for ensuring that the information in this report is accurate and supported.

This report addresses the ORD's research prioritization process for the SSWR StRAP. We did not evaluate other ORD-led StRAP development processes. To conduct our work, we met with ORD and OW managers and staff. We conducted interviews with scientists at the ORD's Atlantic Coastal Environmental Sciences Division laboratory in Narragansett, Rhode Island. We also spoke to researchers and staff at nongovernmental organizations and academic institutions. We analyzed ORD documents for information pertaining to microplastic research priorities.

Prior Report

On April 9, 2018, we issued Report No. 18-P-0151, *EPA's Safe and Sustainable Water Resources Research Program Is Delivering Timely and Relevant Data to the Office of Water.* We reported that ORD SSWR research products were relevant to the OW and were delivered in a timely fashion. We also reported that these products were used or will be used to protect America's waters. We issued no recommendations as a result of that audit.

Results

The EPA's research into plastics is in its early stages, and the ORD has not yet conducted enough research to determine risks to public health and the environment from plastic exposure. The 2019–2022 SSWR StRAP, issued in March 2020, was the first time the ORD included plastics as a research priority. Specifically, the StRAP states that the ORD will deliver recommendations for best practices and standardized methodologies to characterize micro/nanoplastics in sediment and surface water.

In June 2017, the ORD and the OW conducted a Microplastics Expert Workshop with participants from federal agencies, academic institutions, and nongovernmental organizations. The participants identified a broad range of research needs for determining the human health and environmental risks of microplastics, including:

- Establishing precise methods for analysis.
- Conducting research on sources, transport, fate, and distribution in the environment.
- Creating standardized toxicity tests.
- Creating methods and conducting research to characterize human exposure and impacts.

In January 2018, the ORD started developing SSWR StRAP research priorities by consulting with subject matter experts from the EPA, states, and tribes. This process involved several steps, including:

- Problem identification.
- Development of research outputs.
- Review and comment periods for EPA staff and stakeholders.

In April 2019, the ORD issued a draft SSWR StRAP, which identified microplastics as an area of concern for potential impacts to aquatic life and human health. The draft StRAP stated that:

> [R]esearch efforts are needed to better understand the exposure to and potential effects of micro/nano plastic pollution in the aquatic environment to inform CWA [Clean Water Act] regulatory programs and voluntary approaches. Standardized, reliable, reproducible, and environmentally representative methods are fundamental and of paramount importance for sample collection, extraction, characterization, and quantification. These methods will provide the foundation to investigate potential adverse health outcomes in humans and aquatic organisms exposed to micro/nanoplastics.

In the draft SSWR StRAP, the ORD identified three priority areas for microplastics research:

- Develop methods to determine the quantity of microplastics in the environment.
- Investigate the human health effects caused by drinking water containing microplastics.
- Determine the effects of microplastic exposure to aquatic species.

In the final SSWR StRAP, which was issued in March 2020, the OW and the ORD narrowed these three initial priority areas into one:

- Methods to identify and quantify microplastics and nanoplastics in environmental matrices (or "sampling methods").

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According to OW and ORD senior leaders, the decision to narrow the microplastics priority area was necessary for two reasons: 1) sampling methods need to be established before the human health and environmental effects of microplastics exposure can be investigated, and 2) the ORD's resources were deployed to address other research needs in the 2019–2022 SSWR StRAP.

Conclusion

The 2019–2022 SSWR StRAP commits the ORD to deliver recommendations for best practices and standardized methodologies to characterize micro/nanoplastics in sediment and surface water. With these recommendations, the ORD can identify and prioritize the scientific information needed to understand the risks posed by microplastics to human health and the environment from plastic pollution within the waters of the United States. In 2021, the ORD and the OW plan to begin developing the next set of SSWR StRAP research priorities based on the OW's needs. This process will determine whether plastics continue to be a research priority.

cc: Andrew Wheeler, Administrator
Henry Darwin, Assistant Deputy Administrator
Doug Benevento, Associate Deputy Administrator
Mandy Gunasekara, Chief of Staff
Michael Molina, Deputy Chief of Staff/Operations
Tom Brennan, Director, Science Advisory Board Staff Office
David Bloom, Agency Follow-Up Official (the CFO)
David P. Ross, Assistant Administrator for Water
Andrew LeBlanc, Agency Follow-Up Coordinator
David Fotouhi, Acting General Counsel
Joseph Brazauskas, Acting Associate Administrator for Congressional and Intergovernmental Relations
James Hewitt, Associate Administrator for Public Affairs
Anna Wildeman, Principal Deputy Assistant Administrator for Water
Benita Best-Wong, Deputy Assistant Administrator for Water
Chris Robbins, Deputy Assistant Administrator for Management, Office of Research and Development
David Dunlap, Deputy Assistant Administrator for Science Policy, Office of Research and Development
Bruce Rodan, Associate Director for Science, Office of Research and Development
John Steenbock, Acting Associate Assistant Administrator for Research and Development
Suzanne VanDrunick, National Program Director for EPA's Safe and Sustainable Water Resources Research Program, Office of Research and Development
Thomas Sinks, Director, Office of the Science Advisor, Office of Research and Development
John Goodin, Director, Office of Wetlands, Oceans and Watersheds, Office of Water
Stefan Martiyan, Director, Office of Continuous Improvement, Office of the Chief Financial Officer
Michael Benton, Audit Follow-Up Coordinator, Office of the Administrator
Maureen Hingeley, Audit Follow-Up Coordinator, Office of Research and Development
Tiffany Crawford, Audit Follow-Up Coordinator, Office of Water

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Message

From: Carter, Brittany S. [carter.brittanys@epa.gov]
Sent: 1/6/2021 4:03:13 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
CC: Molina, Michael [molina.michael@epa.gov]; Pic, Jordan [pic.jordan@epa.gov]; Burgess, Michael [Burgess.Michael@epa.gov]; Teresa, Tyler [Teresa.Tyler@epa.gov]
Subject: RE: MS Trip Updates

Good morning,

Wanted to check-in on the late lunch question for Sunday. Would AW like to do this and if so, how many people from the EPA will be joining them?

Thank you!

Britt

From: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>
Sent: Tuesday, January 5, 2021 3:10 PM
To: Carter, Brittany S. <carter.brittanys@epa.gov>
Cc: Molina, Michael <molina.michael@epa.gov>; Pic, Jordan <pic.jordan@epa.gov>; Burgess, Michael <Burgess.Michael@epa.gov>; Teresa, Tyler <Teresa.Tyler@epa.gov>
Subject: Re: MS Trip Updates

I'll ask AW. A later lunch would actually be great but let me confirm. Is that at 1:30 or 2?

Sent from my iPhone

> On Jan 5, 2021, at 3:08 PM, Carter, Brittany S. <carter.brittanys@epa.gov> wrote:
>
> Gov office has confirmed 2pm on Sunday at the Governors mansion. They were wondering if we would be interested in a late lunch or anything at that time? Or just a meeting? (If you do want lunch will need to know for how many.) Thank you!
>
> On Jan 4, 2021, at 10:52 AM, Gunasekara, Mandy <Gunasekara.Mandy@epa.gov> wrote:
>
> Michael and Owen will follow up later today once that is set.
>
> Sent from my iPhone
>
>> On Jan 4, 2021, at 10:51 AM, Carter, Brittany S. <carter.brittanys@epa.gov> wrote:
>>
>> Great, thank you. For the Sunday dinner, would we need to provide bios/issues for the key leaders and officials involved? If so, would you mind sharing who is participating?

From: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>
Sent: Monday, January 4, 2021 10:46 AM
To: Carter, Brittany S. <carter.brittanys@epa.gov>; Molina, Michael <molina.michael@epa.gov>
Cc: Pic, Jordan <pic.jordan@epa.gov>; Burgess, Michael <Burgess.Michael@epa.gov>; Teresa, Tyler <Teresa.Tyler@epa.gov>
Subject: RE: MS Trip Updates

Hey Britt –
Michael and Owen and working through the rest of the trip later today. Below is the tentative plan. Also, 2 to 3 on Sunday will work great.

Saturday Evening: AW Lands in Jackson, MS

Sunday: JACKSON

- (Mid to late afternoon) Gov Meeting at the Mansion
- possible tour of MS civil rights museum
- 5:30- 6 pm Dinner with a few key leaders and officials

Monday: VICKSBURG

- Meet at Vicksburg Army Corps HQ with leaders/officials involved with pumps including MS congressional delegation
- Tour USACE ERDC: http://www.erdc.usace.army.mil/
- Farm Event (TBD per Carrie and MS Farm Bureau) to announce new worker protections.
- Fly back to DCA from JAN (2:52 PM)

Sent from my iPhone

From: Carter, Brittany S. <carter.brittanys@epa.gov>
Sent: Monday, January 4, 2021 8:56 AM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Molina, Michael <molina.michael@epa.gov>
Cc: Pic, Jordan <pic.jordan@epa.gov>; Burgess, Michael <Burgess.Michael@epa.gov>; Teresa, Tyler <Teresa.Tyler@epa.gov>
Subject: MS Trip Updates

Good morning,

Hope everyone had a great New Year! We are still confirming if 2-3pm works on Sunday afternoon to meet with the Gov., hope to hear back today. Do you all have any information (time, location) about the Monday events we can share to help get folks confirmed?

Thank you!

-Britt

Message

From: Teresa, Tyler [Teresa.Tyler@epa.gov]
Sent: 1/6/2021 5:23:09 AM
To: Burgess, Michael [Burgess.Michael@epa.gov]; Block, Molly [block.molly@epa.gov]; Allen, Jacob [Allen.Jacob@epa.gov]; Coxen, Carrie [coxen.carrie@epa.gov]; Dickerson, Aaron [dickerson.aaron@epa.gov]; Etheridge, George [Etheridge.George@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Hoverman, Taylor [hoverman.taylor@epa.gov]; Hyman, Alana [Hyman.Alana@epa.gov]; Johnson, Taylor [Johnson.Taylor.C@epa.gov]; Keith, Jennie [Keith.Jennie@epa.gov]; Meadows, Carrie Vicenta [Meadows.CarrieVicenta@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Murray, William [Murray.William@epa.gov]; Ex. 7(C), 7(F); Scott, Corey [scott.corey@epa.gov]; Vella, Sophia [Vella.Sophia@epa.gov]; Tran, Victoria [tran.victoria@epa.gov]; Zimmer, Nathaniel [zimmer.nathaniel@epa.gov]; Barker, Kendal [Barker.Kendal@epa.gov]; Rodriguez, Alejandra (Allie) [rodriguez.alejandra@epa.gov]; Hill-Macon, Cam [Hill-Macon.Cam@epa.gov]; Kasman, Mark [Kasman.Mark@epa.gov]; Gonzalez, Orlando [Gonzalez.Orlando@epa.gov]
CC: Ryder-Rude, Meredith V [RyderrudeMV@state.gov]; Bannister, Sarah J [BannisterSJ@state.gov]; Hall, Sheena [HallS@state.gov]
Subject: V3. LxL Costa Rica
Attachments: v3. LxL Costa Rica.pdf; v3. LxL Costa Rica.docx

All,

Please see the attached v3. LxL for Costa Rica.

Major Updates (per day):
01/06 – Ambassador Day will be in Country Briefing at 3:00 PM
01/07 – Change in MFA personnel attending the Bilateral Meeting with the Vice Minister of Environment
01/07 – Updated run of show for IICA programs
01/07 – Earlier start time for Dinner with Ambassador Day at CMR
01/08 – Ambassador Day will unfortunately not be able to make any of the day events
01/09 – Earlier departure time for Airport

I will have copies ready tomorrow at the Hotel for traveling delegation.

Please let me know if you have any questions!

Best,

Tyler T.

From: Teresa, Tyler
Sent: Monday, January 4, 2021 7:34 AM
To: Burgess, Michael <Burgess.Michael@epa.gov>; Block, Molly <block.molly@epa.gov>; Allen, Jacob <Allen.Jacob@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dickerson, Aaron <dickerson.aaron@epa.gov>; Etheridge, George <Etheridge.George@epa.gov>; Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Hewitt, James <Hewitt.James@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Hyman, Alana <Hyman.Alana@epa.gov>; Johnson, Taylor <Johnson.Taylor.C@epa.gov>; Keith, Jennie <Keith.Jennie@epa.gov>; Meadows, Carrie Vicenta <Meadows.CarrieVicenta@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Murray, William <Murray.William@epa.gov>; Ex. 7(C), 7(F); Scott, Corey <scott.corey@epa.gov>; Vella, Sophia <Vella.Sophia@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Barker, Kendal <Barker.Kendal@epa.gov>; Rodriguez, Alejandra (Allie) <Rodriguez.Alejandra@epa.gov>; Hill-Macon, Cam <Hill-Macon.Cam@epa.gov>; Kasman, Mark <Kasman.Mark@epa.gov>; Gonzalez, Orlando <Gonzalez.Orlando@epa.gov>

Cc: Ryder-Rude, Meredith V <RyderrudeMV@state.gov>; Bannister, Sarah J <BannisterSJ@state.gov>; Hall, Sheena <HallS@state.gov>
Subject: V2. LxL Costa Rica

All,

Attached is the v2. LxL for Costa Rica.

Please let me know if you have any edits or updates!

Best,

Tyler T.

From: Teresa, Tyler
Sent: Thursday, December 31, 2020 11:16 AM
To: Burgess, Michael <Burgess.Michael@epa.gov>; Block, Molly <block.molly@epa.gov>; Allen, Jacob <Allen.Jacob@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dickerson, Aaron <dickerson.aaron@epa.gov>; Etheridge, George <Etheridge.George@epa.gov>; Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Hewitt, James <Hewitt.James@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Hyman, Alana <Hyman.Alana@epa.gov>; Johnson, Taylor <Johnson.Taylor.C@epa.gov>; Keith, Jennie <Keith.Jennie@epa.gov>; Meadows, Carrie Vicenta <Meadows.CarrieVicenta@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Murray, William <Murray.William@epa.gov>; Ex. 7(C), 7(F) ; Scott, Corey <scott.corey@epa.gov>; Vella, Sophia <Vella.Sophia@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Barker, Kendal <Barker.Kendal@epa.gov>; Rodriguez, Alejandra (Allie) <Rodriguez.Alejandra@epa.gov>; Hill-Macon, Cam <Hill-Macon.Cam@epa.gov>; Kasman, Mark <Kasman.Mark@epa.gov>; Gonzalez, Orlando <Gonzalez.Orlando@epa.gov>
Cc: Ryder-Rude, Meredith V <RyderrudeMV@state.gov>; Bannister, Sarah J <BannisterSJ@state.gov>; Hall, Sheena <HallS@state.gov>
Subject: V1. LxL Costa Rica

All,

Attached is the V1. LxL for Costa Rica.

Please send me any edits or updates you might have and have a Happy New Year!

Best,

Tyler T.

Tyler C. Teresa
Deputy Director of Advance
Office of the Administrator
Environmental Protection Agency
202-306-7337 (Cell)

SAN JOSE, COSTA RICA
WEDNESDAY, JANUARY 6 – SATURDAY, JANUARY 9, 2021

WEDNESDAY, JANUARY 6

5:30am ADMINISTRATOR WHEELER departs Personal Residence en route to Ronald Reagan Washington National Airport (DCA)

Vehicle Assignments:
LIMO: ADMINISTRATOR WHEELER
COREY SCOTT
Ex. 7(C); Ex. 7(F) – RF

Drive Time: 25 Minutes

Departure Airport
Ronald Reagan Washington National Airport
2401 Smith Blvd
Arlington, VA

5:55am ADMINISTRATOR WHEELER arrives at Ronald Reagan Washington National Airport (DCA) and proceeds to the gate for boarding

EVENT AIRPORT DEPARTURE

6:48am ADMINISTRATOR WHEELER departs Ronald Reagan Washington National Airport (DCA) en route to Charlotte Douglas International Airport (CLT)

AIRLINE LOCATOR NUMBER: Ex. 6
ADMINISTRATOR SEAT: 19C

AMERICAN AIRLINES (AA400)
ADMINISTRATOR WHEELER
CHAD MCINTOSH
MICHAEL MOLINA
CARRIE MEADOWS
COREY SCOTT
MOLLY BLOCK
JAKE ALLEN
Ex. 7(C); Ex. 7(F)

Flight Time: 1 Hour, 44 Minutes
Time Change: N/A

EVENT AIRPORT CONNECTION

Connection Airport
Charlotte Douglas International Airport
5501 Josh Birmingham Pkwy
Charlotte, NC

8:32am ADMINISTRATOR WHEELER arrives at Charlotte Douglas International Airport (CLT) and proceeds to American Airlines Flight 1707

Layover: 46 Minutes

9:18am ADMINISTRATOR WHEELER departs Charlotte Douglas International Airport (CLT) en route Juan Santamaría International Airport (SJO)

AIRLINE LOCATOR NUMBER: Ex. 6
ADMINISTRATOR SEAT: 25D

AMERICAN AIRLINES (AA1707)
ADMINISTRATOR WHEELER
CHAD MCINTOSH
MICHAEL MOLINA
CARRIE MEADOWS
COREY SCOTT
MOLLY BLOCK
JAKE ALLEN
Ex. 7(C); Ex. 7(F)

Flight Time: 4 Hours, 17 Minutes
Time Change: -1 Hour

EVENT AIRPORT ARRIVAL

Arrival Airport
Juan Santamaría International Airport
Alajuela Province
Alajuela, Costa Rica

12:35pm(CST) ADMINISTRATOR WHEELER arrives at Juan Santamaría International Airport and is escorted to Diplomatic Waiting Room with a small group while bags are cleared through customs and are placed in luggage truck

DIPLOMATIC WAITING ROOM
ADMINISTRATOR WHEELER
CHAD MCINTOSH
MICHAEL MOLINA
COREY SCOTT
Ex. 7(C); Ex. 7(F)

Note: *Remainder of the staff is expedited through customs and proceeds to motorcade for departure*

1:00pm Luggage is cleared; ADMINISTRATOR WHEELER departs Juan Santamaría International Airport (SJO) en route to InterContinental Costa Rica at Multiplaza Mall (RON)

Vehicle Assignments:	
LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	MEREDITH RYDER-RUDE SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) - PSD

Drive Time: 25 Minutes; 12 Miles

RON Location
InterContinental Costa Rica at Multiplaza Mall
Multiplaza Shopping Center,
San José Province, Escazu, 10202, Costa Rica

1:25pm ADMINISTRATOR WHEELER arrives at InterContinental Costa Rica at Multiplaza Mall (RON) and begins Executive Time / Lunch at the Hotel

3:00pm ADMINISTRATOR WHEELER and Delegation concludes Executive Time and proceeds to Robles Room in the hotel lobby for in country briefing

Note: *Ambassador Day will be attending this meeting*

4:00pm Briefing concludes; ADMINISTRATOR WHEELER begins Executive Time

5:45pm Executive Time concludes; ADMINISTRATOR WHEELER departs InterContinental Costa Rica en route to Furca for Dinner

Vehicle Assignments:	
LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	MEREDITH RYDER-RUDE SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) PSD TYLER TERESA

Drive Time: 12 Minutes; 3.7 Miles

Dinner Location
Furca
Nunciatura, San José Province
San José, Costa Rica

6:00pm	ADMINISTRATOR WHEELER arrives at Furca for Dinner
8:00pm	ADMINISTRATOR WHEELER departs Furca en route to the InterContinental Costa Rica (RON)
8:15pm	ADMINISTRATOR WHEELER arrives at InterContinental Costa Rica (RON) and begins Executive time
RON	**INTERCONTINENTAL COSTA RICA**

THURSDAY, JANUARY 7

***Breakfast:** The Market from 6:00am – 10:00am in the lobby

8:40am ADMINISTRATOR WHEELER departs the Hotel en route to the Chief of Missions Residence (CMR) for Bilateral Meeting with Vice Minister Franklin Paniagua, Vice Minister of the Environment, Republic of Costa Rica Ministry of Environment and Energy

Vehicle Assignments:

EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER ADRIAN CASTRO
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) – PSD TYLER TERESA

Drive Time: 10 Minutes

Event Location
The Chief of Mission Residence

8:50am ADMINISTRATOR WHEELER arrives at the CMR

EVENT **BILATERAL MEETING – MINISTRY OF ENVIRONMENT AND ENERGY**

LOCATION: Courtyard - Chief of Missions Residence
TYPE: Bilateral Meeting
SPEAKING: Talking Points
ATTIRE: Business Professional
PRESS: Closed
GIFTS: No
INTERPRETATION: N/A – On Standby
PARTICIPANTS: **EPA**
P. ADMINISTRATOR WHEELER
1. T.H. Sharon Day, U.S. Ambassador to Costa Rica
2. T.H. Chad McIntosh, AA OITA
3. Michael Molina, Deputy Chief of Staff
4. Corey Scott, Executive Advisor to the Administrator
5. Michael Stewart, Economic Section Chief

MINISTRY OF ENVIRONMENT AND ENERGY (MINAE)
P. Franklin Paniagua, Vice Minister of the Environment
1. Haydeé Rodriguez, Vice Minister of Water and Oceans
2. Director Patricia Campos, Climate Change
3. Adolfo Constenla International Cooperation Official for North and Central America, MFA
4. Daniela Villalta, Advisor, MINAE
5. Alejandra Aguilar, Trade & Environment Advisor, Ministry of Foreign Trade (COMEX)

SCENARIO:

8:50am *- ADMINISTRATOR WHEELER and U.S. Delegation arrives to CMR and proceeds to the Courtyard*

8:55am *- Introductions take place in Courtyard between EPA and MINAE*

9:00am *- Delegations take their seats and Bilateral Meeting Begins*

10:00am Event concludes; ADMINISTRATOR WHEELER departs CMR en route to Inter-American Institute for Cooperation on Agriculture (IICA)

Vehicle Assignments:

AMB LIMO:	AMBASSADOR DAY ADMINISTRATOR WHEELER EMBASSY DRIVER – Limo Driver ROBERT WELLS – RSO
FOLLOW (EPA LIMO):	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - RF Ex. 7(C); Ex. 7(F) PSD
SPARE LIMO (EPA FOLLOW):	EMPTY
EPA STAFF VEHICLE:	CHAD MCINTOSH MICHAEL MOLINA COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER TONANTZIN JUAREZ ADRIAN CASTRO
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) PSD TYLER TERESA

Drive Time: 40 Minutes

Event Location

Inter-American Institute for Cooperation on Agriculture (IICA)
600 metros norte del Cruce Ipís Coronado San Isidro
San Jose CR 2200,
San José, Ipis, Costa Rica

10:40am ADMINISTRATOR WHEELR arrives at IICA and begins meetings: Bilateral Meeting with Minister Luis Renato Alvarado, Minister of Agricultural, Republic of Costa Rica Ministry of Agricultural and Livestock and IICA Brief Presentation

EVENT **BILATERAL MEETING WITH MINISTRY OF AGRICULTURAL AND LIVESTOCK AND IICA PRESENTATION**

LOCATION:	Director General's Office - IICA
TYPE:	Roundtable
SPEAKING:	Talking Points
ATTIRE:	Business Professional
PRESS:	Closed
GIFTS:	No
INTERPRETATION:	N/A – On Standby
PARTICIPANTS:	**EPA**

P. ADMINISTRATOR WHEELER
1. T.H. Sharon Day, U.S. Ambassador to Costa Rica
2. T.H. Chad McIntosh, AA OITA
3. Michael Molina, Deputy Chief of Staff
4. Carrie Meadows, Agricultural Advisor

MINISTRY OF AGRICULTURAL AND LIVESTOCK
P. Luis Renato Alvarado, Minister of Agricultural
1. Edgar Mata, Executive Director of Agricultural Planning

IICA – BILATERAL MEETING PARTICIPANTS
P. Lloyd Day, Deputy Director General

IICA – PRESENTATION PARTICIPANTS (TBC)
P. Lloyd Day, Deputy Director General
1. Miguel Angel Arvelo, Chief of Staff
2. Erick Bolaños, Agriculture Sanitation Specialist
3. Ana Marisa Cordero, Interim Manager of Sanitation and Food Quality
4. Pedro Rocha, International Biotechnology and Biosecurity Specialist

SCENARIO:

10:40am	*-ADMINISTRATOR WHEELER arrives and is greeted by Deputy Director General Lloyd Day and is escorted to the Founder Lobby for Delegation Introductions*
10:43am	*- ADMINISTRATOR WHEELER is introduced to Minister Alvarado and Director Mata and takes a Principal photo in the Founder Lobby*
10:45am	*-Delegations are escorted to the Director Generals Office; ADMINISTRATOR WHEELER participates in Bilateral Meeting with Minister Luis Renato Alvardo*
Note:	*Minister Luis Renato Alvardo will be departing after Bilateral Meeting but will have a quick pull aside with Ambassador Day*
11:15am	*- Bilateral Meeting concludes; ADMINISTRATOR WHEELER participates in brief presentation about IICA's work; led by Deputy Director General Lloyd Day*

11:30am Presentation concludes; ADMINISTRATOR WHEELER proceeds to USA Minister for IICA Shareholder Roundtable

EVENT **SHAREHOLDER ROUNDTABLE LUNCHEON - IICA**

LOCATION:	USA Minister Room - IICA
TYPE:	Roundtable Luncheon
SPEAKING:	Talking Points
ATTIRE:	Business Professional
PRESS:	Closed
GIFTS:	No
INTERPRETATION:	N/A – On Standby
PARTICIPANTS:	**EPA** P. ADMINISTRATOR WHEELER 1. T.H. Sharon Day, U.S. Ambassador to Costa Rica 2. T.H. Chad McIntosh, AA OITA 3. Michael Molina, Deputy Chief of Staff 4. Carrie Meadows, Agricultural Advisor BB1. Molly Block, Deputy Associate Administrator for OPA BB2. Corey Scott, Executive Advisor to the Administrator **IICA** P. Mr. Lloyd Day, Deputy Director General 1. Miguel Angel Arvelo, Chief of Staff 2. Erick Bolaños, Agriculture Sanitation Specialist 3. Ana Marisa Cordero, Interim Manager of Sanitation and Food Quality 4. Pedro Rocha, International Biotechnology and Biosecurity Specialist

CROPLIFE
TBC Javier Fernández, Legal Counsel and Director of Regulatory Affairs
TBC Alejandro Hernández, Manager of Central America and Caribbean Biotechnology
TBC Martín Zúñiga, Director Centro América and Caribbean

BAYER
TBC Ronnie Furlong, Regional Manager
TBC Adrián Vargas, Costa Rica T&PD Lead

INDUSTRY LEADERS
TBC Xinia Chaves, Executive Director, Café Institute of Costa Rica (ICAFE)
TBC Sergio Herrera, Manager of Product Stewardship & Regulatory Affairs, BASF Costa Rica
TBC Carlos Hidalgo, Latin America EH&S Leader, CORTEVA
TBC Juan Rafael Lizano, Executive President, National Chamber of Agriculture and Agro-industry
TBC Felipe Madriz, Regional Manager, Sumitomo Chemical
TBC Geovanny Sandi, Regional Manager, Syngenta
TBC Jorge Arturo Sauma, General Manager, National Banana Corporation (CORBANA)
TBC Edgar Villalobos, Comercial Manager for Central America, Corporación FMC
TBC Alfredo Volio, Vice-President, National Chamber of Pineapple Producers and Exporters (CANAPEP)

SCENARIO:

11:30pm *-ADMINISTRATOR WHEELER participates in the Roundtable led by Deputy Director General Lloyd Day*
- *Lloyd Day, Welcome Remarks*
- *Ambassador Day, Remarks*
- *ADMINISTRATOR WHEELER, Remarks*
- *Lloyd Day turns it over to Shareholder; Lunch will be brought out during this time*

12:50pm *- Roundtable concludes; ADMINISTRATOR WHEELER is escorted to the Garden for group photo with IICA Shareholders*

1:00pm Event concludes; ADMINISTRATOR WHEELER departs IICA en route to Mundorep Recycling for meeting with FundaTec

Vehicle Assignments:

EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) – PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER ADRIAN CASRO
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) PSD TYLER TERESA

Drive Time: 45 Minutes; 6.8 Miles

Event Location
Mundorep Recycling
100 metros Sur de Pequeño Mundo,
Los Lagos, San Francisco, Heredia

2:00pm ADMINISTRATOR WHEELER arrives at Mundorep Recycling for Meeting with FubdaTec.

EVENT FUNDATEC. – COSTA RICA MARINE LITTER ACTION PLAN

LOCATION:	Mundorep Recycling
TYPE:	Meeting & Tour
SPEAKING:	Talking Points
ATTIRE:	Business Professional
PRESS:	Closed
GIFTS:	No
INTERPRETATION:	N/A – On Standby
PARTICIPANTS:	**EPA** ADMINISTRATOR WHEELER T.H. Chad McIntosh, AA OITA Michael Molina, Deputy Chief of Staff Carrie Meadows, Agricultural Advisor Molly Block, Deputy Associate Administrator for PA Corey Scott, Executive Advisor to the Administrator **FUNDATEC** Floria Roa Gutierrez, Director for International Affairs, Technology Institute of Costa Rica Jaime Cerdas, Mundorep General Manager José Antonio Salas, Mundorep Co-Owner Lilliana Carranza, Mundorep Communications and Public Relations Advisor

SCENARIO:

2:00pm *- ADMINISTRATOR WHEELER arrives at Mundorep Recyling and is greeted by Jaime Cerdas and begins COVID-19 protocol (temperature checks and hand washing)*

2:02pm *- ADMINISTRATOR WHEELER and small group participates in Meeting wth FundaTec. About Marine Action Plan*

SMALL GROUP
ADMINISTRATOR WHEELER
CHAD MCINTOSH
MICHAEL MOLINA
Ex. 7(C); Ex. 7(F) – RF

2:30pm *- Meeting concludes; ADMINISTRATOR WHEELER tour Mundorep Recycling with small group*

3:00pm *- Tour concludes; ADMINISTRATOR WHEELER participates in Press Interview over the phone with Juan Fernando Lara (La Nación) in Mundorep Recyling Conference Room*

3:30pm Interview concludes; ADMINISTRAOTOR WHEELER departs Mundorep Recyling en route to InterContinental Costa Rica (RON)

Vehicle Assignments:	
EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA COREY SCOTT EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) - RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER ADRIAN CASTRO
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) – PSD TYLER TERESA

Drive Time: 20 Minutes; 9 Miles

RON Location
InterContinental Costa Rica at Multiplaza Mall
Multiplaza Shopping Center,
San José Province, Escazu, 10202, Costa Rica

3:50pm ADMINISTRATOR WHEELER arrives at InterContinental Costa Rica (RON) and begins Executive Time

5:00pm Executive Time concludes; ADMINISTRATOR WHEELER departs InterContinental Costa Rica (RON) en route to CMR for Dinner with the Ambassador Day

Vehicle Assignments:	
LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA COREY SCOTT CHAD MCINTOSH EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) – PSD
CONTROLL VEHICLE:	SARAH BANNISTER

Drive Time: 10 – 15 Minutes

Dinner Location
The Chief of Mission Residence

5:15pm ADMINISTRATOR WHEELER arrives at the CMR and begins dinner program

8:00pm Dinner concludes; ADMINISTRATOR WHEELER departs the CMR en route to the InterContinental Costa Rica (RON)

8:30pm ADMINISTRATOR WHEELER arrives back at the InterContinental Costa Rica (RON) and begins Executive Time

RON **INTERCONTINENTAL COSTA RICA**

FRIDAY, JANUARY 8

***Breakfast:** The Market from 6:00am – 10:00am in the lobby

8:30am ADMINISTRATOR WHEELER departs InterContinental Costa Rica (RON) en route to La Hacienda Alsacia

Vehicle Assignments:	
EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) - RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) PSD TYLER TERESA

Drive Time: 1 Hours; 18 Miles

Event Location
Hacienda Alsacia - Starbucks Coffee Farm
15 KM North from the Alajuela Justice Courts,
Alajuela Dulce Nombre de San Isidro, 20106, Costa Rica

9:30am ADMINISTRATOR WHEELER arrives at Hacienda Alsacia

EVENT **LA HACIENDA ALSACIA**

LOCATION:	Hacienda Alsacia – Starbucks Coffee Farm
TYPE:	Tour
SPEAKING:	N/A
ATTIRE:	Business Rugged (Boots/Tennis Shoes, Khakis, Polo Shirt, and Rain Jacket)
PRESS:	Closed
GIFTS:	No
INTERPRETATION:	N/A
PARTICIPANTS:	**EPA** ADMINISTRATOR WHEELER T.H. Chad McIntosh, AA OITA Michael Molina, Deputy Chief of Staff Carrie Meadows, Agricultural Advisor Molly Block, Deputy Associate Administrator for PA Corey Scott, Executive Advisor to the Administrator **HACIENDA ALSACIA - STARBUCKS COFFEE FARM** Marlon Prendas, Manager

SCENARIO:

9:30am *- ADMINISTRATOR WHEELER arrives at Hacienda Alsacia and is greeted by Marlon Prendas and offered coffee/tea and is split into two groups*

GROUP 1
ADMINISTRATOR WHEELER
CHAD MCINTOSH
MICHAEL MOLINA
COREY SCOTT
JAKE ALLEN – Photographer
Ex. 7(C); Ex. 7(F) – RF

GROUP 2
MOLLY BLOCK
CARRIE MEADOWS
TYLER TERESA
SARAH BANNISTER

9:32am - *ADMINISTRATOR WHEELER begins tour*
- *Welcome Overview*
- *Nursery*
- *Coffee Plant Viewing & Picking*
- *Gazebo - Solar Panels and Coffee Fields*
- *Watermill and Sun Drying*
- *Micro Green House - Research and Development*
- *Visitor Center/Tasting Room/Café*

11:30am Tour concludes; ADMINISTRATOR WHEELER departs Hacienda Alsacia en route to La Paz Waterfall Gardens

Vehicle Assignments:

EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) - PSD TYLER TERESA

Drive Time: 30 Minutes; 13 Miles

Event Location
La Paz Waterfall Gardens
6KM al norte de la Gasolinera
Vara Blanca de Heredia, Costa Rica 20101

12:00pm ADMINISTRATOR WHEELER arrives at La Paz Waterfall Gardens and proceeds to La Paz Waterfall Gardens Restaurant for lunch

1:30pm Lunch concludes; ADMINISTRATOR WHEELER proceeds to the start of the trail

EVENT **LA PAZ WATERFALL GARDENS**

LOCATION:	La Paz Waterfall Gardens
TYPE:	Hike
SPEAKING:	N/A
ATTIRE:	Business Rugged (Boots/Tennis Shoes, Khakis, Polo Shirt, and Rain Jacket)
PRESS:	Closed
GIFTS:	No
INTERPRETATION:	N/A
PARTICIPANTS:	**EPA** ADMINISTRATOR WHEELER T.H. Chad McIntosh, AA OITA Michael Molina, Deputy Chief of Staff Carrie Meadows, Agricultural Advisor Molly Block, Deputy Associate Administrator for PA Corey Scott, Executive Advisor to the Administrator

SCENARIO:

1:30pm - *ADMINISTRATOR WHEELER begins the 2.2-mile trail en route to La Paz Waterfall Gardens to view the biodiversity in the area*

4:30pm Hike concludes; ADMINISTRATOR WHEELER departs La Paz Waterfall Gardens en route to CMR and then InterContinental Costa Rica (RON)

Vehicle Assignments:	
EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) PSD TYLER TERESA

Drive Time: 1 Hour, 30 Minutes; 35 Miles

RON Location
InterContinental Costa Rica at Multiplaza Mall
Multiplaza Shopping Center,
San José Province, Escazu, 10202, Costa Rica

6:00pm ADMINISTRATOR WHEELER arrives to the InterContinental Costa Rica (RON) and begins Executive Time

6:45pm Executive Time concludes; ADMINISTRATOR WHEELER proceeds to TBC Restaurant in the InterContinental Costa Rica for dinner

1) Pimento – *Enjoy incredible Italian gastronomy and wonderful wines. Dine in a cosy Italian style atmosphere. The traditional Italian menu offers a variety of fresh homemade pasta, risottos, fresh seafood, and a great selection of antipasti, soups, and mouth-watering desserts.*
2) Nau Sushi Lounge – *A trendy Asian inspired drinking and eating spot off the lobby. Enjoy fresh sushi and sashimi from the bar while lounge music fills the air in this chic contemporary lounge setting.*
3) Factory Steak and Lobster – *Factory indulges you with imported beef, fresh grilled lobster, and local fish. The glass enclosed kitchen allows you to watch the chefs at work at the grill as you enjoy the surf and turf in a casually elegant ambiance.*

8:45pm Dinner concludes; ADMINISTRATOR WHEELER begins Executive Time

RON **INTERCONTINENTAL COSTA RICA**

SATURDAY, JANUARY 9

***Breakfast:** The Market from 6:00am – 10:00am in the lobby

***Note:** Hotel provides transportation to the airport for staff departing on earlier flight*

11:30am Executive Time concludes; ADMINISTRATOR WHEELER departs the InterContinental Costa Rica (RON) en route to Juan Santamaría International Airport (SJO)

Vehicle Assignments:	
EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) PSD
EPA STAFF VEHICLE:	COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	MEREDITH RYDER-RUDE SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) PSD TYLER TERESA

Drive Time: 25 Minutes; 12 Miles

Departure Airport
Juan Santamaría International Airport
Alajuela Province
Alajuela, Costa Rica

12:00pm ADMINISTRATOR WHEELER arrives at Juan Santamaría International Airport (SJO) and begins boarding process for United Airlines Flight 1099

Note: *Only those flying on ADMINISTRATOR WHEELER flight will be escorted to Diplomatic Waiting Room all other staff will proceed to their gate for departure*

EVENT AIRPORT DEPARTURE

2:20pm ADMINISTRATOR WHEELER departs Juan Santamaría International Airport (SJO) en route to George Bush Intercontinental Airport (IAH)

AIRLINE LOCATOR NUMBER: Ex. 6
ADMINISTRATOR SEAT: 11C

UNITED AIRLINES FLIGHT(UA1099)
ADMINISTRATOR WHEELER
MICHAEL MOLINA
Ex. 7(C); Ex. 7(F) – RF

Flight Time: 3 Hour, 45 Minutes
Time Change: N/A

EVENT AIRPORT CONNECTION

Connection Airport
George Bush Intercontinental Airport
2800 N Terminal Rd,
Houston, TX

6:05pm ADMINISTRATOR WHEELER arrives at George Bush Intercontinental Airport (IAH) and proceeds to United Airlines Flight 4320

Layover: 2 Hours, 19 Minutes

8:25pm ADMINISTRATOR WHEELER departs George Bush Intercontinental Airport (IAH) en route Jackson-Medgar Wiley Evers International Airport (JAN)

AIRLINE LOCATOR NUMBER: Ex. 6
ADMINISTRATOR SEAT: 22A

UNITED AIRLINES FLIGHT(UA4320)
ADMINISTRATOR WHEELER
MICHAEL MOLINA
Ex. 7(C); Ex. 7(F) RF

Flight Time: 1 Hour, 27 Minutes
Time Change: N/A

EVENT AIRPORT ARRIVAL

Arrival Airport
Jackson-Medgar Wiley Evers International Airport
100 International Dr,
Jackson, MS

9:52pm ADMINISTRATOR WHEELER arrives in Jackson Mississippi and begins separate program

Message

From: Frye, Tony (Robert) [frye.robert@epa.gov]
Sent: 1/6/2021 3:58:28 PM
To: Burgess, Michael [Burgess.Michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Carter, Brittany S. [carter.brittanys@epa.gov]; Pic, Jordan [pic.jordan@epa.gov]; Washam, Todd [Washam.Todd@epa.gov]; Brazauskas, Joseph [brazauskas.joseph@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Block, Molly [block.molly@epa.gov]; Walker, Mary [walker.mary@epa.gov]; Meadows, Carrie Vicenta [Meadows.CarrieVicenta@epa.gov]
CC: Teresa, Tyler [Teresa.Tyler@epa.gov]; Ex 7(C), 7(F) Ex 7(C), 7(F) Ex 7(C), 7(F)
Subject: RE: Tentative Schedule - Mississippi

For awareness, I just got confirmation from both Senate offices for Monday's events.

Tony Frye
Assistant Deputy Associate Administrator
Senate Affairs
Office of Congressional Affairs
Environmental Protection Agency
Cell: 202.603.3225

From: Burgess, Michael <Burgess.Michael@epa.gov>
Sent: Wednesday, January 6, 2021 10:17 AM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Carter, Brittany S. <carter.brittanys@epa.gov>; Pic, Jordan <pic.jordan@epa.gov>; Frye, Tony (Robert) <frye.robert@epa.gov>; Washam, Todd <Washam.Todd@epa.gov>; Brazauskas, Joseph <brazauskas.joseph@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Block, Molly <block.molly@epa.gov>; Walker, Mary <walker.mary@epa.gov>; Meadows, Carrie Vicenta <Meadows.CarrieVicenta@epa.gov>
Cc: Teresa, Tyler <Teresa.Tyler@epa.gov>; Ex 7(C), 7(F); Ex 7(C), 7(F) Ex 7(C), 7(F)
Subject: Re: Tentative Schedule - Mississippi

All,

Here is the initial invite list for Sunday's Dinner in Mississippi.

Mike McGrevey
Surya Gunasekara
Phil bryant
Joey songy
George Flaggs
Jeremy hirsch
Johnny Brunini
Bill Lampton
Lynn Fitch
David McRae
Deion sanders
Mayor Lumumba

Regards,
Owen Burgess

Sent from my iPhone

On Jan 5, 2021, at 6:09 PM, Burgess, Michael <Burgess.Michael@epa.gov> wrote:

All,

Please see the tentative schedule below. I will be receiving a list of attendees for Sunday's dinner by tomorrow and will forward it along.

Sunday, January 10th 2021

TBCpm (CDT) Administrator Wheeler tours Civil Rights Museum in Jackson, Mississippi

2:00pm Administrator Wheeler arrives for meeting with Governor Reeves + Lunch at Governor's Residence

4:00pm Administrator Wheeler tours the Capitol building in Jackson, Mississippi with Lt. Gov Hosemann (300 East Capitol Street)

7:00pm Administrator Wheeler arrives at CHAR for Dinner with elected officials (4500 Interstate 55 North Frontage Rd, Jackson, MS 39211)

Monday, January 11th 2021

7:30am Administrator Wheeler arrives at SuperTalk for Radio Interview in Jackson, Mississippi (6311 Ridgewood Road, Jackson, MS)

8:30am Administrator Wheeler arrives at the US ACE Vicksburg District for briefing with elected officials (4155 Clay St. Vicksburg, MS)

9:00am Administrator Wheeler begins press conference

Mandy Gunasekara will MC event
Administrator Wheeler remarks 5 Minutes
Col. Hilliard remarks 5 Minutes
Senator Wicker remarks 5 Minutes
Senator Hyde-Smith remarks 5 Minutes
Gov. Reeves remarks 5 Minutes
RA Mary Walker remarks 5 Minutes
Q&A 10-15 Minutes

9:50am Administrator Wheeler departs US ACE Vicksburg District HQ

10:00am Administrator Wheeler tours the US ACE ERDC facility (3909 Halls Ferry Rd, Vicksburg MS 39180)

10:30am Administrator Wheeler departs Vicksburg en route to Bolton, MS for AG event

11:00am Administrator Wheeler begin AG event at Nutrien Ag Solutions (6800 I-20, Bolton, MS 39041)

TBC Remarks

12:00pm Administrator Wheeler departs Bolton, MS for lunch in Jackson, MS

1:00pm Lunch

2:00pm Administrator Wheeler arrives at Airport

2:52pm Departure

Best,
Owen Burgess

Deputy Director of Logistics
U.S. Environmental Protection Agency
O: (202)-564-8599
C: (202)-816-1090

Message

From: Lopez, Peter [lopez.peter@epa.gov]
Sent: 1/6/2021 7:42:59 PM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
CC: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Meadowcroft, Micah [Meadowcroft.Micah@epa.gov]
Subject: Re: Letter on behalf of Peter D. Lopez

Thank you Beth!

Sincerely,
Pete

Peter D. Lopez
Regional Administrator - R2
290 Broadway, 26th Floor
New York, NY 10007-1866
(212) 637-5000 (work)
(917) 376-2190 (cell)
(212) 637-5024 (fax)

On Jan 6, 2021, at 12:23 PM, Lopez, Peter <lopez.peter@epa.gov> wrote:

Beth Soltani
Executive Assistant to the Regional Administrator
U.S. Environmental Protection Agency, Region 2
290 Broadway
New York, NY 10007
Office: 212.637.5038
Mobile: 646.531.2763

<LTR to Administrator Wheeler 1-6-21.pdf>

Message

From: Meadowcroft, Micah [Meadowcroft.Micah@epa.gov]
Sent: 1/6/2021 8:18:18 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
CC: Barker, Kendal [Barker.Kendal@epa.gov]; Dziadosz, Patricia [Dziadosz.Patricia@epa.gov]; Garber, Kyle [Garber.Kyle@epa.gov]
Subject: Questions and tomorrow
Attachments: Resignation Letter Template 2021.docx

Hi Mandy,

Barring there being a state of national emergency tomorrow or something, my understanding is resignation requests will need to be sent out. Kathryn Smith passed along the attached resignation letter template, which has apparently been approved by OGC, to guide people. That request will prompt Lance McCluney's team to send 1/20-dated SF-52s out to appointees, and the various offices to set up OneDrives for offboarding.

If that all sounds right, there are three things to clarify:

1. I think when we met on Monday you said that letters can be sent to the Administrator's public email, cc'ing you and myself. Since that is not included instructions in the attached template or in the OMS guidance, that should probably be specified in the body of the instruction/request email.
2. Kathryn and Dorothy wondered if, since the AD's serve directly at the discretion of the Administrator, a resignation request to ADs should come from his office rather than your office.
3. Related to ADs, since this would mean she was not to be included in such an email, is it true that Abigail Linsk, Ex. 6 will not be asked to resign? Just want to confirm what I've heard, and if so, note that the above won't apply to her so all involved are on the same page.

To those cc'ed: keep your chin up and don't let the news ruin your day.

Thank you,

Micah Meadowcroft

White House Liaison
U.S. Environmental Protection Agency
William Jefferson Clinton Building North, Room 2402A
1200 Pennsylvania Ave, NW
Washington, DC 20460
Office Phone: (202) 564-0015
Work Cell: (202) 768-4924

2021 Presidential Transition Resignation Letter Templates

All resignations should be emailed to EPA Administrator, Andrew Wheeler; Chief of Staff, Mandy Gunasekara; and White House Liaison, Micah Meadowcroft.

Template resignation letter if resigning before being asked to resign

This email serves as my official notice that I am resigning from the Environmental Protection Agency as [**position title, office name**], effective [**date**]. I am choosing to resign voluntarily and was not asked to resign.

My forwarding email is [**email**] and my mailing address can be found on the back of my resignation SF-52.

Template resignation letter if resigning after being asked to resign

This email serves as my official notice that I am resigning from the Environmental Protection Agency as [**position title, office name**], effective [**date**]. I was asked to resign due to a change in administration.

My forwarding email is [**email**] and my mailing address can be found on the back of my resignation SF-52.

Message

From: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
Sent: 1/6/2021 8:23:43 PM
To: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
CC: Reisman, Larry [Reisman.Larry@epa.gov]
Subject: Detail/Temporary Promotion - Join OPPT's Team: Staff Scientist in OPPT/DGAD/PIB2

The **Office of Chemical Safety and Pollution Prevention, Office of Pollution Prevention and Toxics, Data Gathering and Analysis Division**, has an exciting 120-day opportunity to serve as a staff scientist in the **Prioritization and Informatics Branch 2 (PIB2)**. The staff scientist will support this new branch in the collection, evaluation (including gap analysis), management, and distribution of scientific data for TSCA implementation. The staff scientist will be responsible for assigned projects and will serve as a contracting officers' representative (COR) for dedicated contractor support. The staff scientist will work closely and collaboratively with the other divisions in OPPT responsible for TSCA analyses, determinations, and deliverables.

To view the full announcement and to apply, click the following link: https://usepa.sharepoint.com/sites/OARM/talenthub/details/sitepages/home.aspx#!/positions/2207

Title	Staff Scientist
Duration	120 days
Position Type	Applications will be considered from current GS-11s EPA-Wide.
Location of Position	Washington, D.C.
Closing Date	Tuesday, January 19, 2021

Please do not respond to this email. For questions regarding this opportunity, please contact Larry Reisman at 202-566-0751 or reisman.larry@epa.gov.

Message

From: Block, Molly [block.molly@epa.gov]
Sent: 1/6/2021 8:15:23 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
CC: Burgess, Michael [Burgess.Michael@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Carter, Brittany S. [carter.brittanys@epa.gov]; Pic, Jordan [pic.jordan@epa.gov]; Frye, Tony (Robert) [frye.robert@epa.gov]; Washam, Todd [Washam.Todd@epa.gov]; Brazauskas, Joseph [brazauskas.joseph@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Walker, Mary [walker.mary@epa.gov]; Meadows, Carrie Vicenta [Meadows.CarrieVicenta@epa.gov]; Teresa, Tyler [Teresa.Tyler@epa.gov]; Ex 7(C), 7(F) Ex 7(C), 7(F) Ex 7(C), 7(F)
Subject: Re: Tentative Schedule - Mississippi

Confirmed radio:

Paul Gallo show (in studio)

Time: 7:20 - 7:37 AM
Arrive 10-15 mins early
Host: Paul Gallo

Mandy - would you mind sharing the address of the studio?

Sent from my iPhone

On Jan 6, 2021, at 12:56 PM, Gunasekara, Mandy <gunasekara.Mandy@epa.gov> wrote:

Below and attached is a revised schedule based on some updates from a few entities and a convo with Mary regarding the Vicksburg event.

Sunday, January 10th 2021

9:00 am (CDT) Briefing on Pumps with Mary Walker and Blake

10:00 am **Breakfast with (tentative) MDEQ Director Chris Wells at Brent's Drugs in Fondren District of Jackson, MS**

12:00pm Administrator Wheeler guided tour of Civil Rights Museum in Jackson, Mississippi

2:00pm Administrator Wheeler arrives for meeting with Governor Reeves + Lunch at Governor's Residence

4:00pm Administrator Wheeler tours the Capitol building in Jackson, Mississippi with Lt. Gov Hosemann (300 East Capitol Street)

7:00pm Administrator Wheeler arrives at CHAR for Dinner with elected officials (4500 Interstate 55 North Frontage Rd, Jackson, MS 39211)

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Q&A 10-15 Minutes

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TBC Remarks

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1:00pm Lunch

2:00pm Administrator Wheeler arrives at Airport

2:52pm Departure

From: Burgess, Michael <Burgess.Michael@epa.gov>
Sent: Wednesday, January 6, 2021 10:17 AM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Carter, Brittany S. <carter.brittanys@epa.gov>; Pic, Jordan <pic.jordan@epa.gov>; Frye, Tony (Robert) <frye.robert@epa.gov>; Washam, Todd <Washam.Todd@epa.gov>; Brazauskas, Joseph <brazauskas.joseph@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Block, Molly <block.molly@epa.gov>; Walker, Mary <walker.mary@epa.gov>; Meadows, Carrie Vicenta <Meadows.CarrieVicenta@epa.gov>
Cc: Teresa, Tyler <Teresa.Tyler@epa.gov>; Ex 7(C), 7(F); Ex 7(C), 7(F); Ex 7(C), 7(F); Ex 7(C), 7(F)
Subject: Re: Tentative Schedule - Mississippi

All,

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Phil bryant
Joey songy
George Flaggs
Jeremy hirsch
Johnny Brunini
Bill Lampton
Lynn Fitch
David McRae
Deion sanders
Mayor Lumumba

Regards,
Owen Burgess

Sent from my iPhone

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TBCpm (CDT) Administrator Wheeler tours Civil Rights Museum in Jackson, Mississippi

2:00pm Administrator Wheeler arrives for meeting with Governor Reeves + Lunch at Governor's Residence

4:00pm Administrator Wheeler tours the Capitol building in Jackson, Mississippi with Lt. Gov Hosemann (300 East Capitol Street)

7:00pm Administrator Wheeler arrives at CHAR for Dinner with elected officials (4500 Interstate 55 North Frontage Rd, Jackson, MS 39211)

Monday, January 11th 2021

7:30am Administrator Wheeler arrives at SuperTalk for Radio Interview in Jackson, Mississippi (6311 Ridgewood Road, Jackson, MS)

8:30am Administrator Wheeler arrives at the US ACE Vicksburg District for briefing with elected officials (4155 Clay St. Vicksburg, MS)

9:00am Administrator Wheeler begins press conference

Mandy Gunasekara will MC event
Administrator Wheeler remarks 5 Minutes
Col. Hilliard remarks 5 Minutes
Senator Wicker remarks 5 Minutes
Senator Hyde-Smith remarks 5 Minutes
Gov. Reeves remarks 5 Minutes
RA Mary Walker remarks 5 Minutes
Q&A 10-15 Minutes

9:50am Administrator Wheeler departs US ACE Vicksburg District HQ

10:00am Administrator Wheeler tours the US ACE ERDC facility (3909 Halls Ferry Rd, Vicksburg MS 39180)

10:30am Administrator Wheeler departs Vicksburg en route to Bolton, MS for AG event

11:00am Administrator Wheeler begin AG event at Nutrien Ag Solutions (6800 I-20, Bolton, MS 39041)

TBC Remarks

12:00pm Administrator Wheeler departs Bolton, MS for lunch in Jackson, MS

1:00pm Lunch

2:00pm Administrator Wheeler arrives at Airport

2:52pm Departure

Best,
Owen Burgess

Deputy Director of Logistics
U.S. Environmental Protection Agency
O: (202)-564-8599
C: (202)-816-1090

<MS Agenda_DRAFT .docx>

Message

From: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
Sent: 1/6/2021 8:30:40 PM
To: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
CC: Reisman, Larry [Reisman.Larry@epa.gov]
Subject: Detail/Temporary Promotion - Join OPPT's Team: Staff Scientist in OPPT/DGAD/PIB2

The **Office of Chemical Safety and Pollution Prevention, Office of Pollution Prevention and Toxics, Data Gathering and Analysis Division**, has an exciting 120-day opportunity to serve as a staff scientist in the **Prioritization and Informatics Branch 2 (PIB2)**. The staff scientist will support this new branch in the collection, evaluation (including gap analysis), management, and distribution of scientific data for TSCA implementation. The staff scientist will be responsible for assigned projects and will serve as a contracting officers' representative (COR) for dedicated contractor support. The staff scientist will work closely and collaboratively with the other divisions in OPPT responsible for TSCA analyses, determinations, and deliverables.

To view the full announcement and to apply, click the following link: https://usepa.sharepoint.com/sites/OARM/talenthub/details/sitepages/home.aspx#!/positions/2202

Title	Staff Scientist
Duration	120 days
Position Type	Applications will be considered from current GS-13s EPA-Wide.
Location of Position	Washington, D.C.
Closing Date	Tuesday, January 19, 2021

Please do not respond to this email. For questions regarding this opportunity, please contact Larry Reisman at 202-566-0751 or reisman.larry@epa.gov.

Message

From: Bolen, Brittany [bolen.brittany@epa.gov]
Sent: 1/6/2021 3:31:19 PM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
CC: Molina, Michael [molina.michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Scott, Corey [scott.corey@epa.gov]; Idsal, Anne [idsal.anne@epa.gov]
Subject: For Signature: Cyanide Chemicals Manufacturing RTR proposal
Attachments: FRN Cyanide RTR Proposal 4Jan21_Admin.docx

Administrator –

Attached for your electronic signature is the Cyanide Chemicals Manufacturing RTR proposal. Please digitally sign this file using Word then email it back to me.

Thank you,

Brittany

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2020-0532; FRL-10018-49-OAR]

RIN 2060-AU64

National Emission Standards for Hazardous Air Pollutants: Cyanide Chemicals Manufacturing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing the results of the residual risk and technology review (RTR) for the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Cyanide Chemicals Manufacturing source category as required under the Clean Air Act (CAA). We are proposing to find that risk from emissions of air toxics from this source category is acceptable, and that the current standards provide an ample margin of safety to protect public health. We are also proposing to find that there are no developments in practices, processes, and control technologies, and, as such, we are not proposing any development-based changes to the current standards pursuant to the technology review. The EPA is, however, proposing new emissions standards to address emissions from process wastewater at existing sources. We are proposing to amend provisions addressing startup, shutdown, and malfunction (SSM), to add electronic reporting, and to update the reporting and recordkeeping requirements. We do not expect these proposed amendments to result in changes in emissions from the source category but anticipate improved monitoring, compliance, and implementation of the existing standards.

DATES:.Comments must be received on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Public hearing: If anyone contacts us requesting a public hearing on or before **[INSERT DATE 5 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OAR-2020-0532, by any of the following methods:

- Federal eRulemaking Portal: *https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- Email: *a-and-r-docket@epa.gov*. Include Docket ID No. EPA-HQ-OAR-2020-0532 in the subject line of the message.
- Fax: (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2020-0532.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2020-0532, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

- Hand/Courier Delivery: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. – 4:30 p.m., Monday – Friday (except federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/*, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Nathan Topham, Sector Policies and Programs Division (D243-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-0483; fax number: (919) 541-4991; and email address: *topham.nathan@epa.gov*. For specific information regarding the risk modeling methodology, contact James Hirtz, Health and Environmental Impacts Division (C539-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research

Triangle Park, North Carolina 27711; telephone number: (919) 541-0881; fax number: (919) 541-0840; and email address: *Hirtz.James@epa.gov*.

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. Please note that the EPA is deviating from its typical approach for public hearings because the President has declared a national emergency. Due to the current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID-19, the EPA cannot hold in-person public meetings at this time.

To request a virtual public hearing, contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov*. If requested, the virtual hearing will be held on **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The hearing will convene at 9:00 a.m. Eastern Time (ET) and will conclude at 3:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*.

The EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**, if a hearing is requested. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen* or contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov*. The last day to pre-register to speak at the hearing will be **[INSERT DATE 12 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Prior to the hearing, the EPA will

post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*.

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *topham.nathan@epa.gov*. The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*. While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or a special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your

needs by **[INSERT DATE 7 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA-HQ-OAR-2020-0532. All documents in the docket are listed in *https://www.regulations.gov*. Although listed, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. With the exception of such material, publicly available docket materials are available electronically in Regulations.gov.

Instructions. Direct your comments to Docket ID No. EPA-HQ-OAR-2020-0532. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/*, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia

submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets*.

The EPA is temporarily suspending its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* as there may be a delay in processing mail and faxes. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets*.

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID-19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2020-0532. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

AEGL	acute exposure guideline level
AERMOD	air dispersion model used by the HEM-3 model
CAA	Clean Air Act
CalEPA	California EPA
CBI	Confidential Business Information
CFR	Code of Federal Regulations
EPA	Environmental Protection Agency
ERPG	emergency response planning guideline
ERT	Electronic Reporting Tool
HAP	hazardous air pollutant(s)
HCl	hydrochloric acid
HEM-3	Human Exposure Model, Version 1.5.5
HF	hydrogen fluoride
HI	hazard index
HQ	hazard quotient
IRIS	Integrated Risk Information System
km	kilometer
MACT	maximum achievable control technology
mg/kg-day	milligrams per kilogram per day
mg/m^3	milligrams per cubic meter
MIR	maximum individual risk
NAAQS	National Ambient Air Quality Standards
NAICS	North American Industry Classification System
NESHAP	national emission standards for hazardous air pollutants
NRC	National Research Council
OAQPS	Office of Air Quality Planning and Standards
OMB	Office of Management and Budget
PAH	polycyclic aromatic hydrocarbons
PB-HAP	hazardous air pollutants known to be persistent and bio-accumulative in the environment
PM	particulate matter
POM	polycyclic organic matter
ppm	parts per million
REL	reference exposure level
RFA	Regulatory Flexibility Act
RfC	reference concentration
RfD	reference dose
RTR	residual risk and technology review

SAB	Science Advisory Board
SBA	Small Business Administration
SSM	startup, shutdown, and malfunction
SV	screening value
TOSHI	target organ-specific hazard index
tpy	tons per year
TRIM.FaTE	Total Risk Integrated Methodology.Fate, Transport, and Ecological Exposure model
UF	uncertainty factor
$\mu g/m^3$	microgram per cubic meter
URE	unit risk estimate
VCS	voluntary consensus standards

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
II. Background
A. What is the statutory authority for this action?
B. What is this source category and how does the current NESHAP regulate its HAP emissions?
C. What data collection activities were conducted to support this action?
D. What other relevant background information and data are available?
III. Analytical Procedures and Decision-Making
A. How do we consider risk in our decision-making?
B. How do we perform the technology review?
C. How do we estimate post-MACT risk posed by the source category?
IV. Analytical Results and Proposed Decisions
A. What actions are we taking pursuant to CAA sections 112(d)(2) and 112(d)(3)?
B. What are the results of the risk assessment and analyses?
C. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?
D. What are the results and proposed decisions based on our technology review?
E. What other actions are we proposing?
F. What compliance dates are we proposing?
V. Summary of Cost, Environmental, and Economic Impacts
A. What are the affected sources?
B. What are the air quality impacts?
C. What are the cost impacts?
D. What are the economic impacts?
E. What are the benefits?
VI. Request for Comments
VII. Submitting Data Corrections
VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs
C. Paperwork Reduction Act (PRA)
D. Regulatory Flexibility Act (RFA)
E. Unfunded Mandates Reform Act (UMRA)
F. Executive Order 13132: Federalism
G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act (NTTAA)
K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Does this action apply to me?

The source category that is the subject of this proposal is cyanide chemicals manufacturing major sources regulated under 40 CFR 63, subpart YY. The North American Industry Classification System (NAICS) codes for the cyanide chemicals manufacturing industry are 325188 and 325199. This list of categories and NAICS codes is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, state, local, and tribal government entities would not be affected by this proposed action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576, July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (see EPA-450/3-91-030, July 1992), the Cyanide Chemicals Manufacturing source category is any facility engaged in the production of hydrogen cyanide or sodium cyanide. Hydrogen cyanide production includes, but is not limited to, production of hydrogen cyanide using any of the following

methods: reaction of methane and ammonia over a platinum catalyst, reaction of methane and ammonia over a platinum-rhodium catalyst, co-production with acrylonitrile (via Sohio process), or pyrolysis of formaldehyde. Sodium cyanide production includes, but is not limited to, production of sodium cyanide via the neutralization process, or so-called wet process. In this process, hydrogen cyanide reacts with sodium hydroxide solution usually in a reactor that involves evaporation of water and crystallization of the product, commonly called white cyanide.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website. Information on the overall RTR program is available at *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html*.

The proposed changes to the CFR that would be necessary to incorporate the changes proposed in this action are set out in an attachment to the memorandum titled *Proposed Regulation Edits for 40 CFR Part 63, Subpart YY*, available in the docket for this action (Docket ID No. EPA-HQ-OAR-2020-0532). The document includes the specific proposed amendatory language for revising the CFR and, for the convenience of interested parties, a redline version of the regulation. Following signature by the EPA Administrator, the EPA will also post a copy of this memorandum and the attachments to *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*.

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the CAA, as amended (42 U.S.C. 7401 *et seq.*). Section 112 of the CAA establishes a two-stage regulatory process to develop standards for emissions of hazardous air pollutants (HAP) from stationary sources. Generally, the first stage involves establishing technology-based standards and the second stage involves evaluating those standards that are based on maximum achievable control technology (MACT) to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the "residual risk review." In addition to the residual risk review, the CAA also requires the EPA to review standards set under CAA section 112 every 8 years and revise the standards as necessary taking into account any "developments in practices, processes, or control technologies." This review is commonly referred to as the "technology review." When the two reviews are combined into a single rulemaking, it is commonly referred to as the "risk and technology review." The discussion that follows identifies the most relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology*, in the docket for this rulemaking.

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. "Major sources" are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any

combination of HAP. All other sources are "area sources." For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT "floor." In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as beyond-the-floor standards. For area sources, CAA section 112(d)(5) gives the EPA discretion to set standards based on generally available control technologies or management practices (GACT standards) in lieu of MACT standards.

The second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.,* "residual") risk pursuant to CAA section 112(f). For source categories subject to MACT standards, section 112(f)(2) of the CAA requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. Section 112(d)(5) of the CAA provides that this residual risk review is not required for categories of area sources subject to GACT standards. Section 112(f)(2)(B) of the CAA further expressly preserves the EPA's use of the two-step approach for developing standards to address any residual risk and the Agency's interpretation of "ample margin of safety" developed in the National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP) (54 FR 38044, September 14, 1989). The EPA notified Congress in the

Residual Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA–453/R–99–001, p. ES–11). The EPA subsequently adopted this approach in its residual risk determinations and the United States Court of Appeals for the District of Columbia Circuit (the court) upheld the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. See *NRDC v. EPA*, 529 F.3d 1077, 1083 (D.C. Cir. 2008).

The approach incorporated into the CAA and used by the EPA to evaluate residual risk and to develop standards under CAA section 112(f)(2) is a two-step approach. In the first step, the EPA determines whether risks are acceptable. This determination "considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR)[1] of approximately 1 in 10 thousand." (54 FR 38045). If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health "in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision." *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety

[1] Although defined as "maximum individual risk," MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime.

analysis, we consider whether a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

CAA section 112(d)(6) separately requires the EPA to review standards promulgated under CAA section 112 and revise them "as necessary (taking into account developments in practices, processes, and control technologies)" no less often than every 8 years. In conducting this review, which we call the "technology review," the EPA is not required to recalculate the MACT floor. *Natural Resources Defense Council (NRDC) v. EPA*, 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc. v. EPA*, 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6). The EPA is required to address regulatory gaps, such as missing standards for listed air toxics known to be emitted from the source category. *Louisiana Environmental Action Network (LEAN) v. EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

B. What is this source category and how does the current NESHAP regulate its HAP emissions?

The MACT standards for the Cyanide Chemicals Manufacturing source category are contained in the Generic Maximum Achievable Control Technology (GMACT) NESHAP which also includes MACT standards for several other source categories. The cyanide chemicals manufacturing standards were promulgated on July 12, 2002, (67 FR 46258) and codified at 40 CFR part 63, subpart YY. As promulgated in 2002, the cyanide chemicals manufacturing standards regulate HAP emissions from cyanide chemicals manufacturing units located at major sources. The HAP emitted from the source category include cyanide compounds (hydrogen cyanide and sodium cyanide), acetonitrile, and acrylonitrile.

The NESHAP defines the affected source as each cyanide chemicals manufacturing process unit (CCMPU). The rule states that the CCMPU is the equipment assembled and

connected by hard-piping or duct work to process raw materials to manufacture, store, and transport a cyanide chemicals product. A CCMPU shall be limited to any one of the following: an Andrussow process unit, a Blausaure Methane Anlage process unit, a sodium cyanide process unit, or a Sohio hydrogen cyanide process unit. For the purpose of this subpart, a CCMPU includes reactors and associated unit operations, associated recovery devices, and any feed, intermediate and product storage vessels, product transfer racks, and connected ducts and piping. A CCMPU also includes pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, and control devices or systems.

The NESHAP established emissions standards for process vents, storage vessels, transfer racks, and equipment leaks. Cyanide process vents are subject to a 98 weight-percent reduction of total HAP[2] performance standard or 20 parts per million by volume (ppmv) total HAP outlet exit concentration limit. For storage vessels in the Cyanide Chemicals Manufacturing source category, sources may either choose to comply with a 98 weight-percent reduction of hydrogen cyanide performance standard, a 20 ppmv hydrogen cyanide exit outlet concentration limit, or equipment standards (*e.g.*, use a flare). Transfer racks are subject to equipment standards or the same performance standard or concentration limit[3] as cyanide process vents. Equipment leaks are subject to work practice standards required by either 40 CFR part 63, subpart TT or subpart UU.

C. *What data collection activities were conducted to support this action?*

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[2] "Dry end" process vents at sodium cyanide units must meet a 98 percent reduction performance standard for emissions of sodium cyanide since this is the form of cyanide compounds emitted from these emission points. The HAP emitted from other process vents that make up the "total HAP" emitted from these sources are hydrogen cyanide, acetonitrile, and acrylonitrile.

[3] Transfer racks emissions limits are expressed in terms of hydrogen cyanide as this is the only HAP emitted from these sources.

The EPA used a variety of resources to obtain data about facilities and their emissions for use in our risk assessment. We used the EPA's Enforcement and Compliance History Online (ECHO) database to develop a list of potentially subject facilities. Using this list, we searched state environmental agency websites and correspondence with industry to obtain copies of title V permits to confirm whether facilities have cyanide chemicals manufacturing subject to the NESHAP. Once the facility list was finalized, the EPA used the 2017 National Emissions Inventory (NEI) to get emissions data for each facility. We compared the NEI data to title V permits to provide additional information regarding the applicability of the Cyanide Chemicals Manufacturing NESHAP. Further discussion of the methodology used to develop the emissions dataset for the risk assessment can be found in the memorandum titled *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, which is available in the docket for this action.

D. What other relevant background information and data are available?

We searched for information from the Reasonably Available Control Technology, Best Available Control Technology, and Lowest Achievable Emission Rate Clearinghouse (RBLC) database, reviewed title V permits for each cyanide chemicals manufacturing facility, and reviewed regulatory actions related to emissions controls at similar sources that could be applicable to cyanide chemicals manufacturing. We reviewed the RBLC to identify potential additional control technologies. No additional control technologies applicable to cyanide chemicals manufacturing were found using the RBLC. Additional information related to the promulgation and subsequent amendments of the NESHAP is available in docket ID: No. EPA-HQ-OAR-2004-0041.

III. Analytical Procedures and Decision-Making

In this section, we describe the analyses performed to support the proposed decisions for the RTR and other issues addressed in this proposal.

A. How do we consider risk in our decision-making?

As discussed in section II.A of this preamble and in the Benzene NESHAP, in evaluating and developing standards under CAA section 112(f)(2), we apply a two-step approach to determine whether or not risks are acceptable and to determine if the standards provide an ample margin of safety to protect public health. As explained in the Benzene NESHAP, "the first step judgment on acceptability cannot be reduced to any single factor" and, thus, "[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information." (54 FR at 38046). Similarly, with regard to the ample margin of safety determination, "the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors." *Id.*

The Benzene NESHAP approach provides flexibility regarding factors the EPA may consider in making determinations and how the EPA may weigh those factors for each source category. The EPA conducts a risk assessment that provides estimates of the MIR posed by emissions of HAP that are carcinogens from each source in the source category, the hazard index (HI) for chronic exposures to HAP with the potential to cause noncancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause noncancer health effects.[4] The assessment also provides estimates of the distribution of cancer risk within the

[4] The MIR is defined as the cancer risk associated with a lifetime of exposure at the highest concentration of HAP where people are likely to live. The HQ is the ratio of the potential HAP

exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The scope of the EPA's risk analysis is consistent with the explanation in EPA's response to comments on our policy under the Benzene NESHAP:

> The policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of non-cancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the *Vinyl Chloride* mandate that the Administrator ascertain an acceptable level of risk to the public by employing his expertise to assess available data. It also complies with the Congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and thereby implicitly permits consideration of any and all measures of health risk which the Administrator, in his judgment, believes are appropriate to determining what will "protect the public health.

(54 FR at 38057). Thus, the level of the MIR is only one factor to be weighed in determining acceptability of risk. The Benzene NESHAP explained that "an MIR of approximately one in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes an MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors." *Id.* at 38045. In other words, risks that include an MIR above 100-in-1 million may be determined to be acceptable, and risks with an MIR below that level may be determined to be unacceptable, depending on all of the available health information. Similarly, with regard to the ample margin of safety analysis, the EPA stated in the Benzene NESHAP that: "EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of

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exposure concentration to the noncancer dose-response value; the HI is the sum of HQs for HAP that affect the same target organ or organ system.

safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category." *Id.* at 38061. We also consider the uncertainties associated with the various risk analyses, as discussed earlier in this preamble, in our determinations of acceptability and ample margin of safety.

The EPA notes that it has not considered certain health information to date in making residual risk determinations. At this time, we do not attempt to quantify the HAP risk that may be associated with emissions from other facilities that do not include the source category under review, mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in the category.

The EPA understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. We recognize that such consideration may be particularly important when assessing noncancer risk, where pollutant-specific exposure health reference levels (*e.g.*, reference concentrations (RfCs)) are based on the assumption that thresholds exist for adverse health effects. For example, the EPA recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk of adverse noncancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (*e.g.*, other facilities) to which an individual is exposed may be sufficient to result in an increased risk of adverse noncancer health effects. In May 2010, the Science Advisory Board (SAB) advised the EPA "that RTR assessments will be most useful to decision makers and communities if results are presented in

the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area."[5]

In response to the SAB recommendations, the EPA incorporates cumulative risk analyses into its RTR risk assessments. The Agency (1) conducts facility-wide assessments, which include source category emission points, as well as other emission points within the facilities; (2) combines exposures from multiple sources in the same category that could affect the same individuals; and (3) for some persistent and bioaccumulative pollutants, analyzes the ingestion route of exposure. In addition, the RTR risk assessments consider aggregate cancer risk from all carcinogens and aggregated noncancer HQs for all noncarcinogens affecting the same target organ or target organ system.

Although we are interested in placing source category and facility-wide HAP risk in the context of total HAP risk from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. Estimates of total HAP risk from emission sources other than those that we have studied in depth during this RTR review would have significantly greater associated uncertainties than the source category or facility-wide estimates. Such aggregate or cumulative assessments would compound those uncertainties, making the assessments too unreliable.

B. How do we perform the technology review?

Our technology review primarily focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the

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[5] Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, which is available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf.*

MACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions associated with applying each development. This analysis informs our decision of whether it is "necessary" to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a "development":

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT standards) that could result in additional emissions reduction;
- Any work practice or operational procedure that was not identified or considered during development of the original MACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT standards; and
- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed (or last updated) the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls. We also

review the NESHAP and the available data to determine if there are any unregulated emissions of HAP within the source category and evaluate this data for use in developing new emission standards. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

C. How do we estimate post-MACT risk posed by the source category?

In this section, we provide a complete description of the types of analyses that we generally perform during the risk assessment process. In some cases, we do not perform a specific analysis because it is not relevant. For example, in the absence of emissions of HAP known to be persistent and bioaccumulative in the environment (PB-HAP), we would not perform a multipathway exposure assessment. Where we do not perform an analysis, we state that we do not and provide the reason. While we present all of our risk assessment methods, we only present risk assessment results for the analyses actually conducted (see section IV.B of this preamble).

The EPA conducts a risk assessment that provides estimates of the MIR for cancer posed by the HAP emissions from each source in the source category, the HI for chronic exposures to HAP with the potential to cause noncancer health effects, and the HQ for acute exposures to HAP with the potential to cause noncancer health effects. The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The seven sections that follow this paragraph describe how we estimated emissions and conducted the risk assessment. The docket for this rulemaking contains the following document which provides more information on the risk assessment inputs and models: *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the 2020 Risk and Technology Review Proposed*

Rule. The methods used to assess risk (as described in the seven primary steps below) are consistent with those described by the EPA in the document reviewed by a panel of the EPA's SAB in 2009;[6] and described in the SAB review report issued in 2010. They are also consistent with the key recommendations contained in that report.

1. How did we estimate actual emissions and identify the emissions release characteristics?

The list of facilities subject to the NESHAP was created through searching the EPA's ECHO database, the 2017 NEI, and state databases of title V permits. The list of facilities is available in the memorandum titled *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*. Once the facility list was finalized, available emissions data were obtained from the NEI. Title V permits were used to determine which emission points at each facility are subject to the Cyanide Chemicals Manufacturing NESHAP.

We compared the NEI data to title V permits to confirm that the NEI included all emission points listed as subject to the NESHAP according to the permit. We evaluated latitudes and longitudes listed in the NEI to ensure their accuracy using satellite imagery. All of the latitudes and longitudes used in our dispersion modeling are in the modeling file used for the proposed rule, which is available in Docket ID No. EPA-HQ-OAR-2020-0532. Corrections were made to emission point characteristics for one non-category emission point that appeared to have erroneous stack velocity entered into the NEI. This emission point's stack velocity was corrected

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[6] U.S. EPA. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing*, June 2009. EPA-452/R-09-006. *https://www3.epa.gov/airtoxics/rrisk/rtrpg.html*.

to a default maximum value. All corrections made to emission point parameters are documented in the modeling file, available in Docket ID No. EPA-HQ-OAR-2020-0532.

2. How did we estimate MACT-allowable emissions?

The available emissions data in the RTR emissions dataset include estimates of the mass of HAP emitted during a specified annual time period. These "actual" emission levels are often lower than the emission levels allowed under the requirements of the current MACT standards. The emissions allowed under the MACT standards are referred to as the "MACT-allowable" emissions. We discussed the consideration of both MACT-allowable and actual emissions in the final Coke Oven Batteries RTR (70 FR 19992, 19998 and 19999, April 15, 2005) and in the proposed and final Hazardous Organic NESHAP RTR (71 FR 34421, 34428, June 14, 2006, and 71 FR 76603, 76609, December 21, 2006, respectively). In those actions, we noted that assessing the risk at the MACT-allowable level is inherently reasonable since that risk reflects the maximum level facilities could emit and still comply with national emission standards. We also explained that it is reasonable to consider actual emissions, where such data are available, in both steps of the risk analysis, in accordance with the Benzene NESHAP approach. (54 FR 38044).

We have determined that the actual emissions data are reasonable estimates of the MACT-allowable emissions levels for the Cyanide Chemicals Manufacturing source category. The ability to estimate MACT-allowable emissions from the actual emissions dataset is largely dependent on the format of the standard for a given emissions source as well as the types of controls employed for the source. With respect to the various types of controls used within the Cyanide Chemicals Manufacturing source category, the most prevalent is the use of a flare as a combustion control device. A flare can be used to control emissions for a single emissions source, or, as is generally the case, to control emissions from multiple emission sources/emission

source types. Flares are designed to handle a wide range of flowrates and compositions of combustible waste gases. Within the Cyanide Chemicals Manufacturing source category, flares generally control emissions from multiple emission source types. Consideration of this, along with not having a specific limit on how much gas can be combusted in a flare (given that in many cases multiple emissions sources are being controlled by this control device), means that it is extremely difficult to determine an allowable emission rate for flares. We have determined that flares in the Cyanide Chemicals Manufacturing source category are currently complying with design and operational requirements that are generally expected to achieve 98 percent destruction efficiencies or control, which is the level of control required by the NESHAP. HAP emissions inventories for flares in the Cyanide Chemicals Manufacturing source category are developed using engineering knowledge and, in many instances, presume this 98 percent level of control. The Agency is unaware of any data that suggest that flares used as controls in the Cyanide Chemicals Manufacturing source category are consistently overcontrolling HAP emissions beyond 98 percent control. Thus, weighing all of these factors for flares, we determined that the actual emission levels are a reasonable estimation of the MACT-allowable emissions levels where the performance standards allow the use of a flare as an air pollution control device (*e.g.*, storage vessels, process vents, and transfer racks).

For equipment leaks, which are currently subject to work practice standards, there would be no difference between actual and MACT-allowable emissions for facilities in the Cyanide Chemicals Manufacturing source category, provided the facilities are complying with the MACT standards as well as not conducting additional work practices that would reduce emissions beyond those required by the rule. We are aware of only one rule in the state of Texas, the Texas Commission of Environmental Quality (TCEQ) Highly Reactive Volatile Organic Compounds

(HRVOC) Rule (*i.e.*, 30 TAC Chapter 115, Subchapter H, Division 3), that may contain more stringent leak definitions and/or monitoring frequencies for certain pieces of equipment for the three facilities located in Texas that might be subject to this rule. However, based on our review of the Texas rule, we note the following: (1) specific facilities located in the Houston-Galveston-Brazoria area still conduct a leak detection and repair (LDAR) program using EPA Method 21; (2) the vast majority of equipment, including almost all pieces of equipment in gas and vapor service that would tend to contribute considerably to the overall equipment leak air emissions, are complying with the same leak definition as in the MACT standards; and (3) the TCEQ HRVOC Rule generally requires quarterly monitoring while the MACT standards have varying monitoring frequencies depending on the percentage of leaking equipment that could lead to more stringent, the same, or less stringent frequencies that would require an EPA Method 21 measurement and repair of a leaking component (if measured). Therefore, considering these factors for equipment leaks, we determined that the actual emission levels for equipment leaks are a reasonable estimation of the MACT-allowable emissions levels.

3. How do we conduct dispersion modeling, determine inhalation exposures, and estimate individual and population inhalation risk?

Both long-term and short-term inhalation exposure concentrations and health risk from the source category addressed in this proposal were estimated using the Human Exposure Model (HEM-3).[7] The HEM-3 performs three primary risk assessment activities: (1) conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 kilometers (km) of the

[7] For more information about HEM-3, go to *https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem.*

modeled sources, and (3) estimating individual and population-level inhalation risk using the exposure estimates and quantitative dose-response information.

a. Dispersion Modeling

The air dispersion model AERMOD, used by the HEM-3 model, is one of the EPA's preferred models for assessing air pollutant concentrations from industrial facilities.[8] To perform the dispersion modeling and to develop the preliminary risk estimates, HEM-3 draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes 1 year (2016) of hourly surface and upper air observations from 826 meteorological stations, selected to provide coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block[9] internal point locations and populations provides the basis of human exposure calculations (U.S. Census, 2010). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant-specific dose-response values is used to estimate health risk. These are discussed below.

b. Risk from Chronic Exposure to HAP

In developing the risk assessment for chronic exposures, we use the estimated annual average ambient air concentrations of each HAP emitted by each source in the source category. The HAP air concentrations at each nearby census block centroid located within 50 km of the facility are a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. A distance of 50 km is consistent with both the analysis supporting

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[8] U.S. EPA. Revision to the *Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions* (70 FR 68218, November 9, 2005).

[9] A census block is the smallest geographic area for which census statistics are tabulated.

the 1989 Benzene NESHAP (54 FR 38044) and the limitations of Gaussian dispersion models, including AERMOD.

For each facility, we calculate the MIR as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, 52 weeks per year, 70 years) exposure to the maximum concentration at the centroid of each inhabited census block. We calculate individual cancer risk by multiplying the estimated lifetime exposure to the ambient concentration of each HAP (in micrograms per cubic meter ($\mu g/m^3$)) by its unit risk estimate (URE). The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use UREs from the EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using California EPA (CalEPA) UREs, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate. The pollutant-specific dose-response values used to estimate health risk are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants*.

No data are available on the carcinogenic effects of cyanide compounds in humans via inhalation. Under the U.S. EPA (2005a) *Guidelines for Carcinogen Risk Assessment*, there is "inadequate information to assess the carcinogenic potential" of cyanide compounds.

To estimate individual lifetime cancer risks associated with exposure to HAP emissions from each facility in the source category, we sum the risks for each of the carcinogenic HAP[10] emitted by the modeled facility. We estimate cancer risk at every census block within 50 km of every facility in the source category. The MIR is the highest individual lifetime cancer risk estimated for any of those census blocks. In addition to calculating the MIR, we estimate the distribution of individual cancer risks for the source category by summing the number of individuals within 50 km of the sources whose estimated risk falls within a specified risk range. We also estimate annual cancer incidence by multiplying the estimated lifetime cancer risk at each census block by the number of people residing in that block, summing results for all of the census blocks, and then dividing this result by a 70-year lifetime.

To assess the risk of noncancer health effects from chronic exposure to HAP, we calculate either an HQ or a target organ-specific hazard index (TOSHI). We calculate an HQ when a single noncancer HAP is emitted. Where more than one noncancer HAP is emitted, we sum the HQ for each of the HAP that affects a common target organ or target organ system to obtain a TOSHI. The HQ is the estimated exposure divided by the chronic noncancer dose-

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[10] The EPA's 2005 *Guidelines for Carcinogen Risk Assessment* classifies carcinogens as: "carcinogenic to humans," "likely to be carcinogenic to humans," and "suggestive evidence of carcinogenic potential." These classifications also coincide with the terms "known carcinogen, probable carcinogen, and possible carcinogen," respectively, which are the terms advocated in the EPA's *Guidelines for Carcinogen Risk Assessment*, published in 1986 (51 FR 33992, September 24, 1986). In August 2000, the document, *Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (EPA/630/R-00/002), was published as a supplement to the 1986 document. Copies of both documents can be obtained from *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533&CFID=70315376&CFTOKEN=71597944*. Summing the risk of these individual compounds to obtain the cumulative cancer risk is an approach that was recommended by the EPA's SAB in their 2002 peer review of the EPA's National Air Toxics Assessment (NATA) titled *NATA - Evaluating the National-scale Air Toxics Assessment 1996 Data -- an SAB Advisory*, available at *https://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/$File/ecadv02001.pdf*.

response value, which is a value selected from one of several sources. The preferred chronic noncancer dose-response value is the EPA RfC, defined as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime" (*https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary*). In cases where an RfC from the EPA's IRIS is not available or where the EPA determines that using a value other than the RfC is appropriate, the chronic noncancer dose-response value can be a value from the following prioritized sources, which define their dose-response values similarly to the EPA: (1) the Agency for Toxic Substances and Disease Registry (ATSDR) Minimum Risk Level (*https://www.atsdr.cdc.gov/mrls/index.asp*); (2) the CalEPA Chronic Reference Exposure Level (REL) (*https://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0*); or (3) as noted above, a scientifically credible dose-response value that has been developed in a manner consistent with the EPA guidelines and has undergone a peer review process similar to that used by the EPA. The pollutant-specific dose-response values used to estimate health risks are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants*.

Cyanide is extremely toxic to humans. Acute (10-minute) inhalation exposure to 579 milligrams per cubic meter (mg/m^3) of hydrogen cyanide will cause death in 50 percent of exposed humans. Nonlethal exposures to hydrogen cyanide gas will cause a variety of effects in humans, such as headache, dizziness, upper respiratory irritation, cough, altered sense of smell, nasal congestion, nosebleed, and difficulty breathing. Chronic (long-term) inhalation exposure of

humans to cyanide results primarily in effects on the central nervous system. Other effects in humans include cardiovascular and respiratory effects, effects to the endocrine system (*e.g.*, thyroid enlargement, altered iodine uptake), and irritation to the eyes and skin. However, short term exposure levels below the acute REL and chronic exposures below the RfC are not likely to cause adverse effects.

c. Risk from Acute Exposure to HAP that May Cause Health Effects Other Than Cancer

For each HAP for which appropriate acute inhalation dose-response values are available, the EPA also assesses the potential health risks due to acute exposure. For these assessments, the EPA makes conservative assumptions about emission rates, meteorology, and exposure location. As part of our efforts to continually improve our methodologies to evaluate the risks that HAP emitted from categories of industrial sources pose to human health and the environment,[11] we revised our treatment of meteorological data to use reasonable worst-case air dispersion conditions in our acute risk screening assessments instead of worst-case air dispersion conditions. This revised treatment of meteorological data and the supporting rationale are described in more detail in *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the 2020 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Technical Support Document for Acute Risk Screening Assessment.* This revised approach has been used in this proposed rule and in all other RTR rulemakings proposed on or after June 3, 2019.

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[11] See, *e.g.*, U.S. EPA. *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis* (Draft Report, May 2017. *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html*).

To assess the potential acute risk to the maximally exposed individual, we use the peak hourly emission rate for each emission point,[12] reasonable worst-case air dispersion conditions (*i.e.*, 99th percentile), and the point of highest off-site exposure. Specifically, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions co-occur and that a person is present at the point of maximum exposure.

To characterize the potential health risks associated with estimated acute inhalation exposures to a HAP, we generally use multiple acute dose-response values, including acute RELs, acute exposure guideline levels (AEGLs), and emergency response planning guidelines (ERPG) for 1-hour exposure durations, if available, to calculate acute HQs. The acute HQ is calculated by dividing the estimated acute exposure concentration by the acute dose-response value. For each HAP for which acute dose-response values are available, the EPA calculates acute HQs.

An acute REL is defined as "the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration."[13] Acute RELs are based on the most sensitive, relevant, adverse health effect reported in the peer-reviewed medical and toxicological literature. They are designed to protect the most sensitive individuals in the population through

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[12] In the absence of hourly emission data, we develop estimates of maximum hourly emission rates by multiplying the average actual annual emissions rates by a factor (either a category-specific factor or a default factor of 10) to account for variability. This is documented in *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the 2020 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Technical Support Document for Acute Risk Screening Assessment*. Both are available in the docket for this rulemaking.

[13] CalEPA issues acute RELs as part of its Air Toxics Hot Spots Program, and the 1-hour and 8-hour values are documented in *Air Toxics Hot Spots Program Risk Assessment Guidelines, Part I, The Determination of Acute Reference Exposure Levels for Airborne Toxicants*, which is available at *https://oehha.ca.gov/air/general-info/oehha-acute-8-hour-and-chronic-reference-exposure-level-rel-summary*.

the inclusion of margins of safety. Because margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact. AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to 8 hours.[14] They are guideline levels for "once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals." *Id.* at 21. The AEGL–1 is specifically defined as "the airborne concentration (expressed as ppm (parts per million) or mg/m^3 (milligrams per cubic meter)) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure." The document also notes that "Airborne concentrations below AEGL–1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects." *Id.* AEGL–2 are defined as "the airborne concentration (expressed as parts per million or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape." *Id.*

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[14] National Academy of Sciences, 2001. *Standing Operating Procedures for Developing Acute Exposure Levels for Hazardous Chemicals*, page 2. Available at *https://www.epa.gov/sites/production/files/2015-09/documents/sop_final_standing_operating_procedures_2001.pdf*. Note that the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances ended in October 2011, but the AEGL program continues to operate at the EPA and works with the National Academies to publish final AEGLs (*https://www.epa.gov/aegl*).

ERPGs are "developed for emergency planning and are intended as health-based guideline concentrations for single exposures to chemicals."[15] *Id.* at 1. The ERPG–1 is defined as "the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor." *Id.* at 2. Similarly, the ERPG–2 is defined as "the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action." *Id.* at 1.

An acute REL for 1-hour exposure durations is typically lower than its corresponding AEGL–1 and ERPG–1. Even though their definitions are slightly different, AEGL–1s are often the same as the corresponding ERPG–1s, and AEGL–2s are often equal to ERPG–2s. The maximum HQs from our acute inhalation screening risk assessment typically result when we use the acute REL for a HAP. In cases where the maximum acute HQ exceeds 1, we also report the HQ based on the next highest acute dose-response value (usually the AEGL–1 and/or the ERPG–1).

For this source category, we used acute factors between 2 and 10, depending on the type of source, to estimate peak hourly emissions from annual emissions estimates for input into the risk assessment modeling analysis. Specifically, we used a factor of 2 for process vents and equipment leaks, a factor of 4 for storage vessels, and a factor of 10 for transfer racks. A further

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[15] *ERPGS Procedures and Responsibilities*. March 2014. American Industrial Hygiene Association. Available at: *https://www.aiha.org/get-involved/AIHAGuidelineFoundation/EmergencyResponsePlanningGuidelines/Documents/ERPG%20Committee%20Standard%20Operating%20Procedures%20%20-%20March%202014%20Revision%20%28Updated%2010-2-2014%29.pdf.*

discussion of why these factors were chosen can be found in the memorandum, *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, available in the docket for this rulemaking.

In our acute inhalation screening risk assessment, acute impacts are deemed negligible for HAP for which acute HQs are less than or equal to 1, and no further analysis is performed for these HAP. In cases where an acute HQ from the screening step is greater than 1, we assess the site-specific data to ensure that the acute HQ is at an off-site location. For this source category, no data were conducted.

4. How do we conduct the multipathway exposure and risk screening assessment?

The EPA conducts a tiered screening assessment examining the potential for significant human health risks due to exposures via routes other than inhalation (*i.e.*, ingestion). We first determine whether any sources in the source category emit any HAP known to be persistent and bioaccumulative in the environment, as identified in the EPA's Air Toxics Risk Assessment Library (see Volume 1, Appendix D, at *https://www.epa.gov/fera/risk-assessment-and-modeling-air-toxics-risk-assessment-reference-library)*.

For the Cyanide Chemicals Manufacturing source category, we identified potential PB-HAP emissions of arsenic, cadmium, lead, mercury, and polycyclic organic matter (POM) based on entries in the NEI. We note that for the Cyanide Chemicals Manufacturing source category, we modeled these pollutants to provide a conservative assessment of risks because these pollutants are included in the NEI. However, we do not believe these HAP are emitted from the cyanide chemicals manufacturing process. Very small amounts of these HAP are included in the NEI as byproducts of fuel combustion and are unrelated to cyanide chemicals manufacturing.

After identifying potential PB-HAP emissions, the next step of the evaluation is a tiered screening assessment. Except for lead, the human health risk screening assessment for PB-HAP consists of three progressive tiers. In a Tier 1 screening assessment, we determine whether the magnitude of the facility-specific emissions of PB-HAP warrants further evaluation to characterize human health risk through ingestion exposure. To facilitate this step, we evaluate emissions against previously developed screening threshold emission rates for several PB-HAP that are based on a hypothetical upper-end screening exposure scenario developed for use in conjunction with the EPA's Total Risk Integrated Methodology.Fate, Transport, and Ecological Exposure (TRIM.FaTE) model. The PB-HAP with screening threshold emission rates are arsenic compounds, cadmium compounds, chlorinated dibenzodioxins and furans, mercury compounds, and POM. Based on the EPA estimates of toxicity and bioaccumulation potential, these pollutants represent a conservative list for inclusion in multipathway risk assessments for RTR rules. (See Volume 1, Appendix D at *https://www.epa.gov/sites/production/files/2013-08/documents/volume_1_reflibrary.pdf.*) In this assessment, we compare the facility-specific emission rates of these PB-HAP to the screening threshold emission rates for each PB-HAP to assess the potential for significant human health risks via the ingestion pathway. We call this application of the TRIM.FaTE model the Tier 1 screening assessment. The ratio of a facility's actual emission rate to the Tier 1 screening threshold emission rate is a "screening value (SV)."

We derive the Tier 1 screening threshold emission rates for these PB-HAP (other than lead compounds) to correspond to a maximum excess lifetime cancer risk of 1-in-1 million (*i.e.*, for arsenic compounds, polychlorinated dibenzodioxins and furans, and POM) or, for HAP that cause noncancer health effects (*i.e.*, cadmium compounds and mercury compounds), a maximum HQ of 1. If the emission rate of any one PB-HAP or combination of carcinogenic PB-HAP in the

Tier 1 screening assessment exceeds the Tier 1 screening threshold emission rate for any facility (*i.e.*, the SV is greater than 1), we conduct a second screening assessment, which we call the Tier 2 screening assessment. The Tier 2 screening assessment separates the Tier 1 combined fisher and farmer exposure scenario into fisher, farmer, and gardener scenarios that retain upper-bound ingestion rates.

In the Tier 2 screening assessment, the location of each facility that exceeds a Tier 1 screening threshold emission rate is used to refine the assumptions associated with the Tier 1 fisher and farmer exposure scenarios at that facility. A key assumption in the Tier 1 screening assessment is that a lake and/or farm is located near the facility. As part of the Tier 2 screening assessment, we use a U.S. Geological Survey (USGS) database to identify actual waterbodies within 50 km of each facility and assume the fisher only consumes fish from lakes within that 50 km zone. We also examine the differences between local meteorology near the facility and the meteorology used in the Tier 1 screening assessment. We then adjust the previously-developed Tier 1 screening threshold emission rates for each PB-HAP for each facility based on an understanding of how exposure concentrations estimated for the screening scenario change with the use of local meteorology and the USGS lakes database.

In the Tier 2 farmer scenario, we maintain an assumption that the farm is located within 0.5 km of the facility and that the farmer consumes meat, eggs, dairy, vegetables, and fruit produced near the facility. We may further refine the Tier 2 screening analysis by assessing a gardener scenario to characterize a range of exposures, with the gardener scenario being more plausible in RTR evaluations. Under the gardener scenario, we assume the gardener consumes home-produced eggs, vegetables, and fruit products at the same ingestion rate as the farmer. The Tier 2 screen continues to rely on the high-end food intake assumptions that were applied in Tier

1 for local fish (adult female angler at 99th percentile fish consumption[16]) and locally grown or raised foods (90th percentile consumption of locally grown or raised foods for the farmer and gardener scenarios[17]). If PB-HAP emission rates do not result in a Tier 2 SV greater than 1, we consider those PB-HAP emissions to pose risks below a level of concern. If the PB-HAP emission rates for a facility exceed the Tier 2 screening threshold emission rates, we may conduct a Tier 3 screening assessment.

There are several analyses that can be included in a Tier 3 screening assessment, depending upon the extent of refinement warranted, including validating that the lakes are fishable, locating residential/garden locations for urban and/or rural settings, considering plume-rise to estimate emissions lost above the mixing layer, and considering hourly effects of meteorology and plume-rise on chemical fate and transport (a time-series analysis). If necessary, the EPA may further refine the screening assessment through a site-specific assessment.

In evaluating the potential multipathway risk from emissions of lead compounds, rather than developing a screening threshold emission rate, we compare maximum estimated chronic inhalation exposure concentrations to the level of the current National Ambient Air Quality Standard (NAAQS) for lead.[18] Values below the level of the primary (health-based) lead NAAQS are considered to have a low potential for multipathway risk.

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[16] Burger, J. 2002. *Daily consumption of wild fish and game: Exposures of high end recreationists. International Journal of Environmental Health Research,* 12:343–354.

[17] U.S. EPA. *Exposure Factors Handbook 2011 Edition (Final).* U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–09/052F, 2011.

[18] In doing so, the EPA notes that the legal standard for a primary NAAQS – that a standard is requisite to protect public health and provide an adequate margin of safety (CAA section 109(b)) – differs from the CAA section 112(f) standard (requiring, among other things, that the standard provide an "ample margin of safety to protect public health"). However, the primary lead NAAQS is a reasonable measure of determining risk acceptability (*i.e.*, the first step of the Benzene NESHAP analysis) since it is designed to protect the most susceptible group in the

For further information on the multipathway assessment approach, see the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this action.

5. How do we conduct the environmental risk screening assessment?

a. Adverse Environmental Effect, Environmental HAP, and Ecological Benchmarks

The EPA conducts a screening assessment to examine the potential for an adverse environmental effect as required under section 112(f)(2)(A) of the CAA. Section 112(a)(7) of the CAA defines "adverse environmental effect" as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

The EPA focuses on eight HAP, which are referred to as "environmental HAP," in its screening assessment: six PB-HAP and two acid gases. The PB-HAP included in the screening assessment are arsenic compounds, cadmium compounds, dioxins/furans, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. The acid gases included in the screening assessment are hydrochloric acid (HCl) and hydrogen fluoride (HF).

HAP that persist and bioaccumulate are of particular environmental concern because they accumulate in the soil, sediment, and water. The acid gases, HCl and HF, are included due to their well-documented potential to cause direct damage to terrestrial plants. In the environmental risk screening assessment, we evaluate the following four exposure media: terrestrial soils,

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human population – children, including children living near major lead emitting sources. 73 FR 67002/3; 73 FR 67000/3; 73 FR 67005/1. In addition, applying the level of the primary lead NAAQS at the risk acceptability step is conservative, since that primary lead NAAQS reflects an adequate margin of safety.

surface water bodies (includes water-column and benthic sediments), fish consumed by wildlife, and air. Within these four exposure media, we evaluate nine ecological assessment endpoints, which are defined by the ecological entity and its attributes. For PB-HAP (other than lead), both community-level and population-level endpoints are included. For acid gases, the ecological assessment evaluated is terrestrial plant communities.

An ecological benchmark represents a concentration of HAP that has been linked to a particular environmental effect level. For each environmental HAP, we identified the available ecological benchmarks for each assessment endpoint. We identified, where possible, ecological benchmarks at the following effect levels: probable effect levels, lowest-observed-adverse-effect level, and no-observed-adverse-effect level. In cases where multiple effect levels were available for a particular PB-HAP and assessment endpoint, we use all of the available effect levels to help us to determine whether ecological risks exist and, if so, whether the risks could be considered significant and widespread.

For further information on how the environmental risk screening assessment was conducted, including a discussion of the risk metrics used, how the environmental HAP were identified, and how the ecological benchmarks were selected, see Appendix 9 of the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this action.

b. Environmental Risk Screening Methodology

For the environmental risk screening assessment, the EPA first determined whether any facilities in the Cyanide Chemicals Manufacturing source category emitted any of the environmental HAP. For the Cyanide Chemicals Manufacturing source category, we identified

potential emissions of arsenic, cadmium, lead, mercury, POM, and one acid gas, HCl, based on entries in the NEI. Because one or more of the environmental HAP evaluated may be emitted by at least one facility in the source category, we proceeded to the second step of the evaluation. As noted above, we modeled these emissions to err on the side of an overly conservative analysis because they are included in the NEI; however, we do not believe these HAP are emitted from the Cyanide Chemicals Manufacturing source category. The NEI entries for these HAP from these sources are likely the result of emissions factors that are used for fuel combustion and are unrelated to cyanide chemicals manufacturing.

c. PB-HAP Methodology

The environmental screening assessment includes six PB-HAP, arsenic compounds, cadmium compounds, dioxins/furans, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. With the exception of lead, the environmental risk screening assessment for PB-HAP consists of three tiers. The first tier of the environmental risk screening assessment uses the same health-protective conceptual model that is used for the Tier 1 human health screening assessment. TRIM.FaTE model simulations were used to back-calculate Tier 1 screening threshold emission rates. The screening threshold emission rates represent the emission rate in tons of pollutant per year that results in media concentrations at the facility that equal the relevant ecological benchmark. To assess emissions from each facility in the category, the reported emission rate for each PB-HAP was compared to the Tier 1 screening threshold emission rate for that PB-HAP for each assessment endpoint and effect level. If emissions from a facility do not exceed the Tier 1 screening threshold emission rate, the facility "passes" the screening assessment, and, therefore, is not evaluated further under the screening approach. If

emissions from a facility exceed the Tier 1 screening threshold emission rate, we evaluate the facility further in Tier 2.

In Tier 2 of the environmental screening assessment, the screening threshold emission rates are adjusted to account for local meteorology and the actual location of lakes in the vicinity of facilities that did not pass the Tier 1 screening assessment. For soils, we evaluate the average soil concentration for all soil parcels within a 7.5-km radius for each facility and PB-HAP. For the water, sediment, and fish tissue concentrations, the highest value for each facility for each pollutant is used. If emission concentrations from a facility do not exceed the Tier 2 screening threshold emission rate, the facility "passes" the screening assessment and typically is not evaluated further. If emissions from a facility exceed the Tier 2 screening threshold emission rate, we evaluate the facility further in Tier 3.

As in the multipathway human health risk assessment, in Tier 3 of the environmental screening assessment, we examine the suitability of the lakes around the facilities to support life and remove those that are not suitable (*e.g.*, lakes that have been filled in or are industrial ponds), adjust emissions for plume-rise, and conduct hour-by-hour time-series assessments. If these Tier 3 adjustments to the screening threshold emission rates still indicate the potential for an adverse environmental effect (*i.e.*, facility emission rate exceeds the screening threshold emission rate), we may elect to conduct a more refined assessment using more site-specific information. If, after additional refinement, the facility emission rate still exceeds the screening threshold emission rate, the facility may have the potential to cause an adverse environmental effect.

To evaluate the potential for an adverse environmental effect from lead, we compared the average modeled air concentrations (from HEM-3) of lead around each facility in the source category to the level of the secondary NAAQS for lead. The secondary lead NAAQS is a

reasonable means of evaluating environmental risk because it is set to provide substantial protection against adverse welfare effects which can include "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."

d. Acid Gas Environmental Risk Methodology

The environmental screening assessment for acid gases evaluates the potential phytotoxicity and reduced productivity of plants due to chronic exposure to HF and HCl. The environmental risk screening methodology for acid gases is a single-tier screening assessment that compares modeled ambient air concentrations (from AERMOD) to the ecological benchmarks for each acid gas. To identify a potential adverse environmental effect (as defined in section 112(a)(7) of the CAA) from emissions of HF and HCl, we evaluate the following metrics: the size of the modeled area around each facility that exceeds the ecological benchmark for each acid gas, in acres and square kilometers; the percentage of the modeled area around each facility that exceeds the ecological benchmark for each acid gas; and the area-weighted average SV around each facility (calculated by dividing the area-weighted average concentration over the 50-km modeling domain by the ecological benchmark for each acid gas). For further information on the environmental screening assessment approach, see Appendix 9 of the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this action.

6. How do we conduct facility-wide assessments?

To put the source category risks in context, we typically examine the risks from the entire "facility," where the facility includes all HAP-emitting operations within a contiguous area and

under common control. In other words, we examine the HAP emissions not only from the source category emission points of interest, but also emissions of HAP from all other emission sources at the facility for which we have data. For this source category, we conducted the facility-wide assessment using a dataset compiled from the 2017 NEI. The source category records of that NEI dataset were removed, evaluated, and updated as described in section II.C of this preamble: What data collection activities were conducted to support this action? Once a quality assured source category dataset was available, it was placed back with the remaining records from the NEI for that facility. The facility-wide file was then used to analyze risks due to the inhalation of HAP that are emitted "facility-wide" for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, the modeled source category risks were compared to the facility-wide risks to determine the portion of the facility-wide risks that could be attributed to the source category addressed in this proposal. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

For this source category, we conducted the facility-wide assessment using a dataset that the EPA compiled from the 2017 NEI. We used the NEI data for the facility and did not adjust any category or "non-category" data. Therefore, there could be differences in the dataset from that used for the source category assessments described in this preamble. We analyzed risks due

to the inhalation of HAP that are emitted "facility-wide" for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, we made a reasonable attempt to identify the source category risks, and these risks were compared to the facility-wide risks to determine the portion of facility-wide risks that could be attributed to the source category addressed in this proposal. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

7. How do we consider uncertainties in risk assessment?

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health and environmentally protective. A brief discussion of the uncertainties in the RTR emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. Also included are those uncertainties specific to our acute screening assessments, multipathway screening assessments, and our environmental risk screening assessments. A more thorough discussion of these uncertainties is included in the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this action. If a multipathway site-specific assessment was performed for this source category, a full discussion of the

uncertainties associated with that assessment can be found in Appendix 11 of that document, *Site-Specific Human Health Multipathway Residual Risk Assessment Report*.

a. Uncertainties in the RTR Emissions Dataset

Although the development of the RTR emissions dataset involved quality assurance/quality control processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, errors in emission estimates, and other factors. The emission estimates considered in this analysis generally are annual totals for certain years, and they do not reflect short-term fluctuations during the course of a year or variations from year to year. The estimates of peak hourly emission rates for the acute effects screening assessment were based on an emission adjustment factor applied to the average annual hourly emission rates, which are intended to account for emission fluctuations due to normal facility operations.

b. Uncertainties in Dispersion Modeling

We recognize there is uncertainty in ambient concentration estimates associated with any model, including the EPA's recommended regulatory dispersion model, AERMOD. In using a model to estimate ambient pollutant concentrations, the user chooses certain options to apply. For RTR assessments, we select some model options that have the potential to overestimate ambient air concentrations (*e.g.*, not including plume depletion or pollutant transformation). We select other model options that have the potential to underestimate ambient impacts (*e.g.*, not including building downwash). Other options that we select have the potential to either under- or overestimate ambient levels (*e.g.*, meteorology and receptor locations). On balance, considering the directional nature of the uncertainties commonly present in ambient concentrations estimated

by dispersion models, the approach we apply in the RTR assessments should yield unbiased estimates of ambient HAP concentrations. We also note that the selection of meteorology dataset location could have an impact on the risk estimates. As we continue to update and expand our library of meteorological station data used in our risk assessments, we expect to reduce this variability.

c. Uncertainties in Inhalation Exposure Assessment

Although every effort is made to identify all of the relevant facilities and emission points, as well as to develop accurate estimates of the annual emission rates for all relevant HAP, the uncertainties in our emission inventory likely dominate the uncertainties in the exposure assessment. Some uncertainties in our exposure assessment include human mobility, using the centroid of each census block, assuming lifetime exposure, and assuming only outdoor exposures. For most of these factors, there is neither an under nor overestimate when looking at the maximum individual risk or the incidence, but the shape of the distribution of risks may be affected. With respect to outdoor exposures, actual exposures may not be as high if people spend time indoors, especially for very reactive pollutants or larger particles. For all factors, we reduce uncertainty when possible. For example, with respect to census-block centroids, we analyze large blocks using aerial imagery and adjust locations of the block centroids to better represent the population in the blocks. We also add additional receptor locations where the population of a block is not well represented by a single location.

d. Uncertainties in Dose-Response Relationships

There are uncertainties inherent in the development of the dose-response values used in our risk assessments for cancer effects from chronic exposures and noncancer effects from both chronic and acute exposures. Some uncertainties are generally expressed quantitatively, and

others are generally expressed in qualitative terms. We note, as a preface to this discussion, a point on dose-response uncertainty that is stated in the EPA's *2005 Guidelines for Carcinogen Risk Assessment*; namely, that "the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective" (the EPA's *2005 Guidelines for Carcinogen Risk Assessment*, pages 1 through 7). This is the approach followed here as summarized in the next paragraphs.

Cancer UREs used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk.[19] That is, they represent a "plausible upper limit to the true value of a quantity" (although this is usually not a true statistical confidence limit). In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater.[20] Chronic noncancer RfC and reference dose (RfD) values represent chronic exposure levels that are intended to be health-protective levels. To derive dose-response values that are intended to be "without appreciable risk," the methodology relies upon an uncertainty factor (UF) approach,[21] which considers uncertainty, variability, and gaps in the available data. The UFs are applied to derive dose-response values that are intended to protect against appreciable risk of deleterious effects.

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[19] IRIS glossary (*https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary*).

[20] An exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

[21] See *A Review of the Reference Dose and Reference Concentration Processes*, U.S. EPA, December 2002, and *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*, U.S. EPA, 1994.

Many of the UFs used to account for variability and uncertainty in the development of acute dose-response values are quite similar to those developed for chronic durations. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (*e.g.*, 4 hours) to derive an acute dose-response value at another exposure duration (*e.g.*, 1 hour). Not all acute dose-response values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health effects relative to the dose-response value or values being exceeded. Where relevant to the estimated exposures, the lack of acute dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

Uncertainty also exists in the selection of ecological benchmarks for the environmental risk screening assessment. We established a hierarchy of preferred benchmark sources to allow selection of benchmarks for each environmental HAP at each ecological assessment endpoint. We searched for benchmarks for three effect levels (*i.e.*, no-effects level, threshold-effect level, and probable effect level), but not all combinations of ecological assessment/environmental HAP had benchmarks for all three effect levels. Where multiple effect levels were available for a particular HAP and assessment endpoint, we used all of the available effect levels to help us determine whether risk exists and whether the risk could be considered significant and widespread.

For a group of compounds that are unspeciated (*e.g.*, glycol ethers), we conservatively use the most protective dose-response value of an individual compound in that group to estimate risk. Similarly, for an individual compound in a group (*e.g.*, ethylene glycol diethyl ether) that does not have a specified dose-response value, we also apply the most protective dose-response value from the other compounds in the group to estimate risk.

e. Uncertainties in Acute Inhalation Screening Assessments

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that the EPA conducts as part of the risk review under section 112 of the CAA. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates, meteorology, and the presence of a person. In the acute screening assessment that we conduct under the RTR program, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions (*i.e.*, 99th percentile) co-occur. We then include the additional assumption that a person is located at this point at the same time. Together, these assumptions represent a reasonable worst-case actual exposure scenario. In most cases, it is unlikely that a person would be located at the point of maximum exposure during the time when peak emissions and reasonable worst-case air dispersion conditions occur simultaneously.

f. Uncertainties in the Multipathway and Environmental Risk Screening Assessments

For each source category, we generally rely on site-specific levels of PB-HAP or environmental HAP emissions to determine whether a refined assessment of the impacts from multipathway exposures is necessary or whether it is necessary to perform an environmental screening assessment. This determination is based on the results of a three-tiered screening assessment that relies on the outputs from models – TRIM.FaTE and AERMOD – that estimate environmental pollutant concentrations and human exposures for five PB-HAP (dioxins, POM, mercury, cadmium, and arsenic) and two acid gases (HF and HCl). For lead, we use AERMOD to determine ambient air concentrations, which are then compared to the secondary NAAQS standard for lead. Two important types of uncertainty associated with the use of these models in

RTR risk assessments and inherent to any assessment that relies on environmental modeling are model uncertainty and input uncertainty.[22]

Model uncertainty concerns whether the model adequately represents the actual processes (*e.g.*, movement and accumulation) that might occur in the environment. For example, does the model adequately describe the movement of a pollutant through the soil? This type of uncertainty is difficult to quantify. However, based on feedback received from previous EPA SAB reviews and other reviews, we are confident that the models used in the screening assessments are appropriate and state-of-the-art for the multipathway and environmental screening risk assessments conducted in support of RTRs.

Input uncertainty is concerned with how accurately the models have been configured and parameterized for the assessment at hand. For Tier 1 of the multipathway and environmental screening assessments, we configured the models to avoid underestimating exposure and risk. This was accomplished by selecting upper-end values from nationally representative datasets for the more influential parameters in the environmental model, including selection and spatial configuration of the area of interest, lake location and size, meteorology, surface water, soil characteristics, and structure of the aquatic food web. We also assume an ingestion exposure scenario and values for human exposure factors that represent reasonable maximum exposures.

In Tier 2 of the multipathway and environmental screening assessments, we refine the model inputs to account for meteorological patterns in the vicinity of the facility versus using upper-end national values, and we identify the actual location of lakes near the facility rather

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[22] In the context of this discussion, the term "uncertainty" as it pertains to exposure and risk encompasses both ***variability*** in the range of expected inputs and screening results due to existing spatial, temporal, and other factors, as well as ***uncertainty*** in being able to accurately estimate the true result.

than the default lake location that we apply in Tier 1. By refining the screening approach in Tier 2 to account for local geographical and meteorological data, we decrease the likelihood that concentrations in environmental media are overestimated, thereby increasing the usefulness of the screening assessment. In Tier 3 of the screening assessments, we refine the model inputs again to account for hour-by-hour plume-rise and the height of the mixing layer. We can also use those hour-by-hour meteorological data in a TRIM.FaTE run using the screening configuration corresponding to the lake location. These refinements produce a more accurate estimate of chemical concentrations in the media of interest, thereby reducing the uncertainty with those estimates. The assumptions and the associated uncertainties regarding the selected ingestion exposure scenario are the same for all three tiers.

For the environmental screening assessment for acid gases, we employ a single-tiered approach. We use the modeled air concentrations and compare those with ecological benchmarks.

For all tiers of the multipathway and environmental screening assessments, our approach to addressing model input uncertainty is generally cautious. We choose model inputs from the upper end of the range of possible values for the influential parameters used in the models, and we assume that the exposed individual exhibits ingestion behavior that would lead to a high total exposure. This approach reduces the likelihood of not identifying high risks for adverse impacts.

Despite the uncertainties, when individual pollutants or facilities do not exceed screening threshold emission rates (*i.e.*, screen out), we are confident that the potential for adverse multipathway impacts on human health is very low. On the other hand, when individual pollutants or facilities do exceed screening threshold emission rates, it does not mean that impacts are significant, only that we cannot rule out that possibility and that a refined assessment

for the site might be necessary to obtain a more accurate risk characterization for the source category.

The EPA evaluates the following HAP in the multipathway and/or environmental risk screening assessments, where applicable: arsenic, cadmium, dioxins/furans, lead, mercury (both inorganic and methyl mercury), POM, HCl, and HF. These HAP represent pollutants that can cause adverse impacts either through direct exposure to HAP in the air or through exposure to HAP that are deposited from the air onto soils and surface waters and then through the environment into the food web. These HAP represent those HAP for which we can conduct a meaningful multipathway or environmental screening risk assessment. For other HAP not included in our screening assessments, the model has not been parameterized such that it can be used for that purpose. In some cases, depending on the HAP, we may not have appropriate multipathway models that allow us to predict the concentration of that pollutant. The EPA acknowledges that other HAP beyond these that we are evaluating may have the potential to cause adverse effects and, therefore, the EPA may evaluate other relevant HAP in the future, as modeling science and resources allow.

IV. Analytical Results and Proposed Decisions

A. What actions are we taking pursuant to CAA sections 112(d)(2) and 112(d)(3)?

We are proposing standards pursuant to CAA section 112(d)(2) for process wastewater from existing cyanide chemical manufacturing process units, which was previously unregulated[23]. During development of the initial MACT standards, we identified process

[23] The EPA not only has authority under CAA section 112(d)(2) and (3) to set MACT standards for previously unregulated HAP emissions at any time, but is required to address any previously unregulated HAP emissions as part of its periodic review of MACT standards under CAA section 112(d)(6). *LEAN v. EPA*, 955 F3d at 1091-1099.

wastewater at existing sources as a potential source of emissions of hydrogen cyanide, acetonitrile, and acrylonitrile. See 65 FR 76408, 76411, and 76413, December 6, 2000, for a discussion of the HAP emitted from cyanide chemicals manufacturing. At that time, we identified measures undertaken at cyanide chemicals manufacturing facilities to comply with other NESHAP as the "MACT floor," but we did not include these measures in 40 CFR part 63, subpart YY for existing cyanide chemical manufacturing process units. Based on our review, we are proposing to find that these measures reflect the best performing sources in the source category. The results and proposed decisions based on the analyses performed pursuant to CAA section 112(d)(2) and (3) are presented below.

For this proposal, we reviewed title V permits for facilities subject to the Cyanide Chemicals Manufacturing NESHAP and determined that all cyanide chemicals manufacturing facilities are co-located with processes subject to the Hazardous Organic NESHAP (HON) or substantively similar requirements. In the 2000 NESHAP proposal, we stated that wastewater treatment units at cyanide chemicals manufacturing facilities are typical of synthetic organic chemicals manufacturing facilities subject to the HON. The wastewater requirements of the HON are already an approved means of compliance for wastewater emission sources subject to 40 CFR part 63, subpart YY as stated in 40 CFR 63.1100(g)(5). We are proposing to require compliance with HON wastewater requirements for process wastewater at existing sources, which will ensure all affected sources at cyanide chemicals manufacturing facilities are subject to MACT standards. We are proposing these requirements for cyanide chemicals manufacturing existing sources because such requirements represent: (1) the measures employed by the best performing sources in the category; and (2) an already acceptable means of compliance for wastewater emissions at sources subject to subpart YY. We believe that these requirements will

not require additional controls or emissions reductions since existing sources we have identified as subject to the Cyanide Chemicals Manufacturing NESHAP are already subject to the HON or substantively identical wastewater requirements in another NESHAP.

We are also adding the HON requirements for waste management units upstream of an open or closed biological treatment process to the new source standard to ensure demonstrable compliance measures are in place for these sources; however, we believe these measures would already be employed by any new sources to achieve the combined 93 percent capture and control of HAP emissions from wastewater required for process wastewater emissions at new sources subject to the Cyanide Chemicals Manufacturing NESHAP.

We have identified three HAP that may be present in process wastewater streams at cyanide chemicals manufacturing facilities: hydrogen cyanide, acetonitrile, and acrylonitrile. We are proposing to include hydrogen cyanide in the calculations required to determine compliance with the wastewater standard for the Cyanide Chemicals Manufacturing source category to ensure all HAP potentially present in process wastewater are subject to MACT standards. The other two HAP that may be present in cyanide chemicals manufacturing wastewater (acetonitrile and acrylonitrile) are already included in the list of compounds subject to the HON wastewater provisions. We do not expect significant amounts of hydrogen cyanide to be present in these process wastewater streams. When developing the 2002 NESHAP, facilities that were surveyed reported very low levels of hydrogen cyanide in their wastewaters with one exception. The only facility that had high levels of hydrogen cyanide in its wastewater used add-on controls to remove the hydrogen cyanide prior to discharge. That facility was the basis for the "new source" MACT floor. We expect any facilities with high levels of hydrogen cyanide in their wastewater would already possess add-on controls similar to those present at the single existing source with

high levels of hydrogen cyanide in order to meet effluent discharge limits and protect the biological wastewater treatment systems used at these facilities. We are including hydrogen cyanide in these calculations to ensure that all HAP emitted by the source category are subject to MACT standards.

Nevertheless, we are seeking comment on whether facilities would need to install additional controls, achieve additional emissions reductions, or incur significant costs as a result of the proposed standards for process wastewater. For this proposed rule, we did not identify any new control technologies or developments in existing technologies to evaluate as "beyond-the-floor" controls other than the controls evaluated during the initial MACT standards. We did not find any data to support changing the conclusion that application of the new source MACT limit for process wastewater emissions to existing sources is unreasonable (See 65 FR 76419 and Docket Item No. EPA-HQ-OAR-2004-0041-0003).

B. What are the results of the risk assessment and analyses?

1. Chronic Inhalation Risk Assessment Results

The EPA estimated inhalation risk based on actual and allowable emissions, which we determined are the same for this category. The estimated baseline inhalation MIR posed by the source category is 5-in-1 million based on actual emissions and MACT-allowable emissions. The total estimated cancer incidence based on actual or allowable emission levels is 0.004 excess cancer cases per year, or one case every 250 years. Emissions of acrylonitrile from process vents account for 95 percent of the cancer incidence. Approximately 61,653 people are exposed to cancer risk greater than or equal to 1-in-1 million based upon actual and allowable emissions (see Table 1 of this preamble).

The maximum chronic noncancer TOSHI values for the source category were estimated to be 1 for neurological effects based on actual and allowable emissions. For both actual and allowable emissions, risk was driven by hydrogen cyanide emissions from process vents, wastewater, and equipment leaks.

TABLE 1: INHALATION RISK ASSESSMENT SUMMARY FOR CYANIDE CHEMICALS MANUFACTURING[1] SOURCE CATEGORY (40 CFR PART 63, SUBPART YY)

Risk Assessment	Number of Facilities[2]	Maximum Individual Cancer Risk (1-in-1 million)[3]	Estimated Population at Increased Risk of Cancer ≥ 1-in-1 Million	Estimated Annual Cancer Incidence (cases per year)	Maximum Chronic Noncancer TOSHI[4]	Maximum Screening Acute Noncancer HQ[5]
Baseline Actual Emissions						
Source Category	13	5	61,653	0.004	1 (neurological)	1 (REL)
Facility-Wide	13	200	266,532	0.04	1 (neurological)	-
Baseline Allowable Emissions						
Source Category	13	5	61,653	0.004	1 (neurological)	-

[1] Based on actual and allowable emissions.
[2] Number of facilities evaluated in the risk assessment. Includes 13 operating facilities subject to 40 CFR part 63, subpart YY.
[3] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[4] Maximum TOSHI. The target organ with the highest TOSHI for the Cyanide Chemicals Manufacturing source category is the neurological system.
[5] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of HQ values. The acute HQ shown was based upon the lowest acute 1-hour dose-response value, the REL for hydrogen cyanide. When an HQ exceeds 1, we also show the HQ using the next lowest available acute dose-response value.

2. Screening Level Acute Risk Assessment Results

Based on our screening analysis of reasonable worst-case acute exposure to actual emissions from the category, no HAP exposures result in an HQ greater than 1 based upon the 1-hour REL. As discussed in section III.C.3.c of this preamble, for this source category, we used acute factors between 2 and 10, depending on the type of source. Specifically, we used a factor of 2 for process vents and equipment leaks, a factor of 4 for storage vessels, and a factor of 10 for transfer racks. A further discussion of why these factors were chosen can be found in the memorandum, *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, available in the docket for this rulemaking.

3. Multipathway Risk Screening Results

Three of the 13 facilities in this source category reported emissions of PB-HAP in the NEI which include POM (of which polycyclic aromatic hydrocarbons is a subset), lead compounds, arsenic compounds, cadmium compounds, and mercury compounds. We note that for the Cyanide Chemicals Manufacturing source category, while we modeled these emissions, none of these HAP are expected to be emitted from the source category and they were only modeled to provide a conservative estimate of risk because they were included in the NEI. To identify potential multipathway health risks from PB-HAP other than lead, we first performed a tiered screening assessment (Tiers 1, 2, and 3) based on emissions of PB-HAP emitted from each facility in the source category. Arsenic emissions from a single facility exceeded the Tier 1 cancer screening threshold emission rate with a maximum SV of 2. No facilities had POM emissions exceeding the Tier 1 cancer screening threshold emission rate. Mercury emissions from a single facility exceeded the Tier 1 noncancer screening threshold emission rate with a maximum SV of 2. No facilities had cadmium emissions exceeding the Tier 1 noncancer screening threshold emission rate. For the facilities and HAP for which the Tier 1 threshold

emissions rates were exceeded (*i.e.*, SV greater than 1), we conducted a Tier 2 screening analysis. In the Tier 2 screening analysis, no facilities had an SV greater than 1. Specifically, the maximum Tier 2 cancer SV was less than 1 for both the farmer scenario for arsenic (0.4) and the fisher scenario for mercury (0.3).

Further facility details on the multipathway screening analysis can be found in Appendix 10 of the *Residual Risk Assessment for the Cyanide Chemical Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule.*

An SV in any of the tiers is not an estimate of the cancer risk or a noncancer HQ. Rather, an SV represents a high-end estimate of what the risk or HQ may be. For example, facility emissions resulting in an SV of 2 for a non-carcinogen can be interpreted to mean that we are confident that the HQ would be lower than 2. Similarly, facility emissions resulting in a cancer SV of 20 for a carcinogen means that we are confident that the cancer risk is lower than 20-in-1 million. Our confidence comes from the health-protective assumptions that are incorporated into the screens: we choose inputs from the upper end of the range of possible values for the influential parameters used in the screens and we assume food consumption behaviors that would lead to high total exposure. This risk assessment estimates the maximum hazard for mercury and cadmium through fish consumption based on upper bound screens and the maximum excess cancer risks from POM and arsenic through ingestion of fish and farm produce.

In evaluating the potential for adverse health effects from emissions of lead, the EPA compared modeled annual lead concentrations to the secondary NAAQS level for lead (0.15 $\mu g/m^3$, arithmetic mean concentration over a 3-month period). The highest annual average lead concentration, 0.00000065 $\mu g/m^3$, is orders of magnitude below the NAAQS level for lead, indicating a low potential for adverse health impacts.

4. Environmental Risk Screening Results

As described in section III.A of this preamble, we conducted an environmental risk screening assessment for the Cyanide Chemical Manufacturing source category for the following pollutants: arsenic, cadmium, HCl, lead, mercury (methyl mercury and mercuric chloride), and POM. As noted in our discussion of the multipathway risk assessment results, these HAP are not associated with cyanide chemicals manufacturing and are not emitted from the source category. There were NEI entries for small amounts of these pollutants and we chose to model these emissions to err on the side of an overly conservative assessment.

In the Tier 1 screening analysis for the above PB-HAP (other than lead, which was evaluated differently), the maximum Tier 1 SV was less than or equal to 1 for all PB-HAP.

For lead, we did not estimate any exceedances of the secondary lead NAAQS. For HCl, the average modeled concentration around each facility (*i.e.,* the average concentration of all off-site data points in the modeling domain) did not exceed any ecological benchmark. In addition, for the one facility that reported HCl emissions, each individual modeled concentration of HCl (*i.e.,* each off-site data point in the modeling domain) was below the ecological benchmarks for HCl.

Based on the results of the environmental risk screening analysis, we do not expect an adverse environmental effect as a result of HAP emissions from this source category.

5. Facility-Wide Risk Results

The EPA estimated inhalation risk based on facility-wide emissions. The estimated maximum individual excess lifetime cancer risk based on facility-wide emissions was 200-in-1 million, with 0.04 excess cancer cases per year, or one case every 25 years. This cancer risk is driven by emissions sources that are not in the Cyanide Chemicals Manufacturing source

category; specifically, emissions of ethylene oxide and coke oven emissions from non-category sources account for 95 percent of the cancer incidence. Approximately 150 people are exposed to an excess cancer risk greater than or equal to 100-in-1 million, with 266,532 people exposed to an excess cancer risk above 1-in-1 million (see Table 1 of this preamble). The estimated maximum chronic noncancer TOSHI values for the facility-wide assessment was the same as estimated based on actual and allowable emissions from the source category -- a TOSHI equal to 1 for neurological effects driven by hydrogen cyanide emissions from process vents, wastewater, and equipment leaks.

Regarding the facility-wide risks due to ethylene oxide, which are emitted by sources that are not part of the Cyanide Chemicals Manufacturing source category, we intend to continue to evaluate those facility-wide estimated emissions and risks further and may address these in separate actions, as appropriate. In particular, the EPA is addressing ethylene oxide in response to the results of the latest NATA released in August 2018, which identified the chemical as a potential concern in several areas across the country (NATA is the Agency's nationwide air toxics screening tool, designed to help the EPA and state, local, and tribal air agencies identify areas, pollutants, or types of sources for further examination). The latest NATA estimates that ethylene oxide significantly contributes to potential elevated cancer risks in some census tracts across the U.S. (less than 1 percent of the total number of tracts). These elevated risks are largely driven by an EPA risk value that was updated in late 2016. The EPA will work with industry and state, local, and tribal air agencies as the EPA takes a two-pronged approach to address ethylene oxide emissions by: (1) reviewing and, as appropriate, revising CAA regulations for facilities that emit ethylene oxide – starting with air toxics emissions standards for miscellaneous organic chemical manufacturing facilities (85 FR 49084, August 12, 2020) and commercial sterilizers;

and (2) conducting site-specific risk assessments and, as necessary, implementing emission control strategies for targeted high-risk facilities. The EPA will post updates on its work to address ethylene oxide on its website at: *https://www.epa.gov/ethylene-oxide*.

6. What demographic groups might benefit from this regulation?

To examine the potential for any environmental justice issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risk to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risk from the Cyanide Chemicals Manufacturing source category across different demographic groups within the populations living near facilities.[24]

The results of the demographic analysis are summarized in Table 2 below. These results, for various demographic groups, are based on the estimated risk from actual emissions levels for the population living within 50 km of the facilities.

TABLE 2. CYANIDE CHEMICALS MANUFACTURING DEMOGRAPHIC RISK ANALYSIS RESULTS

	Nationwide	Population with Cancer Risk at or Above 1-in-1 Million Due to Cyanide Chemicals Manufacturing	Population with Chronic HI Above 1 Due to Cyanide Chemicals Manufacturing
Total Population	317,746,049	61,653	0
Race by Percent			
White	62	73	
All Other Races	38	27	
Race by Percent			
White	62	73	

[24] Demographic groups included in the analysis are: White, African American, Native American, other races and multiracial, Hispanic or Latino, children 17 years of age and under, adults 18 to 64 years of age, adults 65 years of age and over, adults without a high school diploma, people living below the poverty level, people living two times the poverty level, and linguistically isolated people.

African American	12	19	
Native American	0.8	0.4	
Other and Multiracial	7	4	
Ethnicity by Percent			
Hispanic	18	3	
Non-Hispanic	82	97	
Income by Percent			
Below Poverty Level	14	16	
Above Poverty Level	86	84	
Education by Percent			
Over 25 and without High School Diploma	14	16	
Over 25 and with a High School Diploma	86	84	

The results of the Cyanide Chemicals Manufacturing source category demographic analysis indicate that emissions from the source category expose approximately 61,653 people to a cancer risk at or above 1-in-1 million and nobody to a chronic noncancer TOSHI greater than 1. The percentages of the at-risk population in the White, African American, Below Poverty, and Over 25 without High School Diploma demographic groups are greater than their respective nationwide percentages.

The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review – Analysis of Demographic Factors for Populations Living Near Cyanide Chemicals Manufacturing*, available in the docket for this action.

C. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?

1. Risk Acceptability

As explained in section II.A of this preamble, the EPA sets standards under CAA section 112(f)(2) using "a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual risk (MIR) of approximately 1-in-10 thousand." (54 FR 38045, September 14, 1989). The EPA weighed all health risk measures and information, including science policy assumptions and estimation uncertainties, in determining whether risk posed by emissions from the source category is acceptable.

The estimated maximum cancer risk for inhalation exposure to actual and allowable emissions from the Cyanide Chemicals Manufacturing source category was 5-in-1 million, 20 times below 100-in-1 million, which is the presumptive upper limit of acceptable risk. The EPA estimates emissions from the category would result in a cancer incidence of 0.004 excess cancer cases per year, or one case every 250 years. Inhalation exposures to HAP associated with chronic noncancer health effects result in a TOSHI of 1 based on actual and allowable emissions, an exposure level that the EPA has determined is without appreciable risk of adverse health effects. Exposures to HAP associated with acute noncancer health effects also are below levels of health concern with no HAP exposures resulting in an HQ greater than 1 based upon the 1-hour REL.

Maximum cancer risk due to ingestion exposures, estimated using health-protective risk screening assumptions, is below 1-in-1 million for the Tier 2 farmer exposure scenario. Tier 2 screening analyses of mercury exposure due to fish ingestion determined that the maximum HQ for mercury would be less than 1 as explained in section III.C.4 of this preamble.

Considering all of the health risk information and factors discussed above, as well as the uncertainties discussed in section III of this preamble, we propose that the risks posed by emissions from the Cyanide Chemicals Manufacturing source category are acceptable.

2. Ample Margin of Safety Analysis

As directed by CAA section 112(f)(2), we conducted an analysis to determine whether the current emissions standards provide an ample margin of safety to protect public health. Under the ample margin of safety analysis, we evaluated the cost and feasibility of available control technologies and other measures (including the controls, measures, and costs reviewed under the technology review) that could be applied to this source category to further reduce the risks (or potential risks) due to emissions of HAP from the source category. In light of the low cancer and noncancer risk posed to individuals exposed to HAP emitted from this source category and lack of additional control technologies, we are proposing to conclude that the existing standards under the NESHAP provide an ample margin of safety to protect public health.

3. Adverse Environmental Effect

Based on the results of our environmental risk screening analysis, we do not anticipate an adverse environmental effect as a result of HAP emissions from this source category. Therefore, the EPA is proposing that it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

D. What are the results and proposed decisions based on our technology review?

As part of the technology review, we identified a previously unregulated process, and are proposing a MACT standard for the process under CAA section 112(d)(2) and (3), as described in Section IV.A of this preamble, above. We did not identify any developments in processes, practices, or control technologies for cyanide chemicals manufacturing facilities during our analysis for this proposal. Facilities subject to this NESHAP use flares to control emissions from point sources and LDAR programs to address emissions from equipment leaks. As discussed in

the memorandum titled *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, we did not identify any developments in these technologies during our technology review.

E. What other actions are we proposing?

In addition to the proposed actions described above, we are proposing additional revisions to the NESHAP. We are proposing revisions to the SSM provisions of the MACT rule in order to ensure that they are consistent with the decision in *Sierra Club v. EPA*, 551 F. 3d 1019 (D.C. Cir. 2008), in which the court vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We note that for the Cyanide Chemicals Manufacturing source category, the NESHAP currently does not include an exemption for SSM events, and already includes standards that apply at all times, including periods of SSM. Therefore, we have determined that the NESHAP is already consistent with the court decision mentioned above. However, we are making revisions to the MACT rule at 40 CFR 63.1108 through 40 CFR 63.1112 to ensure this is clearly and consistently communicated throughout and no confusion results from referenced subparts associated with the GMACT that may contain SSM exemptions for other source categories. We also are proposing other changes to add electronic reporting. Our analyses and proposed changes related to these issues are discussed below.

Electronic Reporting. The EPA is proposing that owners and operators of cyanide chemicals manufacturing facilities submit electronic copies of required notifications of compliance, performance test reports, and periodic reports through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum, *Electronic*

Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules, available in the docket for this action. The proposed rule requires that performance test results collected using test methods that are supported by the EPA's Electronic Reporting Tool (ERT) as listed on the ERT website[25] at the time of the test be submitted in the format generated through the use of the ERT or an electronic file consistent with the xml schema on the ERT website, and other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. The proposed rule requires that Notification of Compliance Status (NOCS) be submitted as a PDF upload in CEDRI.

For periodic reports, the proposed rule requires that owners and operators use the appropriate spreadsheet template to submit information to CEDRI. A draft version of the proposed template for these reports is included in the docket for this action.[26] The EPA specifically requests comment on the content, layout, and overall design of the template. Additionally, the EPA has identified two broad circumstances in which electronic reporting extensions may be provided. These circumstances are (1) outages of the EPA's CDX or CEDRI which preclude an owner or operator from accessing the system and submitting required reports and (2) *force majeure* events, which are defined as events that will be or have been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevent an owner or operator from complying with the requirement to submit a report electronically. Examples of *force majeure* events are acts of nature, acts of war or

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[25] *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*
[26] See Draft Form_5900-485_Subpart_YY_Cyanide_Draft_Periodic_Report_Template_Proposal.xlsm , available at Docket ID No. EPA-HQ-OAR-2020-0532.

terrorism, or equipment failure or safety hazards beyond the control of the facility. The EPA is providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible.

The electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA's plan[27] to implement Executive Order 13563 and is in keeping with the EPA's Agency-wide policy[28] developed in

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[27] EPA's Final Plan for Periodic Retrospective Reviews, August 2011. Available at: *https://www.regulations.gov/document?D=EPA-HQ-OA-2011-0156-0154.*

[28] E-Reporting Policy Statement for EPA Regulations, September 2013. Available at: *https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf.*

response to the White House's Digital Government Strategy.[29] For more information on the benefits of electronic reporting, see the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules*, referenced earlier in this section.

F. What compliance dates are we proposing?

The EPA is proposing that existing affected sources and affected sources that commenced construction or reconstruction on or before **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, must comply with the proposed process wastewater standards no later than 365 days after the effective date of the final rule and all of the other amendments no later than 180 days after the effective date of the final rule. The final action is not expected to be a ''major rule'' as defined by 5 U.S.C. 804(2), so the effective date of the final rule will be the promulgation date as specified in CAA section 112(d)(10). For existing sources, we are proposing a change that would impact ongoing compliance requirements for 40 CFR part 63, subpart YY. As discussed elsewhere in this preamble, we are proposing to change the requirements for SSM by removing references to exemptions in other subparts. Our experience with similar industries shows that this sort of regulated facility generally requires a time period of 180 days to read and understand the amended rule requirements; to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; and to update their operations to reflect the revised requirements.

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[29] Digital Government: Building a 21st Century Platform to Better Serve the American People, May 2012. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html*.

From our assessment of the timeframe needed for compliance with the revised requirements, the EPA considers a period of 180 days to be the most expeditious compliance period practicable, and, thus, is proposing that existing affected sources be in compliance with this regulation's revised requirements within 180 days of the regulation's effective date. We solicit comment on this proposed compliance period, and we specifically request submission of information from sources in this source category regarding specific actions that would need to be undertaken to comply with the proposed amended requirements, including the proposed amendments related to recordkeeping and reporting and the time needed to make the adjustments for compliance with them. We note that information provided may result in changes to the proposed compliance date; however, we expect the proposed compliance time to be sufficient given that cyanide chemicals manufacturing facilities are already subject to standards during these periods. We are proposing that facilities will have 1 year to comply with the proposed process wastewater standards for existing sources. We note that we do not expect the proposed wastewater standards for existing sources to require installation of any additional controls. We believe that all affected sources are already complying with the proposed wastewater requirements or requirements that are substantively identical. We are proposing that facilities must comply within 365 days in order to provide time to evaluate wastewater operations, perform compliance calculations, and adjust plans and reports as necessary. We are seeking comment on the assumption that facilities will not need to install additional add-on controls and whether facilities would require more or less time to comply with the proposed process wastewater requirements. Affected sources that commence construction or reconstruction after **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, must comply with all requirements of the subpart, including the amendments being proposed, no later than the

effective date of the final rule or upon startup, whichever is later. All affected facilities would have to continue to meet the current requirements of 40 CFR part 63, subpart YY, until the applicable compliance date of the amended rule.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

There are 13 cyanide chemicals manufacturing facilities currently operating as major sources of HAP subject to the proposed amendments. A list of facilities that are currently subject to the MACT standards is available in the memorandum titled *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, available in Docket ID No. EPA-HQ-OAR-2020-0532.

B. What are the air quality impacts?

We do not anticipate that the proposed amendments to this subpart will impact air quality. We are not proposing changes to the standard that will result in additional emission reductions beyond the levels already achieved by the NESHAP.

C. What are the cost impacts?

The proposed amendments will have a limited cost impact on affected facilities. Total estimated costs are $47,527 based on a $3,656 per facility cost for all 13 facilities. The costs result from reading and understanding rule requirements and adjusting compliance plans based on the rule proposal. All costs are one-time expenses expected to occur in the first year after the rule is finalized. Costs are based on Agency knowledge and experience with the NESHAP program, related ICRs, and Bureau of Labor Statistics data.

D. What are the economic impacts?

Economic impact analyses focus on changes in market prices and output levels. If changes in market prices and output levels in the primary markets are significant enough, impacts on other markets may also be examined. Both the magnitude of costs associated with the proposed requirements and the distribution of these costs among affected facilities can have a role in determining how the market will change in response to a proposed rule.

Economic costs to owners of cyanide chemicals manufacturing facilities were measured in present value (PV) total costs and equivalent annual value (EAV) costs. All cyanide chemicals manufacturing facilities were estimated to have similar costs. All costs are presented in 2019 dollars. See section V.C of this preamble for additional information on costs.

PV total costs and EAV costs were measured at the 3 percent and 7 percent discount rates. The duration of analysis was 8 years. Per facility PV total cost estimate is $3,656 at the 3 percent and 7 percent discount rates. The similarity in both discount rates is due to the costs all occuring in the first year after the rule is finalized. EAV costs per facility are measured to be $521 and $612 at the 3 percent and 7 percent discount rates, respectively. Combined total PV cost of the proposed requirements for all facilities is measured to be $47,527 at the 3 percent and 7 percent discount rates. The similarity in both discount rates is due to the costs all coming in the first year that the rule will be finalized. Combined EAV costs of the proposed requirements for all facilities are measured to be $6,771 and $7,959 at the 3 percent and 7 percent discount rates, respectively.

As required by the Regulatory Flexibility Act (RFA), we performed an analysis to determine if any small entities would be unduly burdened by the proposed amendments. We determined that all facilities subject to the NESHAP are owned by large parent entities based on Small Business Administration standards. No significant economic impacts from the proposed

amendments are anticipated because the PV and EAV costs associated with the proposed revisions are minimal.

E. What are the benefits?

As discussed in section V.B of this preamble, we do not anticipate the proposed amendments to this subpart to impact air quality. The electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements, and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public.

VI. Request for Comments

We solicit comments on this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the risk assessments and other analyses. We are specifically interested in receiving any improvements to the data used in the site-specific emissions profiles used for risk modeling. Such data should include supporting documentation in sufficient detail to allow characterization of the quality and representativeness of the data or information. Section VII of this preamble provides more information on submitting data.

VII. Submitting Data Corrections

The site-specific emissions profiles used in the source category risk and demographic analyses and instructions are available for download on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*. The data files include detailed information for each HAP emissions release point for the facilities in the source category.

If you believe that the data are not representative or are inaccurate, please identify the data in question, provide your reason for concern, and provide any "improved" data that you have, if available. When you submit data, we request that you provide documentation of the basis for the revised values to support your suggested changes. To submit comments on the data downloaded from the RTR website, complete the following steps:

1. Within this downloaded file, enter suggested revisions to the data fields appropriate for that information.

2. Fill in the commenter information fields for each suggested revision (*i.e.*, commenter name, commenter organization, commenter email address, commenter phone number, and revision comments).

3. Gather documentation for any suggested emissions revisions (*e.g.*, performance test reports, material balance calculations).

4. Send the entire downloaded file with suggested revisions in Microsoft® Access format and all accompanying documentation to Docket ID No. EPA-HQ-OAR-2020-0532 (through the method described in the **ADDRESSES** section of this preamble).

5. If you are providing comments on a single facility or multiple facilities, you need only submit one file for all facilities. The file should contain all suggested changes for all sources at

that facility (or facilities). We request that all data revision comments be submitted in the form of updated Microsoft® Excel files that are generated by the Microsoft® Access file. These files are provided on the project website at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*.

VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted to the OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2678.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The EPA is proposing amendments that revise provisions pertaining to emissions during periods of SSM, add requirements for electronic reporting of NOCS, periodic reports, and performance test results, and make other minor clarifications and corrections. This information will be collected to assure compliance with the Cyanide Chemicals Manufacturing NESHAP.

Respondents/affected entities: Owners or operators of cyanide chemicals manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart YY).

Estimated number of respondents: 13 (assumes no new respondents over the next 3 years).

Frequency of response: Initially, occasionally, and annually.

Total estimated burden: 160 hours (per year) to comply with all of the requirements in the NESHAP. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $15,800 (per year), including no annualized capital or operation and maintenance costs, to comply with all of the requirements in the NESHAP.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments n later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. There are no small entities among the eight ultimate parent companies impacted by this proposed action given the Small Business Administration small business size definition for this industry (1,000 employees or greater for NAICS 325180 – Other Basic Inorganic Chemical Manufacturing), and no significant economic impact on any of these entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. None of the cyanide chemicals manufacturing production facilities that have been identified as being affected by this proposed action are owned or operated by tribal governments or located within tribal lands. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section IV.B of this preamble and the document, *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this rulemaking.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards. Therefore, the EPA conducted a search to identify potentially applicable voluntary consensus standards. However, the Agency identified no such standards. A thorough summary of the search and results are included in the memorandum titled *Voluntary Consensus Standard Results for Cyanide Chemicals Manufacturing Residual Risk and Technology Review*, which is available in the docket for this action.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in section IV.B of this preamble and in the technical report, *Risk and Technology Review—Analysis of Demographic Factors for*

Populations Living Near Cyanide Chemicals Manufacturing Facilities, available in the docket for this action.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Andrew Wheeler,

Administrator.

Message

From: HQ_Facilities_Updates [HQ_Facilities_Updates@epa.gov]
Sent: 1/6/2021 10:47:59 PM
To: All HQ Feds-nonFeds [All_HQ_Feds-nonFeds@epa.gov]
Subject: Revised Update: Mandatory City-Wide Curfew Schedule to Begin 6:00 PM Today

EPA

Office of Mission Support

This email message is being sent to HQ EPA employees

DC Mayor Bowser has instituted a city-wide curfew beginning at 6:00PM this evening. All entrances to EPA buildings at the Federal Triangle will be locked at that time. We encourage all EPA staff and contractors to exit the facilities before 6:00pm.

If you are still in the building after 6pm and require assistance, please contact the HQ Guard Command Center at 202-564-1120. For all other inquiries, please send an email to HQSECURITY@epa.gov.

Please monitor news outlets for further information on the DC operational status.

Message

From: Bolen, Brittany [bolen.brittany@epa.gov]
Sent: 1/6/2021 7:10:57 PM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
CC: Molina, Michael [molina.michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Scott, Corey [scott.corey@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]
Subject: For Signature: Product Performance Data Requirements Invertebrate Pests proposal
Attachments: 10011-06_FR_Doc_Product Performance Data_eSignature_EPA_ADMIN.docx

Administrator –

Attached for your electronic signature is the Product Performance Data Requirements Invertebrate Pests proposal. Please digitally sign this file using Word then email it back to me.

Thank you,

Brittany

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[EPA-HQ-OPP-2020-0124; FRL-10011-06]

RIN 2070-AJ49

Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to codify product performance data requirements to support registration of pesticidal products claiming efficacy against three categories of invertebrate pests: those identified to be of significant public health importance (e.g., ticks, mosquitoes, cockroaches, etc.), wood-destroying insects (e.g., termites), and certain invasive invertebrate species (e.g., Asian longhorned beetle). The latter two categories are pests considered to be of significant economic or ecological importance. Product performance data (efficacy studies) document how well the pesticide performs the intended function, such as killing or repelling, against an invertebrate pest.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE ***FEDERAL REGISTER***].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2020-0124, through the Federal eRulemaking Portal at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at [HYPERLINK "http://www.epa.gov/dockets/contacts.html"].

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Sara Kemme, Mission Support Division (7101M), Office of Program Support, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347-8533; e-mail address: *kemme.sara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You potentially may be affected by this action if you are a producer or registrant of pesticide products making claims against the specified categories of invertebrate pests. The North American Industrial Classification System (NAICS) codes are provided to assist you and others in determining if this action might apply to certain entities. This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. Other types of entities not listed could also be affected. Potentially affected entities may include, but are not limited to,

• Chemical Producers (NAICS 32532), e.g., pesticide manufacturers or formulators of

pesticide products, pesticide importers or any person or company who seeks to register a pesticide.

• Research and Development in the Physical, Engineering, and Life Sciences (NAICS code 541712), e.g., research and development laboratories or services that perform efficacy testing for invertebrate pests.

• Colleges, universities, and professional schools (NAICS code 611310), e.g., establishments of higher learning which are engaged in development and marketing of products for invertebrate pest control.

B. What action is the Agency taking?

EPA is proposing to codify product performance data requirements for pesticide products claiming efficacy against three categories of invertebrate pests: those identified to be of significant public health importance (e.g., ticks, mosquitoes, cockroaches, etc.), wood-destroying insects (e.g., termites), and certain invasive invertebrate species (e.g., Asian longhorned beetle). The latter two categories are considered to be of significant economic and/or ecological importance.

Product performance data (efficacy studies) document how well the product performs the intended function, such as killing or repelling, against an invertebrate pest. The product performance data requirements being proposed would inform the data needed to substantiate pesticidal claim(s) made on the label of the pesticide products. The proposed numerical performance standards specify the level of efficacy that would need to be achieved for EPA to deem the submitted data as acceptable for a product bearing the specified claim(s) against the invertebrate pest. For the most part, the data requirements that EPA is proposing for codification are consistent with EPA's current practices in data supporting applications for registration of a

pesticide product that bears a pesticidal claim against one or more of these pests.

This proposed rule presents the data requirements in tabular format. These tables link the efficacy claim on the label of a pesticide product with the data needed to substantiate that claim. EPA is proposing that the studies submitted by an applicant demonstrate the product's efficacy in studies using specified test species and with results demonstrating that the product achieved a specified level of performance, called a performance standard. Numerical performance standards, such as the percent mortality, percent repellency, percent knockdown, or complete protection time would need to be achieved to deem the data acceptable for the purpose of supporting a product making a claim against an invertebrate pest. The Agency believes that codifying essential elements relating to test species and performance standards will provide the regulated community a better understanding of the data EPA believes to be necessary to support registration of a product that claims efficacy against invertebrate pests.

EPA is proposing to:

• Codify a new subpart R in 40 CFR part 158 entitled, "Product Performance for Products Claiming Effectiveness Against Invertebrate Pests;"

• Rename 40 CFR part 158, subpart E to "Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion-related Claims, and Products for Control of Organisms Producing Mycotoxins" in order to add specificity to the title and reduce the potential for confusion with the proposed subpart R; and

• Revise the data requirements for biochemicals in 40 CFR 158.2070 and microbials in 40 CFR 158.2160 to clarify the requirements for claims that would be subject to both subpart R and either subpart U or V.

Additionally, EPA proposes to update 40 CFR 158.1(c) to insert references to the

subparts to categorize them under the "scope of the subparts" section. EPA is also proposing to update subpart W at 40 CFR 158.2200(b) to insert a cross reference to the proposed subpart R to clarify the status of a product that bears both an antimicrobial claim and a non-antimicrobial claim against one of the pests specified in proposed subpart R.

C. What is EPA's authority for taking this action?

This action is issued under the authority of sections 3, 5, 10, 12, and 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136-136y), as amended. Under FIFRA section 3(c)(2)(A), EPA is required to specify "the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time." EPA's codification of these data requirements is in 40 CFR part 158.

Additionally, the Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) (7 U.S.C. 136 note, 133 Stat. 484) was enacted into law on March 8, 2019. PRIA was developed by a coalition of pesticide stakeholders representing seven different trade groups within the pesticide industry and public interest groups reflecting the environmental and farmworker safety communities. The result of this collaboration is that there are elements of PRIA 4 important to all the represented stakeholder entities in the coalition. PRIA 4 specifically establishes a new maintenance fee set-aside of up to $500,000/year to develop and finalize rulemaking and guidance for product performance data requirements for certain invertebrate pests of significant public health or economic importance. Specific to this rule, PRIA 4 requires EPA to finalize product performance data requirements by September 30, 2021. Specifically, the Act states that, "The Administrator shall, not later than September 30, 2021, issue regulations prescribing product performance data requirements for any pesticide intended for preventing, destroying, repelling, or mitigating any invertebrate pest of significant public health or economic importance

specified in clauses (i) through (iv) of subparagraph (B) [bed bugs; premise (including crawling insects, flying insects, and baits), pests of pets (including pet pests controlled by spot-ons, collars, shampoos, powders, or dips), and fire ants]."

This proposed rule includes product performance data requirements for the categories of invertebrate pests specified in PRIA 4 and, thus, is intended to satisfy the aforementioned rulemaking requirement. EPA notes that this proposed rule covers some invertebrate pests in addition to those specified in PRIA 4 due to their public health, economic, or ecological significance.

D. Why is EPA taking this action?

The following objectives were considered by EPA in developing this proposed rule:

1. *Obtaining reliable data to make the statutory finding*. The data submitted to EPA for review and evaluation as a result of this rule, once final, are expected to improve the Agency's understanding of the effectiveness of pesticides that make claims against pests of public health or significant economic importance.

2. *Provide clear and transparent data requirements*. Once final, the regulatory text proposed in this rule is intended to identify the specific data requirements that apply to pesticides making claims against certain categories of invertebrate pests. As with the original design of part 158 in 1984, and continued in 2007, given the variations in pesticide chemistry, exposure, and hazard, this proposal for product performance data requirements is intended to be clear and transparent while retaining sufficient flexibility to account for special circumstances.

E. What are the estimated incremental impacts?

In conjunction with this proposed rulemaking, EPA prepared an economic analysis entitled, "Cost Analysis of the Proposed Product Performance Rule" (Ref. 1) which presents an

analysis of the effects of codifying data requirements for product performance, as well as the effects of changes to label claim data requirements published simultaneously.

As noted previously, FIFRA mandates the Agency to register pesticides, including those used against invertebrate pests of public health importance, invertebrate wood destroying pests, and invasive invertebrate pests, under conditions of use such that the pesticide is of a composition to warrant the proposed claims. To make this finding, the Agency requires that registrants submit data demonstrating product efficacy against invertebrate pests of public health importance, invertebrate wood destroying pests, and invasive invertebrate pests. The product performance data requirements historically sought by the EPA and those being proposed in the rule are for claims against pests that either pose a threat to human health (e.g., mosquitoes and cockroaches) or have significant economic impacts, against which the efficacy of a pesticide cannot be readily determined by the user (e.g., termites and emerald ash borers). In those situations, market forces may operate too slowly to remove ineffective products. The proposal, once final, would codify data requirements for support of label claims that have, to date, been necessary, as determined on a case-by-case basis, to conduct assessments of product performance. This will provide needed clarity to firms seeking to develop and market products to control invertebrate pests of public health importance, invertebrate wood destroying pests, and invertebrate invasive pests.

This rule, when finalized, will clarify data requirements and therefore improve efficiency and effective use of resources by both the Agency and industry. Moreover, this rule-making measure will serve the public by ensuring that appropriate efficacy data are available to substantiate public health pest claims. While experience over time has led to a fairly standardized set of data requirements for invertebrate pests of significant public health importance, wood-

destroying insects, and invasive pests, codifying these data needs will ensure that new entrants to the field are clear about the information necessary to support registration. As a result, this rule, when finalized, would help alleviate uncertainties in the regulatory process and enhance transparency for stakeholders. The Agency is specifying data requirements for invertebrate pests of significant public health importance, wood-destroying insects, and invasive invertebrate pests to better indicate when certain data are needed or not. Consistent with 40 CFR 158.45 and proposed 40 CFR 158.1707, on a case-by-case basis the Agency may consider alternative data that are more appropriate than the proposed requirements considering the intended purpose and pesticidal claims of a pesticidal product.

EPA estimates that the proposed rule would result in cost savings of one million dollars annually across all registrants seeking label claims against invertebrate pests of significant public health importance, wood-destroying insects, and invasive invertebrate pests, equivalent to about $17,000 in savings per data package submitted to the Agency (Table 1). The average savings per registrant is $5,500 annually, considering that registrants do not submit products for review every year. This impact is expected to remain consistent over the next ten years, with total cost savings to industry of $1 million annually using either a 3% or a 7% discount rate. Over ten years, this amounts to about $8.5 million in savings at a 3% discount rate or about $7 million in savings at a 7% discount rate. The most expansive estimate of registrant cost savings of the proposed rule, including all likely impacts of the publication of the rule and the impact of changes in data requirements published concurrently with the rule, is $1.7 million annually. The estimated worst case is a cost increase to registrants of $600,000 annually.

EPA's registration program and efficacy review has substantial benefits for consumers. It ensures product efficacy and label consistency across products, increases consumer confidence in

product efficacy, and reduces consumer search costs for effective products. This may help reduce the incidence of vector-borne diseases and damage from wood-destroying and invasive pests. Clarity in data requirements would enhance the efficiency of the registration process and aid new products to market, providing consumers with more product choices.

Table 1—Benefits and Costs of the Proposed Rule

Expected Benefits of the Proposed Rule	
Cost savings per data package submitted	• Average impact per submitted data package of $17,000
Cost savings per registrant submitting data packages	• Average annual impact per registrant of $5,500
Annualized Cost Savings	• $1 million at both 3% and 7% discount rates • This projection assumes 60 data packages submitted annually to the Agency.
Qualitative Effects	• For registrants: Quicker label changes, lower discovery costs, lower barriers to innovation. • For consumers: Ensuring product efficacy and label consistency; increased consumer confidence in product efficacy; reduced search costs for effective products; and reduction in damage from covered pests.
Expected Costs of the Proposed Rule	
No increased risk to human health or the environment is expected from publication of the proposed rule. No increased costs to registrants or consumers are expected from publication of the proposed rule. Expected direction of costs for the Agency from the proposed rule are unknown.	
Other Impacts	
Small Business Impacts	• No significant impact on a substantial number of small entities • Affected NAICS codes contain up to 5,438 small entities. No increased costs to small entities expected, and cost savings may be relatively larger for small firms who do not have experience with the registration process for invertebrate pests of public health importance, invertebrate wood destroying pests, and invertebrate invasive pests.

F. What should I consider as I prepare my comments for EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the

outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at [HYPERLINK "http://www.epa.gov/dockets/comments.html"].

II. Statutory Framework

As a general matter, no person may distribute or sell an unregistered pesticide in the U.S. (FIFRA section 3(a)). The process for obtaining a registration for a pesticide so that it may be distributed or sold begins with submission to EPA of an application with the necessary data to review the application request. Taking into account the information submitted, EPA must grant the requested registration, if it concludes, when considered with any restrictions imposed, that:

• Composition of the proposed pesticide is such as to warrant the proposed claims for it;

• Labeling for the proposed pesticide and other material required to be submitted comply with the requirements of FIFRA;

• The proposed pesticide will perform its intended function without unreasonable adverse effects on the environment; and

• When used in accordance with widespread and commonly recognized practice, the proposed pesticide will not generally cause unreasonable adverse effects on the environment.

FIFRA section 3(c)(5) further provides that EPA "may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy."

The proposed regulations identify the data requirements EPA believes are necessary to determine whether the proposed claims of efficacy are warranted, the opportunity for waiver is covered by 40 CFR 158.45 and proposed 40 CFR 158.1707.

EPA notes that "unreasonable adverse effects on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs, and benefits of the use of any pesticide …" as described in FIFRA section 2(bb). That definition was amended in 1998 as part of the Food Quality Protection Act, requiring EPA to consider "the risks and benefits of public health pesticide separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this Act, the administrator shall weigh any risks of the pesticide against the health risks such as the disease transmitted by the vector to be controlled by the pesticide." While this rule proposes to codify product performance data requirements for invertebrate pests of significant public health importance, (Ref. 2) this rule does not address classification of pesticides as "public health pesticides" as that term is defined in FIFRA section 3(nn). The data requirements proposed in this rule will be used to make appropriate determinations under the FIFRA "unreasonable adverse effects" standard.

To determine whether the proposed use of the pesticide will not cause unreasonable adverse effects, EPA generally considers the maximum proposed use of a new pesticide to estimate the maximum exposure potential, evaluates the hazard data on the pesticide, and compares the rates at which effects are found based on well conducted studies with the maximum exposure estimate. However, for pesticides intended for use against pests of public health or economic importance, EPA has for some time considered whether the pesticide may cause human health, environmental or economic harm if its use as proposed will not work as

intended or claimed. Data on the pesticide's performance under the conditions of use proposed are essential to make this determination.

A. Registration

Section 3 of FIFRA contains the requirements for granting and maintaining registration. FIFRA section 3(c)(2) provides EPA broad authority, before and after registration, to require scientific testing and submission of the resulting data to the Agency. Under this authority, EPA requires such testing and submission of data through rulemaking, see, 40 CFR part 158 or, for existing registrations, through issuance of a "data call-in." (See, FIFRA section 3(c)(2)(B)). EPA may also request further data if the data submitted fail to adequately address an issue necessary for making the requisite statutory findings. (See, 40 CFR 158.75). Consistent with the requirements EPA has imposed and the data that have been identified as needed to review applications for registration of pesticides of significant health or economic importance, an applicant for registration must furnish EPA with data on the pesticide, its composition, toxicity, potential human exposure, environmental properties and ecological effects, as well as its product performance (efficacy).

B. Registration Review

FIFRA section 3(g) mandates that the registrations of all pesticides are to be periodically reviewed. Periodic review is needed as changes in science, public policy, and pesticide use practices occur over time. The registration review program was implemented via a regulation promulgated on August 9, 2006 (71 FR 45719) (FRL-8080-4). Therefore, starting in 2006, registration review began to replace EPA's reregistration program as the mechanism for systematic review of existing pesticides. The registration review process begins by reviewing the available information in the possession of the Agency and then determining if and what data are

needed to assess the current risks of a particular pesticide. Thus, as with registration, the data needed and the scope and depth of the Agency's review for registration review continue to be tailored to the specific circumstances and use of the registered pesticide. Section 3(g)(2)(A) of FIFRA authorizes EPA to require generation and submission of additional data necessary for registration review pursuant to its authority under FIFRA section 3(c)(2)(B).

III. Regulatory Framework

The existing regulatory data requirements for product performance for pesticides are contained in 40 CFR part 158, subpart E, and for the most part the table in 40 CFR 158.400(d) is specific to vertebrates (e.g., birds, rodents, etc.); 40 CFR part 158 subpart W also contains pesticide data requirements for antimicrobials. However, subpart E does not specifically require submission of product performance data for those pesticide products claiming effectiveness against invertebrate pests (e.g., insects, spiders, etc.). Instead, the test note in 40 CFR 158.400(e)(1) contemplates requiring the submission of product performance data on a case-by-case basis, consistent with the general authority in 40 CFR 158.75 to require additional data as part of the registration process, if the information that is required and submitted for registration is not sufficient to make the requisite statutory findings. EPA has relied on these authorities for some years to obtain needed product performance data for conventional pesticides intended for use against certain invertebrate pests of public health or economic significance.

Although the updating of 40 CFR part 158 regulations began years ago, EPA made no changes to the product performance data requirements at 40 CFR part 158, subpart E, as they relate to the invertebrate pests covered in this action. (72 FR 60934, October 26, 2007) (FRL-8106-5). However, EPA did make some changes to the data requirements for biochemical and microbial pesticides by codifying product performance data requirements for biochemical and

microbial pesticides in 40 CFR 158.2070 and 158.2160, subparts U and V, respectively (72 FR 60934, October 26, 2007) (FRL-8106-5). That final rule adopted the requirement for applicants to submit product performance data to support registration of biochemical and microbial products claiming effectiveness against invertebrate species.

This rulemaking proposes to create a new subpart R for invertebrate product performance requirements to capture the updates to the product performance data requirements for pesticides, and to make conforming edits to subparts E, U, V, and W.

IV. Background

Since the early years of the registration program, EPA has waived the need for product performance data for many pesticides, consistent with the congressional authority in FIFRA section 3(c)(5), to waive such data and to not make the finding that a proposed pesticide's "composition is such as to warrant the proposed claims for it." (44 FR 27932, May 11, 1979) (FRL-2767-8). However, EPA did not codify its early intent not to waive product performance data for pesticides intended for use against certain invertebrate pests. Specifically, in May of 1979, EPA initially announced the need for product performance data for "[i]nvertebrate control products intended for use in or on humans (or in or on pets for control of pests which attack humans) to control pests such as fleas, mites, lice, ticks, biting flies, and mosquitoes" and for"[i]nvertebrate control products intended for use either in premises or in the environment to control pests of sanitary or public health significance such as mosquitoes, biting flies, ticks, fleas, houseflies, cockroaches, fire ants, hornets, wasps, poisonous spiders, scorpions, centipedes, and bedbugs." (44 FR 27932, May 11, 1979) (FRL-2767-8). In contrast, in other subsequent rulemaking actions, EPA announced its intent to require product performance data only for products "where lack of control would clearly result in adverse health effects" (47 FR 40659,

September 15, 1982) (FRL-2138-1) or where "control cannot reasonably be observed by the user…" (47 FR 40659, 40661) because other pests were more of an aesthetic and nuisance problem rather than one of public health.

Ultimately, EPA's final part 158 rule announced that EPA had "decided to rescind the proposed efficacy data waiver with respect to vertebrate control agents intended for control of pests that directly or indirectly transmit disease to humans" and included a test note indicating that EPA waived product performance data "unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his/her product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration." (49 FR 42856, 42875, October 24, 1984) (FRL-2591-5); 40 CFR 158.400(e)(1). That provision remains largely unchanged today, although in the subsequent updates to the data requirements for microbial and biochemical pesticides, EPA made clear that the submission of efficacy data would be required if "the pesticide product bears a claim to control … invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans." (40 CFR 158.2160). Thus, existing EPA regulations for conventional pesticides continue to presume the waiver of product performance data for invertebrate pests unless EPA exercises its discretion to require on a case-by-case basis submission of the data to support claims against pests, including

pests of significant public health importance.

In 2002, EPA issued Pesticide Registration Notice (PRN) 2002-1 in compliance with the requirement in FIFRA section 28(d) to coordinate with United States Department of Health and Human Services (HHS) and United States Department of Agriculture (USDA) in identifying pests of significant public health importance. The list of pests identified in that PRN was "derived in large part from review of the pesticide/pest combinations for which efficacy (product performance) data are generally required to be submitted and reviewed prior to registration." (Ref. 2). EPA is the process of updating this document and has recently made an updated draft available for public comment (Ref. 2).

A. Why does product performance matter?

The primary goal of this proposal is to assure that pesticide products claiming effectiveness against an invertebrate pest of significant public health or economic importance perform effectively. This action addresses both health concerns and economic consequences stemming from pesticide products that might not perform as claimed on the label. EPA acknowledges that use of the term arthropod would include all the pests identified in this document. However, product performance data for additional invertebrate species, such as (but not limited to) gastropods (snails and slugs) that serve as intermediate parasite hosts or invasive mussels of ecological concern could be needed in the future. To account for the potential for future data needs, EPA will use the terms invertebrates or invertebrate pests in reference to pests in all three categories (pests of significant public health importance, invasive species, and wood-destroying insects).

Consistent with the regulatory text in 40 CFR 158.400(e)(1) and as noted in PRN 2002-1 and PRN 96-7: Termiticide Labeling, (Ref. 3). EPA has regularly exercised its discretion to

require submission of product performance data for pesticides intended for use against invertebrate pests of significant public health importance and of product performance data on pesticides intended for use against invertebrate pests of significant economic importance. Since 1984, particularly for insect repellents, the awareness of the incidence and severity of mosquito- and tick-borne diseases in the U.S. has changed. Mosquitoes and ticks are not merely nuisance pests: The Centers for Disease Control and Prevention (CDC) has determined that a single bite can transmit sufficient infectious material, i.e., a sufficient amount of pathogen, to cause serious, and sometimes fatal, disease. (Ref. 4). This is true for both mosquito-borne diseases such as West Nile Virus, St. Louis Encephalitis, and the Zika virus, and tick-borne diseases such as Lyme Disease. (Refs. 5 and 6).

If a person can become ill because of a single insect bite, a person using an ineffective insect repellent may not have the opportunity to realize that the insect repellent did not work as expected and then correct the situation by purchasing another product. Given the nature of these and other mosquito- and tick-borne diseases, an ineffective insect repellent can have serious and sometimes fatal consequences to a person's health.

Consequences can also include both health and economic impacts. For example, the common bed bug (*Cimex lectularius*) has long been a pest, feeding on blood, causing itchy bites and generally irritating their human hosts. EPA, CDC, and the USDA all consider bed bugs a pest of significant public health importance. Bed bugs can cause a variety of negative physical health, mental health, and economic consequences. Effects can include:

• Allergic reactions to the bed bug bites, which can range from no reaction to a small bite mark to, in rare cases, anaphylaxis (severe, whole-body reaction).

• Secondary infections of the skin, such as impetigo, ecthyma, and lymphangitis.

• Mental health impacts on people living in infested homes. Reported effects include anxiety, insomnia and systemic reactions. (Refs. 7 and 8).

Bed bug infestations are also an economic burden on society. The economic losses from health care, lost wages, lost revenue and reduced productivity can be substantial. The cost of effectively eliminating bed bugs may be significantly more than the cost of eliminating other pests because bed bug control usually requires multiple visits by a licensed pest control operator and diligence on the part of those who are experiencing the infestation. Control in multi-family homes is much more difficult than in single family homes because bed bugs frequently travel between units, either by direct transport by humans or through voids in the walls. Thus, there are additional costs and complexities associated with coordinating and encouraging participation from multiple residents. Also, if the pesticide product claiming to treat bed bugs is not effective and families are forced into repeated (and expensive) cycles of re-treatment, then serious health and economic impacts can occur.

While wood-destroying insects/structural pests are not pests of significant public health importance, they are similar in that the consequences of ineffective treatments can be severe. Unfortunately, the effectiveness of a treatment to protect a wooden structure is not readily apparent to the applicator at the time of application or during the occupancy of the building or home. It is only after the damage becomes apparent that the extent of needed repairs is determined. There is a potential for significant financial loss to the property owner. Thus, demonstrating the efficacy of pesticides intended to control structural pests has a unique importance. Data on the level of economic damage caused by structural pests on an annual basis are difficult to obtain but several authors have attempted to quantify it. The economic costs of termite property damage, preventative treatments, and structural repairs can be quite severe, with

estimated cost at approximately $5 billion annually. (Refs. 9 and 10). While these estimates are indicative of the cost nationwide, the costs borne by an individual property owner can be significant in their own right, up to and including, loss of the structure.

B. Labels

1. *Label requirements*. Pesticide product labeling provides information to users on, among other things, the product's intended uses, and how to handle and apply the produEPA's labeling regulations are contained in 40 CFR part 156. EPA reviews pesticide labels to determine whether the labeling is consistent with EPA's regulations, and is accurate, clear and enforceable. The accuracy of the information on the labeling is of particular importance for products making a claim to kill or repel pests of significant public health importance and wood-destroying pests. Such pests, if uncontrolled, can transmit disease pathogens, thus posing a widely recognized and significant risk to human health, and can result in significant economic impacts.

Consumers purchase products that claim effectiveness against a pest of significant public health importance precisely to avoid the harm these pests can cause. Consumers have a reasonable expectation that the claims on the pesticide label have a scientific basis, i.e., are based on valid evidence, and are neither false nor misleading. Such claims should be expressed using wording or graphics that are easily understood and require little or no interpretation by the consumer. To ensure that labeling provides consumers with accurate information concerning how long and how well the product works, EPA reviews and evaluates product performance (efficacy) data. Once the data have been reviewed and evaluated, then the Agency works to ensure that the labeling use directions and labeling claims are clear and consistent with the results of the supporting product performance data.

EPA believes that having reliable information concerning the effectiveness of pesticide

products that claim effectiveness against invertebrate pests results in sound regulatory decisions and accurate information on the labeling. Accurate labeling claims provide consumers with information they need concerning the effectiveness of the pesticide.

2. *Label Review Manual.* Consistently, the Agency has in the Label Review Manual explained the historical need for product performance data for products intended for invertebrate control. The Label Review Manual has for some time summarized the Agency's current practice of requiring product performance data to support claims for pesticides intended for use in or on humans (or in or on pets for control of pests which attack humans such as fleas, ticks, mosquitoes, and biting flies) and in premises or in the environment to control pests of sanitary or significant public health importance such as termites, wasps, scorpions, poisonous spiders, fire ants, cockroaches, centipedes, and bedbugs. (Ref. 11).

C. EPA's Harmonized Test Guidelines for Invertebrate Product Performance

1. *Existing Guidelines*. EPA has established a unified library for test guidelines issued by the Office of Chemical Safety and Pollution Prevention (OCSPP) for use in testing chemical substances to develop data for submission to EPA under the Toxic Substances Control Act (TSCA) and FIFRA. This library of test guidelines represents an Agency effort that began in 1991 to harmonize the test guidelines within OCSPP, as well as to harmonize the OCSPP test guidelines with those of the Organization for Economic Cooperation and Development, which includes representation of countries, including the U.S., throughout the world. The process for developing and amending the test guidelines includes several opportunities for public participation and extensive involvement of the scientific community, including peer review by the FIFRA Scientific Advisory Panel (SAP), the Science Advisory Board (SAB), and other expert scientific organizations. New or revised guidelines are typically presented to SAP for peer

review. The purpose for harmonizing these guidelines into a single set of OCSPP guidelines is to standardize testing procedures that should be performed to meet the Agency's data requirements under FIFRA and TSCA. EPA's Invertebrate Control Agents, Product Performance Guidelines are listed in Table 2.

The guidelines themselves do not impose requirements. Instead, they provide recognized methods for conducting acceptable tests, guidance on reporting data, and definitions of terms. Since these are guidance, pesticide registrants are not required to use these guidelines to fulfill data requirements. Applicants may instead seek to fulfill the data requirements by other appropriate means or by using a non-guideline protocol. The applicant may submit a protocol of his own devising for the Agency to review. EPA notes that there is a PRIA fee category for submitting a protocol for EPA to review.

The guidelines identify thresholds for determining whether a product is effective. Since these thresholds are in guidance (not codified requirements), they are considered recommendations and not mandatory. EPA also acknowledges that the older (1998) guidelines, in particular, generally lack adequate, up-to-date guidance on efficacy data development, test protocols, and representative test species.

EPA notes that the Product Performance Guideline 810.1000 entitled, "Overview, Definitions, and General Considerations," discusses that product performance data are needed for any product that "bears a claim to control pests that may pose a threat to human health." This is specifically stated to include:

Public health uses of invertebrate control agents including, but not limited to, agents intended to control the following: Mosquitoes, biting flies, ticks, fleas, houseflies, cockroaches, fire ants, hornets, wasps, poisonous spiders, scorpions, biting midges, centipedes, bedbugs,

human lice, and dust mites. (Ref. 12).

Table 2—EPA's Series 810, Group C – Invertebrate Control Agents, Product Performance Guidelines

OCSPP Guideline Number	Guideline Title (Date)
810.3000	General Considerations for Efficacy of Invertebrate Control Agents (1998)
810.3100	Soil Treatments for Imported Fire Ants (1998)
810.3200	Livestock, Poultry, Fur- and Wool-Bearing Animal Treatment (1998)
810.3300	Treatments to Control Pests of Humans and Pets (March 1998)
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments (1998)
810.3500	Premise Treatments (2019)
810.3600	Structural Treatments (1998)
810.3700	Insect Repellents to Be Applied to Human Skin (2010)
810.3800	Methods for Efficacy Testing of Termite Baits (2004)
810.3900	Laboratory Product Performance Testing Methods for Bed Bug Pesticide Products (2017)

D. Guideline Modifications Needed for the Future

Those guidelines from 2004 and before require revision to remove any stated performance standards. Until the revisions can be made, this rule would supersede any species requirements or performance standards stated, or implied, in the guidelines applicable to invertebrate pests. EPA intends that any inconsistency that may exist between the guidelines and this rule should be resolved in favor of the regulations, once those regulations are finalized.

V. Selection of Pest Categories for Subpart R

EPA has selected three pest categories for this proposed rule: Pests of significant public health importance, wood-destroying insects, and invasive species. The rationale for selection of these three categories follows.

A. Pests of Significant Public Health Importance.

1. *Background*. As previously noted, in 2002, EPA issued Pesticide Registration Notice (PRN) 2002-1 (Ref. 2), which presented the "List of Pests of Significant Public Health Importance." This document is currently under revision within the Agency. The 2002 list was

derived in large part from review of the pesticide/pest combinations for which product performance data have been required on a case-by-case basis to be submitted and reviewed prior to registration. This list was developed cooperatively by the U.S. Department of Housing and Urban Development, USDA, and EPA, with input from some non-governmental entities. EPA's Office of Pesticide Programs coordinated the review by experts in public health and/or pesticide use patterns to compile this list.

As indicated in PRN 2002-1 (page 1), the criteria for inclusion on the list were defined "broadly, to include pests that pose a widely recognized risk to significant numbers of people."

The listing of invertebrate pests (pages 6-9) is specified by the taxonomic name, as not all members of a particular taxon may be considered a pest of significant public health importance. EPA takes this approach when only certain members of a taxonomic group may be of public health significance because labels usually do not identify specific individual species. However, even if the label did identify a specific species, most product users are not able to distinguish among the members of a taxonomic group (i.e., identifying one tick species from another).

The invertebrate species of significant public health importance identified in this proposed rule as requiring submission of product performance data are derived from the invertebrate pest list identified in PR Notice 2002-1. Differences that exist between the species identified in the PR Notice and this proposed rulemaking represent the evolution of our understanding of the testing required to support claims against pests of public health concern. These invertebrate pests pose a threat of injury, disease transmission and/or pathogen transfer, and allergen production. Table 3 provides the rationale for inclusion in this rule of an invertebrate pest as a pest of significant public health importance.

Table 3—Pests of Significant Public Health Importance from PRN 2002-1

Invertebrate Pest	Rationale for Inclusion

(Common Species Name)	
Mites	Produces allergens Triggers asthma Scabies Itching and skin irritation with risk of secondary infection
Chiggers	Itching and skin irritation with risk of secondary infection
Ticks	Rocky Mountain Spotted Fever Lyme Disease Ehrlichiosis
Scorpions	Venomous sting
Spiders	Venomous bite
Centipedes	Venomous bite
Lice	Skin irritation and rashes Epidemic typhus Trench fever
Fleas	Annoying bites, allergic reactions, and rash Plague
Cockroaches	Allergies Transmission of Salmonella Fecal contamination Hepatitis
Bot Flies	Infest host and live under the skin with risk of secondary infection
Filth Flies	Carry pathogens Food-borne illness
Mosquitoes	West Nile Virus Dengue Fever Malaria Encephalitis Yellow Fever Chikungunya Fever Zika
Biting Flies	Painful or annoying bites with allergic reactions
Sand Flies	Leishmaniasis
Triatomine Bugs	Allergic reactions Chagas disease
Bed Bugs	Bites and allergic reactions
Ants	Stings to painful stings; May be accompanied by severe or life-threatening reactions
Bees	Painful stings that may cause life-threatening reactions
Wasps, Hornets, and Yellowjackets	Painful stings that may cause life-threatening reactions

2. *Disease Pressures*. EPA's proposal to establish product performance data requirements

for pesticide products claiming to control invertebrate pests reflects the most up-to-date science and is responsive to the improved understanding of the diseases being transmitted by invertebrates and the prevalence of these diseases. Since 1984, additional vector borne diseases have emerged. Mosquitoes and ticks can no longer be considered as merely annoying insects.

West Nile Virus was first identified in the U.S. in New York in 1999. Since then, West Nile Virus spread throughout the country and cases have been reported in the 48 contiguous states. West Nile Virus is carried by common mosquitoes (primarily species of *Culex*, though *Aedes* and *Anopheles* can also carry the virus).

• Serious Symptoms in a Few People—Approximately one in 150 people infected with West Nile Virus will develop severe illness. The severe symptoms can include high fever, headache, neck stiffness, stupor, disorientation, coma, tremors, convulsions, muscle weakness, vision loss, numbness and paralysis. These symptoms may last several weeks, and neurological effects may be permanent. This is referred to as neuroinvasive West Nile disease and may result in death.

• Milder Symptoms in Some People—Up to 20 percent of the people who become infected have symptoms such as fever, headache, and body aches, nausea, vomiting, and sometimes swollen lymph glands or a skin rash on the chest, stomach and back. Symptoms can last for as short as a few days, though even healthy people have become sick for several weeks. This is referred to as West Nile Fever.

• No Symptoms in Most People—Approximately 80 percent of people (about 4 out of 5) who are infected with West Nile Virus will not show any symptoms at all.

Today, experts believe West Nile Virus is established as a seasonal epidemic in North America that flares up in the summer and continues into the fall. Persons over 50 years of age

have the highest risk of severe disease. (Ref. 13).

The Zika virus spreads to people primarily through the bite of an infected Aedes species mosquito (*Ae. aegypti* and *Ae. albopictus*). Zika can be passed from a pregnant woman to her fetus, which can cause certain birth defects. There is no vaccine for Zika. In 2015 and 2016, large outbreaks of Zika virus occurred in the Americas, resulting in an increase in travel-associated cases in the U.S., including widespread transmission in Puerto Rico and the U.S. Virgin Islands, and limited local transmission in Florida and Texas. In 2018 and 2019, there were no reports of Zika virus transmission by mosquitoes in the continental U.S. (Ref. 14).

In the past 20-25 years, Lyme Disease has increased in geographical distribution and in number of cases. The disease is carried by blacklegged (deer) ticks (*Ixodes scapularis* and *Ixodes pacificus*). The number and distribution of Lyme Disease cases correlates with the number and distribution of white tail deer, among other animal hosts. (Ref. 15). Deer populations have risen steadily in the last two decades, especially in suburban areas. (Refs. 16 and 17).

The first sign of infection is usually a circular rash, occurring in approximately 70 to 80% of infected persons. It begins at the site of a tick bite after a delay of 3-30 days and may gradually expand over a period of several days. The center of the rash may clear as it enlarges, resulting in a bull's-eye appearance. Patients also experience symptoms of fatigue, chills, fever, headache, and muscle and joint aches, and swollen lymph nodes. In some cases, these may be the only symptoms of infection.

Untreated, the infection may spread to other parts of the body within a few days to weeks, producing an array of discrete symptoms. These include loss of muscle tone on one or both sides of the face (called facial or Bell's palsy), severe headaches and neck stiffness due to meningitis, shooting pains that may interfere with sleep, heart palpitations and dizziness due to changes in

heartbeat, and pain that moves from joint to joint. Many of these symptoms will resolve, even without treatment.

After several months, approximately 60 percent of patients with untreated infection will begin to have intermittent bouts of arthritis, with severe joint pain and swelling. Large joints are most often affected, particularly the knees. In addition, up to 5 percent of untreated patients may develop chronic neurological complaints months to years after infection. These include shooting pains, numbness or tingling in the hands or feet, and problems with concentration and short-term memory.

Most cases of Lyme Disease can be cured with antibiotics, especially if treatment is begun early in the course of illness. However, a small percentage of patients with Lyme disease have symptoms that last months to years after treatment with antibiotics. (Refs. 18 and 19).

Rocky Mountain Spotted Fever is the most severe tick-borne rickettsial illness in the U.S. This disease is caused by infection with the bacterial organism *Rickettsia rickettsii*; it is carried primarily by dog ticks (*Dermacentor variabilis*) and wood ticks (*Dermacentor andersoni*). The initial symptoms of Rocky Mountain Spotted Fever include fever, nausea, vomiting, muscle pain, lack of appetite, and severe headache. Later symptoms include rash, abdominal pain, joint pain, and diarrhea. Pain and fluid loss can be so severe that hospitalization may be required. (Refs. 20 and 21).

EPA believes that tick and mosquito repellents have roles in disease prevention. Today, there is renewed interest in methods of preventing transmission of these diseases. CDC and other public health authorities have determined that efficacious insect repellents have a primary role in a multi-barrier approach in protecting the public from insect or tick-borne diseases. CDC recommends several personal protective practices to prevent tick and mosquito bites: one of the

most prominent and consistent messages is to use an insect repellent containing an EPA-registered active ingredient. (Refs. 22 and 23).

2. *Bed Bugs*. The U.S. has experienced a resurgence in the population of bed bugs. Bed bugs can impact people's physical and mental health. Physical impacts can include mild and severe allergic reactions to the bites, and secondary infections of the skin. Reported mental effects include anxiety and insomnia. (Refs. 7 and 8).

Both the EPA and the CDC believe that an integrated pest management program that combines both chemical and non-chemical treatments is the most effective way to control bed bugs. Among the integrated pest management methods, use of an effective pesticide product, labeled for use against bed bugs, applied according to the label directions is often necessary to control the population of bed bugs. (Ref. 8).

3. *Other pests of significant public health importance*. Other invertebrate pests cause painful bites and stings, provoke allergic responses, and transmit serious diseases. As discussed in PRN 2002-1, "cockroaches are controlled to halt the spread of asthma, allergy, and food contamination" and lice are controlled to prevent the "occurrence of louse-borne diseases such as epidemic typhus, trench fever, and epidemic relapsing fever in the United States." (Ref. 2).

B. Wood-destroying Insects

As previously explained, structural pests differ from pests of significant public health importance because health of individuals is not imperiled. However, the effectiveness of the treatment is not readily apparent to the applicator at the time of application or during the occupancy of the building or home, and a potential for significant financial loss to the property owner exists. EPA has generally required submission of product performance data for wood-destroying insects for over 40 years. USDA registered pesticides prior to establishment of the

EPA and also required product performance data in support of wood-destroying insects. The Agency issued PRN 96-7, entitled "Termiticide Labeling," (October 1, 1996) (Ref. 3) to provide guidance on label statements and minimum levels of product performance for soil treatment use of termiticide products. According to the PRN:

> The Agency believes that registration of a [termiticide] product demonstrating less than five (5) years of efficacy for control of termites is generally not appropriate from a safety or efficacy standpoint, considering the costs of treatment and the potential damage that could occur. The Agency does not believe that the homeowner should be subjected to such costly protection as would occur with products that are only efficacious for one year. Such products could, quite possibly, pose unreasonable adverse effects to the environment and/or humans because of higher risks than longer-acting alternatives. The more frequent treatments required could result in greater exposure and risk, or lower benefits, because of being less effective if not retreated, or more expensive if retreated.
> . . .
> EPA has always required efficacy data to be submitted by registrants to demonstrate that termiticides perform their intended function as claimed. EPA has reviewed such data prior to registration to assure that the benefits of the use would outweigh the potential risks.

C. Invasive Species

On February 8, 1999, President Clinton signed The Executive Order 13112 (64 FR 6183) (February 8. 1999), which is intended to "…to prevent the introduction of invasive species and provide for their control and to minimize the economic, ecological, and human health impacts that invasive species cause…." The Executive Order directed each federal agency to use relevant programs and authorities to:

• Prevent the introduction of invasive species;

• Detect and respond rapidly to and control populations of such species in a cost-effective and environmentally sound manner;

• Monitor invasive species populations accurately and reliably;

• Provide for restoration of native species and habitat conditions in ecosystems that have been invaded;

• Conduct research on invasive species and develop technologies to prevent introduction and provide for environmentally sound control of invasive species; and

• Promote public education on invasive species and the means to address them.

Invertebrate invasive species can impose serious economic costs by causing or vectoring diseases against native species that have little or no natural defenses. For example, an invasive species of significant note is the emerald ash borer, a wood boring beetle that is native to Asia. The emerald ash borer kills ash trees. Its presence was reported in southeast Michigan and Windsor, Ontario in 2002. Since then it has spread to at least 35 states and five Canadian provinces. Infested areas are under quarantine and restrictions have been imposed on moving fire wood. EPA has registered several pesticide products for use against the emerald ash borer after reviewing submitted efficacy data. (Ref. 24)

Another invasive invertebrate species, the Asian longhorned beetle, is also native to Asia and was first discovered in New York in 1996. The Asian longhorned beetle kills maple trees and other hardwoods. (Ref. 25). A very serious situation/crisis exists in New England, and USDA has established an extensive eradication program. EPA has also registered several products for use against the Asian longhorned beetle.

Invertebrates such as the emerald ash borer and the Asian longhorned beetle kill trees over very large geographic areas, thus, having substantial ecological and economic impacts by destroying both urban cover and forests used for recreation purposes and timber stands. According to a 2011 analysis (Ref. 26) entitled, "Economic Impacts of Non-Native Forest Insects in the Continental United States," the following five categories of expenditures and losses can be used to illustrate impacts on forests.

• Federal government expenditures (survey, research, regulation, management, and

outreach),

- Local government expenditures (tree removal, replacement, and treatment),
- Household expenditures (tree removal, replacement, and treatment),
- Residential property value losses, and
- Timber value losses to forest landowners.

Within the 2011 analysis were cost estimates using the five previously described categories of the damage caused by three types of invasive insects: borers, sap feeders, and foliage feeders. Since some of the economic categories overlap, the total sum of all economic categories would include some double counting. However, the total of the insect types can be summed without double counting, which means that it is appropriate to sum the columns, but not the rows. Table 4 shows that most of the costs are borne by local governments and households, and the total damage is several billion dollars.

Table 4—Annualized Invasive Species Damages in the U.S. ($ millions)

	Federal Government Expenditures	**Local Government Expenditures**	**Household Expenditures**	**Residential Property Value Loss**	**Forest Landowner Timber Costs**
Borers	$92	$1,700	$760	$830	$130
Sap Feeder	$14	$170	$130	$260	$4
Foliage Feeders	$110	$170	$160	$410	$18
Total	**$216**	**$2,040**	**$1,050**	**$1,500**	**$152**

Pesticide products are an important tool for managing the spread of an invertebrate invasive species and the related significant economic impacts. The availability of pesticide products with proven performance against an invasive species is important to slowing the spread of the invasive species. When circumstances necessitate the submission or citation of reliable data to support claims for controlling invasive species, EPA has the authority to require such product performance data.

Due to the sudden appearance and often rapid spread of invasive species, EPA does not

presently propose to codify a comprehensive list of all the specific invasive species for which product performance data might be deemed necessary. At this time, EPA is specifically proposing to codify product performance data submission requirements for the emerald ash borer and the Asian longhorned beetle. The submission of product performance data to support claims for effectiveness against other invasive invertebrate pests will be considered on a case-by-case basis.

VI. Development of Invertebrate Pest Groups and Subgroups

EPA has identified pest groupings on the basis of the biology and life history characteristics of the pests identified as public health or wood destroying pests. (Ref. 28). The groupings are taxonomically based. "Pest groups" and "pest sub-groups" are designations simply intended to convey the fact that some pests groups are part of larger groups. Therefore, when practical, "pest sub-groups" have been identified to define a meaningful subset of the larger group.

EPA developed the pest groups and pest sub-groups with the intention that product performance testing performed on a particular species can adequately represent all members of the pest group (or pest sub-group). The Agency intends these pest groupings to decrease data submission burdens on applicants and data review burden on the Agency as well as increasing the consistency, reliability, and integrity of data submitted to EPA. In some cases, EPA is proposing pest-specific claims, in addition to group and sub-group claims.

To develop these groupings, EPA considered species sensitivity. In certain cases, one member of a pest grouping is known to be significantly harder to kill, control, or repel than other members of the grouping. If product performance testing is performed using the species that is harder to kill, control, or repel, then logically, it can be assumed that the results of this testing

can be extrapolated to other members of the grouping. Additional considerations included the availability of species in a laboratory setting, the occurrence of species over wide areas and/or those species most commonly associated with transmission of diseases to humans.

VII. Introduction to Part 158, Subpart R

A. General

EPA is proposing to codify product performance data requirements pertaining to registration of pesticide products claiming efficacy against certain invertebrate pests. The proposed data requirements are consistent with the Agency's current practices concerning the data needed to register a pesticide product that claims effectiveness against invertebrate pests.

The proposed data requirements are presented, as appropriate, in table formats, with the needed data specified according to the claim on the label, the species to be tested, and the performance standards to be met. Once final, the regulations will provide the regulated community and other interested parties a better understanding of the data required to support registration of a pesticide product making a claim against an invertebrate pest identified to be a public health concern (e.g., ticks, mosquitoes, cockroaches, etc.), a wood-destroying insect (e.g. termites), or an invasive invertebrate species (e.g. Asian longhorned beetle).

The Agency is proposing to title the new subpart R in part 158, "Product Performance for Products Claiming Effectiveness Against Invertebrate Pests." The existing product performance data requirements in subpart E will be renamed "Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion-related Claims, and Products for Control of Organisms Producing Mycotoxins." Additionally, EPA is proposing conforming edits to subparts U, V, and W.

B. Contents of Proposed Subpart R

1. *General requirements*. Proposed 40 CFR 158.1700 contains the general requirements that would be applicable to any pesticide product that is making a claim(s) against an invertebrate pest, and describes how to use the data tables in proposed subpart R. These general requirements describe when product performance data may be required, specifically for products that bear a claim against a pest of significant public health importance or a pest of economic significance. The required tests must be conducted using the end-use product to ensure that the product's claims are supported in the form in which the user will be using the product.

Additionally, proposed 40 CFR 158.1700 provides a set of instructions on how to determine the product performance data required to support the pesticide product use for which registration is sought. This includes referring to all parts of subpart R, identifying the claims intended to be made on the product labeling, reviewing and understanding the performance standards that must be met or exceeded for the identified claims against the target pests, and understanding all applicable test notes.

2. *Definitions*. In order to ensure consistent implementation of proposed subpart R, EPA is proposing definitions specific to the subpart. Proposed 40 CFR 158.1701 and 158.1703 contain the definitions pertaining to subpart R. In particular, proposed 40 CFR 158.1701 defines many of the terms that are needed to assure a common understanding of the requirements and performance standards being proposed for codification under subpart R.

During the 2013 SAP, EPA received public comments and feedback from the SAP on the proposed definitions in the Technical Support Document (TSD) provided to the SAP. (Ref. 28). In addition, the SAP recommended several additional definitions that should be considered under this proposed rulemaking. After considering the comments provided, and based on the data requirements being proposed in this rulemaking, the proposed definitions represent those that are

most essential for understanding the requirements and regulatory text of the proposed subpart R. For those definitions that the SAP and public commenters provided feedback on or that were recommended then, but not included in this proposal, EPA intends to consider the utility of those definitions and will consider incorporating them into future guidance and rulemakings. The SAP and public comments on definitions associated with product performance data requirements are available in the docket for the SAP [EPA-HQ-OPP-2012-0574]. EPA's response to those comments are discussed in this document and associated docket. Other definitions included in the TSD have since been adopted in testing guidelines.

Where applicable, EPA derived the proposed subpart R definitions from existing guidelines. The definition for *Complete protection time* is very similar to the one found in Guideline 810.3700. The proposed definition of *Skin-applied insect repellent* is taken from Guideline 810.3700. The proposed definitions for *Soil-applied termiticides*, and *Bait treatment* were derived from information in Guidelines 810.3600 and 810.3800. For example, the *Bait treatment* proposed definition is similar to *Termite bait* in Guideline 810.3800. The definition of *Vector* is very similar to that in FIFRA 2(oo).

In the TSD presented to the 2013 SAP, EPA explained a pesticide for use against invertebrates and meeting one of the following circumstances might be characterized as making a public health pest claim requiring submission of product performance data:

• A claim is made to control, kill, knockdown, and/or repel specific invertebrate organisms that are directly or indirectly infectious or pathogenic or injurious to humans (or both humans and animals). For example: A claim is made to repel mosquitoes and/or ticks. Both mosquitoes and ticks transmit disease to humans. Or, a claim is made to kill bed bugs. Bed bugs are injurious to humans.

• The pesticide product is used in public health programs for vector control or for other recognized health protection uses to prevent or mitigate threats to public health.

• The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health organism and there is no other functional purpose for the ingredient in the product.

• The pesticide product is similar in composition to a registered pesticide product that makes explicit public health claims for control of invertebrate organisms.

EPA still agrees that these circumstances, in principle, identify the kinds of pesticides for which product performance data may be necessary. However, EPA is not proposing to codify the term "public health pest claim" as a means of identifying when data are required. Such a term is not necessary given the proposed regulatory text includes sections that specify the invertebrate pests and invertebrate pest groups/subgroups that would be subject to the proposed product performance data requirements if the pesticide is intended for use against those pests. EPA requests comment on whether there is utility in codifying an overarching definition of a "public health pest claim" for the purposes of subpart R, and if so, whether the definition presented to the SAP is appropriate.

In the 2013 TSD EPA wrote that:

> *A* ***public health claim*** is asserted if one or more of the following apply:
> --A claim is made to control, kill, knockdown, and/or repel specific invertebrate organisms that are directly or indirectly infectious or pathogenic or injurious to man (or both man and animals). For example: A claim is made to repel mosquitoes and/or ticks. Both mosquitoes and ticks transmit disease to man. Or, a claim is made to kill bedbugs. Bedbugs are injurious to man.
> --The pesticide product is used in public health programs for vector control or for other recognized health protection uses to prevent or mitigate threats to public health.
> --The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health organism and there is no other functional purpose for the ingredient in the product.
> --The pesticide product is similar in composition to a registered pesticide product that makes explicit public health claims for control of invertebrate organisms. (Ref. 28)

EPA believes that the circumstances presented in the 2013 TSD, in principle, identify the kinds of pesticides for which product performance data may be necessary. EPA also notes that existing regulations at 40 CFR 158.2204 provides definitions for a "public health claim" and a "nonpublic health claim" as they pertain to antimicrobial pesticide claims. EPA is not proposing to make any modifications to that provision, and any definition for a "public health pest claim" added to subpart R would be applicable only within proposed subpart R.

3. *Application Categories*. In proposed 40 CFR 158.1703, EPA is proposing to define a set of application categories to assist in defining the data needed to support registration. This section would only define application categories to the extent the terms appear in the proposed regulatory text and EPA believes they require definition. For example, the terms "bait treatments" and "spatial repellents" are defined. This section does not provide a listing of all application categories that would be covered by the proposed subpart R data submission requirements.

Application categories describe how and/or where the product is intended to be applied or used. The proposed application categories were derived after consideration of current practices and review of the application sites included in the Harmonized Test Guidelines (810.3000 through 810.3900). Oftentimes, these application categories will be used on pesticide product labeling, and, therefore, may be identified as a product performance labeling claim within the data requirement tables. Similar to the definitions in 40 CFR 158.1701, EPA received SAP feedback on some of the application category definitions. (Ref. 29). The application categories proposed in 40 CFR 158.1703 represent EPA's responses to that feedback for the application categories as applicable. These application categories are referred to in the portions of the

proposed regulatory text for the wood-destroying invertebrate pests.

4. *Performance Standards*. In proposed 40 CFR 158.1704, EPA is proposing a set of performance standards that, in the absence of performance standards specified elsewhere in subpart R, will apply generally and must be met for data cited to be considered acceptable in support of a specific labeling claim on the product's labeling.

a. *Performance standards for skin-applied insect repellents*: EPA is proposing that for skin-applied insect repellent labeling claims, the performance standard must be greater than or equal to 2-hours complete protection time.

Complete protection time (CPT) is defined in Guideline 810.3700 as "the time from application of a repellent until efficacy failure as it is defined in each study—for example, the time from application until the first efficacy failure event confirmed within 30 minutes by a second similar event." CPT has been the existing practice for determining efficacy of skin-applied insect repellents since the guideline was finalized in 2010. EPA presented this concept, along with a proposed minimum protection time of 2-hours, to the SAP in the TSD, as a means of ensuring that a skin-applied repellency product protects for a minimum amount of time given the potential variability of product results across different people.

The Agency believes that establishing a minimum CPT for skin-applied repellency products should be required because of the large variability in protection times experienced by susceptible individuals in the population. The SAP agreed that this was a reasonable standard, stating that "[i]f CPT is to be used, a minimum CPT of 2 hours was suggested by the Panel as a minimal criterion for product registration… A repellent of shorter duration may not provide sufficient, useful protection in practical terms and will give consumers a false sense of protection." (Ref. 29).

Additionally, EPA is proposing regulatory text for skin-applied products that reinforces that any testing required under part 158 which involves any human subjects must comply with all applicable requirements under 40 CFR part 26. For example, 40 CFR part 26 requirements are pertinent to 40 CFR part 158 testing requirements if the testing involves intentional exposure of human subjects. Protocols for such testing must be submitted to EPA for review prior to study initiation. Those protocols determined by EPA to involve intentional exposure of human subjects also require review by EPA's Human Studies Review Board (HSRB)) prior to study initiation.

b. *Performance standards for products other than skin-applied insect repellents*. Unless otherwise specified in the proposed 40 CFR 158.1700 – 158.1786, EPA proposes that the performance standard for a product performance claim against a pest must be greater than or equal to 90 percent. For non-wearable spatial repellents, the proposed performance standard is greater than or equal to 75%.

In the TSD presented to the SAP, EPA was considering performance standards of 95% for all other pest claims, with the exception of mites, lice, carpenter ants, wood destroying beetles, and termites. The 95% performance standards were initially chosen because they represented widely accepted standards at the time. (Refs. 28, 29, 30 and 31). EPA proposed these standards as a way to "define the levels of product performance that would need to be met in order for the studies to support product registration and labeling," and that proposing a specified threshold level or performance standard would be the "best means to assure that the products used to control invertebrate species are effective under conditions of use." (Ref. 28).

In response to the proposal, both the SAP and public commenters believed that a 95% performance standard would create a burden for unattainable results and would be cost prohibitive in most situations, particularly for large scale field trials, or in general, any field trial

using a 100% standard expectation. They argued that a minimum 90% performance under controlled laboratory conditions would be adequate. (Refs. 28 and 29). While they made this recommendation, the SAP stated that in special cases, EPA should retain the authority to overrule these standards if proper justification is provided by the applicants with regard to why the standards should not be applicable to a particular product. Additionally, the SAP stated that registrants should be allowed to compete by achieving higher than required performance standards, proving the superiority of their products.

After considering the SAP and public comments, with the exception of pests such as human mites, carpenter ants, termites, and wood-destroying beetles, EPA is proposing performance standards of 90% or greater instead of 95%. EPA believes that this standard will enable acceptance of registrations for products that provide a satisfactory level of control. Human mites and lice will retain a 100% standard, while the wood-destroying pests will have a 95% or greater standard for prevention of damage to wood, except for non-structural wood preservative treatments, which will have a standard of 100%. The standards for human mites, lice, and wood-destroying pests will be discussed in more detail in other sections of this proposed rule.

5. *Test Guidelines*. In proposed 40 CFR 158.1705, EPA is codifying a reference to EPA's Harmonized Test Guidelines, which set forth a recommended approach to generate the data required for product performance testing.

6. *Data Requirement Modifications*. In proposed 40 CFR 158.1707, EPA is proposing to state that on a case-by-case basis, the data requirements identified in subpart R may need to be adjusted for novel technologies or because a product's unusual physical, chemical, or biological properties or atypical use patterns would make particular data requirements inappropriate, either

because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. EPA recommends that registrants of novel technologies contact the Agency prior to conducting product performance testing. It should be noted that EPA has historically taken the position that data requirements can be adjusted or waived on a case-by-case basis per the procedures described in 40 CFR 158.45. This provision is not intended to supersede or alter the provisions at 40 CFR 158.45, but rather to clarify that EPA is proposing that the data requirements, including the performance standards, in subpart R may also be adjusted using the procedures consistent with those in 40 CFR 158.45.

7. *Invasive Species Claims*. In proposed 40 CFR 158.1708, EPA is proposing that when an application for registration or amended registration requests to put a claim(s) on its pesticide product's labeling for effectiveness against an invasive invertebrate species, then on a case-by-case basis, EPA may require submission of product performance data to support those claims for effectiveness. Due to the sudden appearance and often rapid spread of invasive species, EPA does not presently intend to codify a comprehensive list of the specific invasive species for which product performance data might be deemed necessary. USDA maintains a list of invasive species profiles, which can be used as guidance. (Ref. 32). EPA is specifically proposing to codify product performance data submission requirements for the emerald ash borer and the Asian longhorned beetle. The submission of product performance data to support claims for effectiveness against other invasive invertebrate pests will be considered on a case-by-case basis.

EPA notes that the Agency currently has authority to require data submission on a case-by-case basis when necessary to evaluate a pesticide product (see 40 CFR 158.75). This provision is intended to clarify that whether or not a claim is against an invasive species is a factor in determining whether product performance data is necessary to evaluate a pesticide.

8. *Invertebrate Disease Vector Claims*. In proposed 40 CFR 158.1709, EPA is proposing that if a registrant requests a labeling claim specific to a disease vector, additional testing conducted with the species specific to that disease vector claim is required if that species is not already required under subpart R as part of the pest group tested. For example, if a product claims to repel Asian longhorned ticks that may carry Japanese spotted fever, caused by *Rickettsia japonica*, then the registrant must generate data using the species that is known to carry the disease indicated, the Asian longhorned tick in this case. This requirement will ensure that all disease vector claims are supported by appropriate product performance data demonstrating the required performance standard should an unknown public health threat emerge in the future.

9. *Structural and Wood-destroying Pest Claims*. In proposed 40 CFR 158.1710, EPA is proposing that if an application for registration or amended registration requests a labeling claim specific to a structural or wood-destroying pest that is not identified in 40 CFR 158.1782 through 158.1786, EPA may require submission of product performance data to support those claims for effectiveness. This requirement will ensure that any claim against structural and wood-destroying pests that have not been accounted for at this time are supported by product performance data in the event that a new threat emerges.

10. *Pest Specific Claims*. EPA is proposing to codify product performance data submission requirements for pest groups, sub-groups, and some specific species. EPA uses the term "Pest group labeling claim" to mean a claim or statement on the labeling of the pesticide product that the product is effective against a group of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species for the entire assemblage of taxa. The term "Pest sub-group labeling

claim" means a claim or statement on the labeling of the pesticide product that the product is effective against a set of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species and part of a larger identified taxonomic grouping (e.g., Biting flies) that includes other pest species, which may or may not have a proposed pest group. The term "Pest-specific labeling claim" means a claim or statement on the labeling of the pesticide product that the product is effective against a particular arthropod species, such as German cockroach or house fly.

In addition to the group and sub-group claims, EPA is proposing to codify requiring product performance data for a number of pest-specific claims. As previously noted, the representative test species were selected on the basis of vigor of the pest species and the likely ability of the species to serve as an adequate surrogate for other pests in the group, as well as other factors including their availability for laboratory testing, ubiquity, and whether they are one of the primary drivers of the human health concerns within a grouping. (Ref. 1). The 2013 TSD envisioned that in many cases "[i]f representative taxa are provided, species specific data may not be required, as the group and any/all individual species within the group can be supported by supporting the general claim." (Ref. 28).

For pests that are not listed as a "pest-specific claim" in proposed subpart R, EPA proposes that the data required to support a group claim would also be sufficient to support pest-specific claims for species within that group. For example, the pavement ant (*Tetramorium caespitum*) is not listed as a pest-specific claim in proposed subpart R because it is not a pest of significant public-health importance (nor is it a wood-destroying insect) and no pest-specific product performance data would need to be submitted to add a claim against pavement ants to a label. In contrast, cluster flies (*Pollenia rudis*) are listed as a pest-specific claim in this proposed

rule because of their significant public health importance. These pest-specific claims are consistent with EPA's current practices. Thus, consistent with the Agency's current practices, pest-specific data would need to be submitted to add a pest-specific claim against cluster flies to a label in addition to any data submitted to support the group claim against "filth flies." EPA also notes that the provisions at 40 CFR 158.75 and proposed 40 CFR 158.1708 would also permit the EPA to require pest-specific data on a case-by-case basis when necessary to evaluate a pesticide product. These provisions allow EPA to address the Agency's data needs in the face of emergent invertebrate pest concerns.

EPA requests comment on the pest-specific claims covered by this proposed rule and whether there should be additional pest-specific claims added to subpart R, or if some of the ones included in the rule are unnecessary.

C. Data Requirements for Subpart R

The data requirements that EPA is proposing for codification are consistent with the Agency's current practices when considering the product performance data needed to register a pesticide product that bears a pesticidal claim against one or more of these pests or pest groups/sub-groups. FIFRA section 3(c)(2) directs EPA to specify the kinds of data that applicants and registrants must submit to EPA to support regulatory determinations under FIFRA. The data requirements for pesticide products are codified in 40 CFR part 158. Product performance data (efficacy studies) document how well the product performs the intended function (such as killing or repelling) against an invertebrate pest. The product performance data needs being considered in this rule would link the labeling claim for pesticide products claiming efficacy against an invertebrate pest with the data needed to substantiate that claim. EPA views these standards as performance standards for the acceptability of data, and

thus EPA views them as waivable under 40 CFR 158.45.

1. *Mites (excluding Chiggers)*. In 40 CFR 158.1712, EPA is proposing the required test species and performance standards in order to make a labeling claim against dog follicle mites, dust mites, and the human itch or scabies mite. EPA is proposing to list chiggers, which are mites, in a separate section.

As indicated in the TSD presented to the SAP, dog follicle mite infestations are typically commensal in nature, but can cause demodectic mange in susceptible animals. This can pose a serious risk to stricken individuals, which typically have pre-existing immune system issues. For this reason, a 100% performance standard is being considered for these applications.

Dust mites pose no direct threat of injury, disease transmission, or discomfort. However, dust mites are included as a pest of significant public health importance because they produce allergens in their feces and cast exoskeleton that can result in asthma and allergic reactions. EPA believes that it is impractical to expect complete elimination of the dust mite population in a structure. The focus should be to reduce the agent of concern (i.e., the allergen) to acceptable levels. This can be achieved through a reduction in the target pest that is less than is generally necessary for a pest that acts directly against its host. EPA initially proposed a 75% performance standard to the SAP for surface and fabric treatments, and a 95% performance standard for direct application to dust mites. However, after considering the responses received through the SAP and public comment, EPA is proposing a 90% performance standard for dust mites to be consistent with the recommendations provided on the performance standards for other species testing.

During the SAP, one commenter indicated that for mites, the proposed performance standard of 100%, as considered by EPA, was too high. Instead the commenter advocated for

90%, while indicating that 95% would be achievable. (Ref. 33). The 90% standard is being proposed for some labeling claims for the dog follicle and dust mites, but for human itch or scabies mites, EPA disagrees with lowering the performance standard since scabies mites directly infect and are easily transferred among hosts. A human skin-applied topical repellent performance standard of ≥ 2-hour complete protection time is also being proposed.

EPA also notes that any testing conducted with human subjects must comply with all applicable requirements under 40 CFR part 26.

2. *Chiggers*. In the proposed 40 CFR 158.1714, EPA is proposing to require testing for labeling claims against chiggers. Chiggers are being proposed in the rulemaking due to their bites causing itching and skin irritation with the risk of a secondary infection. Additionally, EPA is proposing the performance standards established under 40 CFR 158.1704 to apply to testing for chiggers.

During the SAP, the Panel noted that *Trombicula alfreddugesi* (as presented in the TSD) is now renamed as *Eutrombicula cinnibars*. EPA was unable to verify this and has maintained *Trombicula alfreddugesi* as was presented in the TSD. EPA requests comment on whether this is correct, and if the name has changed, EPA requests a reference to the revised name.

3. *Ticks*. In the proposed 40 CFR 158.1718, EPA is proposing to require the test species and performance standards to labeling claims against ticks, cattle ticks, and soft ticks. EPA is proposing several tick species due to their potential to transmit diseases, such as Rocky Mountain Spotted Fever, Lyme disease, and ehrlichiosis. For performance standards, EPA is proposing standards consistent with 40 CFR 158.1704.

To make a claim against "ticks," EPA is proposing to require a total of three hard tick species as representative of ticks in general. As presented in the TSD and based on

recommendations from the SAP, products claiming "ticks" must test for the blacklegged tick (*Ixodes scapularis*) and lone star tick (*Amblyomma americanum*), and a third species tested must be either the American dog tick (*Dermacentor variabilis*), the brown dog tick (*Rhipicephalus sanguineus*), or, as suggested by the SAP, the Rocky Mountain wood tick (*Dermacentor andersoni*). Because ticks are high stakes disease vectors and because consumers have difficulty differentiating between species, for a claim against any specific species of "ticks" all the representative species for the "ticks" claim must be tested. In addition, because these are pests of significant public health importance that the public strongly associates with the diseases they vector, EPA would also require submission of data on the specific pest claimed. EPA does not typically receive pest-specific claims for ticks other than those that are representative species for ticks. However, the Asian longhorn tick is an emergent pest in this category and EPA would require pest-specific data for a pest-specific claim against the Asian longhorn tick or any other pest specific tick claim. This would be in addition to testing on the representative species.

In addition to the required test species for a "tick" labeling claim, EPA is also proposing specific parameters regarding required species for "ticks" under certain testing circumstances. These specific parameters include:

i. For products intended to be applied to dogs, testing is required on three species: blacklegged tick (*Ixodes scapularis*), American dog tick (*Dermacentor variabilis*), and brown dog tick (*Rhipicephalus sanguineus*).

ii. For products intended to be applied to cats, testing is required on three species: blacklegged tick (*Ixodes scapularis*), lone star tick (*Amblyomma americanum*), and American dog tick (*Dermacentor variabilis*).

The species identified under each of these circumstances were identified as a result of

their occurrence on dogs and cats and the biology/behavior of the ticks.

For a claim against cattle ticks, EPA is proposing testing on either the Southern cattle tick (*Rhipicephalus microplus*) or the cattle fever tick (*Rhipicephalus annulatus*). When presented to the SAP, the SAP noted that if pests of veterinary importance are not the primary objective for this proposal, then pests such as cattle ticks should be removed from the tables. While the emphasis is on pests of significant public health importance and wood-destroying insects due to their significant economic impacts, EPA maintains that cattle ticks should be included in this proposal because of the potential for these ticks to carry diseases such as Texas cattle fever, which can result in significant economic losses to the cattle industry. (Ref. 34) Additionally, the cattle fever tick poses a risk to a small, but highly vulnerable population of humans. Specifically, those people that have had splenectomies are susceptible to a potentially fatal bovine babesiosis infection from an infected cattle fever tick. (Ref. 35).

For a claim against soft ticks, EPA is proposing testing on the species *Ornithodoros hermsi*. Humans typically come into contact with soft ticks when they sleep in rodent infested cabins. The ticks emerge at night and feed briefly while the person is sleeping. The bites are painless, and most people are unaware that they have been bitten. These ticks may transmit tick-borne relapsing fever (*Borrelia hermsii*, *B. parkerii*, or *B. turicatae*).

4. *Scorpions*. In proposed 40 CFR 158.1722, EPA is proposing to require data for a "scorpion" labeling claim due to their venomous sting. In the TSD to the SAP, EPA proposed to only require the striped bark scorpion (*Centruroides vittatus*). For scorpions, EPA is proposing the performance standards under proposed 40 CFR 158.1704.

One public commenter during the SAP questioned why EPA provided only one species for testing, stating that they believed this to be too restrictive. (Ref. 36). EPA chose the striped

bark scorpion as the required test species because it is a larger species of scorpion, and larger species can be harder to kill. Using such a species as the required test species means greater certainty that testing on one species would be representative of testing on other species. The commenter did not provide the name of a species that they consider suitable for testing. The Agency would welcome information to better inform the decision on selection of a suitable test species for scorpions.

5. *Spiders*. In proposed 40 CFR 158.1726, EPA is proposing data requirements for one pest group (Spiders), one pest sub-group (black widow spiders), and five pest-specific spider claims. EPA's current practice for spiders is to require product performance data to be submitted with certain species-specific claims (e.g. "Northern black widow spider"), certain pest-subgroup claims (e.g., "black widow spiders"), or pest-group claims for either "spiders" or "spiders unless the label expressly excludes black widow or brown recluse spiders." The black widow and the brown recluse spiders can deliver bites with potentially serious medical implications, and therefore are considered pests of significant public health importance. Thus, if an applicant submits a draft label with a labeling claim for "spiders (excluding black widow or brown recluse)," the applicant does not need to submit product performance data to EPA with an application for registration. Instead, the applicant would generate product performance data to confirm that the product is effective against these pests and hold those data in their files. In contrast, a general "kill spiders" claim encompasses pests of significant public health importance, i.e., the black widow and brown recluse spiders, and therefore, the applicant would need to submit two product performance studies to EPA to verify this claim, one study each for the brown recluse spider and black widow spider (either Northern black widow spider, the Southern black widow spider, or Western black widow spider).

For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

6. *Centipedes*. In proposed 40 CFR 158.1732, EPA is proposing data requirements for centipedes. EPA proposes testing on either the house centipede, the Florida blue centipede, or on one species from the *Scolopendra* genus. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

The SAP noted that centipedes are generally harmless and considered beneficial insects, behaving as active predators of other arthropod s within structures. Although a species such as the Florida blue centipede (*Hemicolopendra marginata*) can inflict a painful bite, the SAP questioned whether it was sufficient to include centipedes as a pest of significant public health importance. While some species of centipedes may be "harmless," species such as the Florida blue centipede can envenomate with painful bites, which can be categorized as similar to that of a bee sting. Effects can include anaphylactic shock in some individuals. EPA believes that these types of effects are sufficient to be considered as a pest of significant public health importance, and are thus included in this proposed rulemaking.

7. *Lice*. In proposed 40 CFR 158.1736, EPA is proposing data requirements on either the Head louse or the Body louse in order to make a labeling claim against lice. EPA is also proposing a performance standard of 100% for all efficacy claims made against lice. The SAP did not express any opinions on the proposed required test species or performance standards.

8. *Fleas*. In proposed 40 CFR 158.1740, EPA is proposing data requirements for one pest group (Fleas) and six pest-specific claims (cat flea, chigoe flea, dog flea, hen flea, human flea, and oriental rat flea). For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

Historically, EPA has only required testing on the cat flea in order to make a "flea" claim. The cat flea is common and easy to rear in the laboratory. Additionally, because the cat flea is the most common species that infests pets, most of the available pesticide products target the cat flea.

In the SAP response to the TSD, the Panel suggested adding the oriental rat flea (*Xenopsylla cheopis*) in addition to the cat flea for a "flea" labeling claim. The oriental rat flea (also known as the tropical rat flea) is a vector for bubonic plague (caused by *Yersinia pestis*), which is extremely rare in the U.S. EPA does not believe requiring this additional species provides immediate benefits at this time and would be an additional cost and burden on applicants to provide such data. EPA notes that 40 CFR 158.1709 would cover invertebrate diseases vector claims. In the future, if the plague becomes a significant issue in the U.S., then EPA would consider requiring the submission of data on the oriental rat flea in addition to the cat flea. Since the risk of the oriental rat flea is rare, EPA intends to continue with its existing practice to only require the larger cat flea for a "flea" claim, and is therefore proposing it as the only required test species at this time.

9. *Cockroaches*. In proposed 40 CFR 158.1744, EPA is proposing data requirements for one pest group (cockroaches) and seven pest-specific claims (American cockroach, Australian cockroach, brown cockroach, brownbanded cockroach, German cockroach, oriental cockroach, and the smokybrown cockroach). For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For the "Cockroach" pest group claim, EPA has historically required testing on both the American cockroach and the German cockroach, and is proposing to codify this requirement. These are the most common cockroaches requested on product labels and are commonly

controlled to halt the spread of asthma, allergy, and food contamination. The SAP was supportive of these species as the required test species for this pest group claim.

The SAP suggested adding *Periplaneta fuliginosa* and *P. brunnea* (smokybrown and brown cockroach, respectively) to the cockroach pest group. EPA is proposing these pests as a pest-specific labeling claims. Even with these additions, EPA continues to believe that for a general cockroach claim, the German and American cockroach are appropriate representative test species for the overarching pest group.

The Turkestan cockroach (*Blatta lateralis*) is thought to be displacing the Oriental cockroach in the southwestern U.S. and, like other cockroaches, can transfer food-borne pathogens. Because of this development, EPA is adding a pest-specific claim for the Turkestan cockroach to 40 CFR 158.1744.

10. *Keds, Screwworms, and Bot Flies*. In proposed 40 CFR 158.1748, EPA is proposing data requirements for bot flies (excluding human bot fly), the human bot fly, keds, and screwworms. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For bot flies (excluding human bot fly), EPA is proposing to require testing on one of the three following species: horse bot fly, throat bot fly, or the nose bot fly. The SAP suggested specifying the test species as *Gasterophilus* spp. instead of listing three specific *Gasterophilus* species, as specified in the TSD. EPA continues to believe that testing on either the horse bot fly, throat bot fly, or the nose bot fly were the most appropriate for efficacy testing because they are large and can be found throughout the U.S. While they are primarily pests of horses, larvae of these three species may occasionally parasitize humans.

For the human bot fly, EPA is proposing testing on the human bot fly (*Dermatobia*

hominis). The human bot fly is not known to vector disease, but the larvae will infest the skin of mammals and live out the larval stage in the subcutaneous layer, causing painful pustules that secrete fluids. The infestation of any fly larvae inside the body is known as myiasis. (Ref. 37). Under bot flies, the SAP stated that human bot fly should be retained as this is frequently introduced by travelers.

In addition to the three proposed options for bot flies, the SAP also suggested EPA consider the *Hypoderma* spp. and *Oestrus ovis* (the sheep bot fly) as additional options. EPA is not proposing to include these species since the Agency has not historically required or received data on these pests. However, EPA requests public comment on whether there is a need to codify product performance data requirements for *Hypoderma* spp. and *Oestrus ovis*.

For screwworms, EPA is proposing to require testing on either the screwworm (*Cochliomyia hominivorax*) or the secondary screwworm (*Cochliomyia macellaria*). The SAP indicated that *Cochliomyia hominivorax* is an eradicated species in the U.S. While EPA acknowledges that the sterile insect eradication program was a success, the species was recently found in Florida. If, in the future, an applicant wanted to make a label claim against screwworms, then *Cochliomyia hominivorax* would be the appropriate test species. Providing this option provides flexibility to the pesticide registrant. (Ref. 38).

For keds, EPA is proposing to require testing on the sheep ked. The sheep ked has historically been the representative species for a "keds" claim, and the SAP expressed general support of the Sheep ked as the required test species. Therefore, EPA is proposing to maintain this practice.

11. *Filth Flies*. In proposed 40 CFR 158.1752, EPA is proposing data requirements for one pest group claim against "Filth flies" and six pest-specific claims (blow fly, cluster fly, face

fly, flesh fly, house fly, and little house fly). For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For a "Filth Flies" pest group claim, EPA is proposing to require testing on the house fly (*Musca domestica*) and either one species of flesh fly (*Sarcophaga* spp., *Wohlfahrtia* spp., and other genera of flesh fly) or one species of blow fly (*Phaenicia* spp., *Calliphora* spp., and other genera of blow fly). One public commenter during the SAP questioned why EPA asked for testing in two species. The commenter indicated that for a direct spray application, only testing with the house fly is needed. The commenter suggested that testing with more than one species should only be needed for more specialized claims, such as fly baits. (Ref. 36).

In response, EPA included house flies and the option to select between blow flies and flesh flies because these types of flies move bacteria around from place-to-place when they land. This takes place by touching surfaces, as these flies generally do not bite. "Filth flies" is a large grouping and testing on two species provides greater assurance that the product would be effective against most members of the pest group. House flies are generally the smallest in size of these three groups and therefore may be more susceptible to insecticides. Testing against the larger filth flesh/blow flies reduces the likelihood of overestimating efficacy.

Additionally, the SAP suggested the cluster fly (*Pollenia rudis*) be deleted as a test species. Instead, flies in the genus *Fannia* can be included since they can be relatively easy to rear in laboratory conditions. *Fannia benjamini* complex and *Fannia scalaris* (canyon fly and latrine fly) were specifically mentioned. In response, the cluster fly was not listed as a required test species for a claim against "Filth Flies" in the TSD. The cluster fly was specified as a test species if an applicant makes a pest-specific claim against the cluster fly. Because house flies, blow flies, and flesh flies are considered better representative species for the pest group claim

against "Filth Flies," flies in the genus *Fannia* are not considered a representative alternative to cluster flies.

12. *Mosquitoes*. In proposed 40 CFR 158.1756, EPA is proposing data requirements for a pest group claim against "Mosquitoes." For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704. For the required test species, EPA is proposing that testing be required on at least one mosquito species from three different genera (i.e., one out of three proposed *Culex* spp.; one out of two proposed *Aedes* spp.; and one out of six proposed *Anopheles* spp.).

One public commenter during the SAP asked why the species *Anopheles stephensi* was missing from the list of species for mosquito testing in the TSD, as it is a common, representative lab insect. (Ref. 36). EPA agrees that the *Anopheles stephensi* could be used for testing, and has added *Anopheles stephensi* to the list of species for mosquito testing in EPA's proposal.

Additionally, the SAP comments were much more extensive regarding mosquitoes, as the SAP response covered both required test species as well as how one arrives at conducting the tests to collect the data. These comments are, as follows:

- Suggested having separate tables for killing and repelling and for field and lab testing
- Questioned the suitability of *Culex pipiens* and *C. quinquefasciatus* in repellent studies
- Suggested using *Culex* spp. instead of hybrids *C. pipiens* and *C. quinquefasciatus*
- Indicated *Anopheles freeborni* and *A. punctipennis* are suitable for field testing and not lab testing
- Indicated *Anopheles quadrimaculatus* is not suitable for indoor repellent testing
- Suggested adding *Anopheles albimanus* and *Anopheles stephensi*

• Indicated *Psorophora* is acceptable for field testing

The SAP also noted that for field testing of mosquitoes, certain species provided in EPA's list could not readily be obtained in a field test in the U.S.

In response, EPA agrees that a listing of specific mosquito test species as provided in the TSD was confusing when considered in the context of field testing. With lab testing and semi-field or "caged" testing a particular test species can be selected. The particular species selected for testing could depend on the colonies maintained by the laboratory, as well as the type of product being tested, and EPA believes providing a list of representative species that is comprehensive means that an appropriate species could be identified for a wide variety of product types or claims.

With regards to *Culex pipiens* and *Culex quinquefasciatus*, EPA is aware that these are now considered to be a hybrid mosquito complex. However, EPA believes that retaining the historical names of the *Culex* species provides more appropriate context, given the possibility of more name changes over time.

With regards to *Anopheles* mosquitoes, EPA has provided several species for the applicant to consider because some *Anopheles* mosquitoes may not be appropriate for all types of testing, or colonies of some *Anopheles* mosquitoes may be difficult to maintain in a laboratory. Additionally, EPA is proposing to add *Anopheles albimanus* and *A. stephensi*.

EPA agrees that *Psorophora* might be reported in a field study. Even though this is another genus of mosquito, *Psorophora* is not a major vector of diseases in the U.S. Other species may better inform the decisions that EPA needs to make.

For testing of skin-applied insect repellents, EPA's Guideline 810.3700, entitled, "Insect Repellents to be Applied to Human Skin" provides specific guidance (page 27) on the choice of

field testing sites. (Ref. 39). According to the Guidance, "Field tests for mosquito repellency should be conducted in at least two distinct habitats (e.g., forest, grassland, salt marsh, wetland, beach, barns, or urban environments) where the predominant mosquito species differ."

In field testing, a wide variety of species are encountered. Thus, for field testing, the applicant's submission will provide information on the species captured during the testing. EPA will review the data submitted to determine if a sufficient number and type of species were present. Generally, EPA expects three different genera to be present: *Culex*, *Aedes*, and *Anopheles*.

Claims against specific vector/disease combinations must be supported by testing of the specified vector. Additionally, because mosquitoes are high stakes vectors and because of the difficulty consumers have in differentiating between species, for a claim against any specific species of mosquito, all the required test genera must be tested.

EPA also agrees that certain species of the mosquitoes specified in the TSD might not be obtained in a field test. However, the purpose of providing multiple species is to offer flexibility in how one complies with the data requirements. In the proposal, EPA has not differentiated between what species may be more obtainable in a field versus laboratory test.

Additionally, two commenters provided other comments about how to obtain mosquito data, particularly in relation to using foreign data and foreign species as surrogate data. One commenter, for example, suggested that foreign data be considered acceptable as long as the study is conducted according to the 810.3700 guidelines. (Ref. 40). Another commenter indicated that foreign species could be useful if sufficient colonies of domestic species are not available (e.g., declining colonies of US anopheline mosquito species). (Ref. 41). EPA would like to note that conducting studies according to EPA guidelines is always recommended, but is

not enough to show that a foreign species is an acceptable surrogate for a domestic species. However, the Agency acknowledges that situations may arise where data showing efficacy of a product against foreign species can be useful. Therefore, the Agency will consider bridging data from foreign species to domestic species on a case-by-case basis. With this in mind, EPA is seeking comment on whether other species should be considered as part of the required test species.

13. *Biting Flies*. In proposed 40 CFR 158.1765, EPA is proposing data requirements for the pest group "Biting flies (excluding Sand flies)," the pest sub-groups "Large Biting Flies" and "Small Biting Flies (excluding Sand flies)," and nine pest-specific claims of biting flies. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

Since the SAP, the Agency has revised the proposed data requirements to be clearer than initially presented to the SAP. EPA proposed the pest group "Biting flies (excluding Sand flies)" to be consistent with experience on how the Agency receives labeling requests. Sand flies are vectors for Leishmaniasis, a parasitic disease that is found in parts of the tropics, subtropics, and southern Europe which can either cause skin sores or affect several internal organs (usually spleen, liver, and bone marrow). (Ref. 42). This differentiation improves the clarity and is consistent with how products have typically been labeled.

The Agency is also proposing to split the pest sub-groups further into "Large Biting Flies" and "Small Biting Flies (excluding Sand flies)." This is in response to the fact that periodically, the Agency receives requests for claims against large biting flies or claims against small biting flies. This proposal is to provide that flexibility in the codified data requirements.

During the SAP, the Panel suggested that the stable fly (*Stomoxys calcitrans*) and the horn fly (*Haematobia irritans*) be included in the filth fly category. The Panel also questioned

why both species need to be tested. In response, EPA considers both the stable fly and the horn fly to be biting flies. The Agency is proposing stable flies as one of the three representative species for the "Biting Fly (excluding sand flies)" pest group claim and one of the two required test species the "Large Biting Flies" pest sub-group claim. Testing of both species as described in the TSD to obtain a claim against stable flies was an error. Instead, in the absence of an appropriate pest group or pest sub-group representation, the Agency is proposing to require testing against stable flies for a pest-specific efficacy claim against stable flies and testing against horn flies for a pest-specific claim against horn flies.

The SAP suggested adding *Leptoconops kereszi* complex and *L. torrens* (black gnats) to pest sub-group biting midges in the TSD. For claims against biting midges, the Agency was proposing testing against one *Culicoides* species and one *Leptoconops* species. The specific species of *Leptoconops* required are not specified; therefore EPA would consider the species suggested by the commenter (*Leptoconops kereszi* complex and *L. torrens*) to be acceptable. The biting midges pest sub-group has since been revised to be represented as the "Small Biting Flies (excluding Sand flies)" pest sub-group claim. Both biting midges and black gnats are listed separately under the pest-specific claims.

14. *Bed Bugs*. In proposed 40 CFR 158.1768, EPA is proposing data requirements for the pest group claim "Bed bugs" and pest-specific claims for both the Common bed bug and the Tropical bed bug. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For "Bed bugs," one commenter indicated that only one species is important to the vast majority of consumers and thus only one species needs to be tested to support this kind of product registration. For this proposal, EPA agrees that testing to include only the common bed

bug, *Cimex lectularius*, is appropriate as the lone required bed bug test species.

In the TSD, the EPA initially proposed a 95% performance standard for bed bug products. One commenter stated that the performance standard for bed bug control products that claim residual control and ovicidal control should be 90% rather the 95% standard in the TSD. Additionally, the commenter indicated that bed bug products need to have residual activity, because control of bed bugs is not possible via direct contact. They indicated that there must be residual activity in order for the product to claim "control" and if the product does not have residual activity, then this statement should be on the product label. The commenter also stated that a performance standard applicable to bed bug products that claim to kill bed bugs when bed bugs come into contact with a treated surface is needed. Therefore, EPA has decided to propose a performance standard of 90%, instead of the 95% in the TSD.

15. *Conenose Bugs and Kissing Bugs*. For proposed 40 CFR 158.1772, EPA is proposing data requirements for labeling claims against conenose bugs and kissing bugs. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

Initially proposed as "True bugs (excluding bed bugs)" in the TSD, EPA is proposing to focus primarily on the two required test species, the conenose bug and the kissing bug. This proposal has now separated them as pest-specific claims since experience has shown that labeling and data are usually submitted with the intent of labeling for the specific pest.

During the SAP, one commenter asked why the common stink bug species is missing from "true bugs." (Ref. 36). In response, the common stink bug is not a disease vector or otherwise a pest of significant public health importance, and therefore EPA did not include it as a test species in the TSD presented to the SAP. Since the "true bug" claims have changed in this group, stink bugs are no longer relevant to this group.

Similarly, the SAP suggested that both the conenose and the kissing bug be required test species. Both the kissing bug and the conenose bug (*Triatoma protracta* and *Triatoma sanguisuga*, respectively) are in the same genus and are both vectors of Chagas disease. Given these similarities and to reduce the number of studies to be submitted, EPA did not believe it was necessary to require both when a "true bug" claim was still in consideration. Based on experience, EPA has since opted to propose that they be separate pest-specific claims.

16. *Ants (excluding carpenter ants)*. In the proposed 40 CFR 158.1776, the EPA is proposing data requirements for pest group "Ants (excluding carpenter ants)," for the pest sub-groups "Fire and Harvester ants," "Fire and Harvester ant colonies," and "Fire ants," and for seven pest-specific claims in the absences of a pest group or sub-group claim.

For colony claims, testing must be done specific to the species listed. For colony claims against the red and/or black imported fire ants, testing may be done on the red imported fire ant (RIFA) (*Solenopsis invicta*), the black imported fire ant (*Solenopsis richteri*) or their hybrid.

Data for the pharaoh ant (*Monomorium pharaonis*) and red imported fire ant (*Solenopsis invicta*) would be required to support a general claim against ants, except carpenter ants. EPA proposes RIFA to receive a claim against fire and harvester ants for direct spray kill and residual surface application claims against foraging ants only (excluding colony claims). For bait products or claims involving outdoor use, testing must be specific to the species listed. For colony claims, testing must be specific to the species listed. For colony claims against the red and/or black imported fire ants, testing may be done on, *S. invicta*, *S. richteri*, or their hybrid.

Public comments on the 2013 SAP suggested that additional clarity was needed for categories such as "ants" where only certain members of the group would be considered pests of significant public health importance. (See, e.g., Ref. 40). Similar to EPA's current practice for

spiders, EPA requires product performance data for certain species-specific claims (e.g. "fire ants") and for general claims against "ants" or "ants, unless certain species are expressly excluded, i.e., fire, pharaoh, harvester, and carpenter ants." Fire and harvester ants are considered pests of significant public health importance, due to their painful stings that may result in anaphylaxis, while pharaoh ants are considered pests of significant public health importance because they can transfer numerous pathogens much like cockroaches. As discussed separately in more detail in Unit VII.C.18 of this proposal, Carpenter ants are structural pests which also require the submission of efficacy data. As a result, if an applicant submits a draft label with a claim against "ants (excluding fire, pharaoh, harvester, and carpenter ants)," the applicant does not need to provide product performance data to EPA. Instead, the applicant would generate efficacy data to confirm that the product is effective against these non-public health pests and then hold those data in their files. However, a label claim against "ants" encompasses, pests of significant public health importance and structural pests, and therefore for a "kills ants" label claim, the applicant would need to submit at least three product performance studies to EPA to verify this claim, one study each for the fire ant (which can be bridged to cover the harvester ant for a direct spray test), pharaoh ant, and carpenter ant. For a more detailed discussion of the "Carpenter ants" claim, see Unit VII.C.18 of this proposal.

The SAP also suggested adding the following ants to the "Ants (except carpenter ants)" group: European fire ant, odorous house ant, red imported fire ant (RIFA), tropical fire ant, thief ant, dark rover ant, hairy crazy ant, Caribbean crazy ant, yellow crazy ant, pavement ant, and *Crematogaster* spp. Fire ants (*Solenopsis* spp.). Some of the species suggested for inclusion are not pests of significant public health importance (odorous house ant, thief ant, dark rover ant, hairy crazy ant, Caribbean crazy ant, yellow crazy ant, and pavement ant), and thus EPA is not

proposing product performance data requirements specific to these species.

17. *Bees, Wasps, Yellowjackets, and Hornets*. For proposed 40 CFR 158.1780, EPA is proposing data requirement for a pest group claim "Bees, Wasps, Yellowjackets, and Hornets" and pest-specific claim for bald-faced hornet, mud dauber wasp, paper wasp, and yellowjackets. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704. For colony claims against *Vespula* spp. EPA is proposing a performance standard of 100%.

For the pest group claim, EPA is proposing data on two yellowjacket species (one *Vespula* sp. and the bald-faced hornet (*Dolichovespula maculata*)) and one paper wasp (*Polistes* sp.). These required test species were chosen based on their painful stings that may cause life-threatening reactions. The SAP was supportive of the selection of these species as representative to this pest group.

For the pest-specific claims that were proposed, one commenter indicated that stinging bees and wasps, solitary and ground nesting Hymenoptera such as mud daubers, digger wasps/bees, and spider wasps should not be included as pests of significant public health importance. The commenter believed that these females use their stingers for hunting, not defense, which means that it is unlikely such a pest would pose a public health threat. (Ref. 40). Another commenter added that they are also beneficial insects. (Ref. 41). However, these insects can inflict painful stings that may cause life-threatening allergic reactions and therefore are considered pests of significant public health importance and incorporated into the pest-specific claims.

The Asian giant hornet, *Vespa mandarinia*, has recently been sighted in the U.S. At the time EPA developed the pest grouping for "Bees, Wasps, Yellowjackets, and Hornets", this

species was not in the U.S. EPA requests comment on whether there are data to suggest the representative taxa should cover this species, or alternatively, data to suggest the opposite.

18. *Carpenter Ants*. Carpenter ants are structural pests which also require the submission of efficacy data. For proposed 40 CFR 158.1782, EPA is proposing data requirement for a pest group claim "Carpenter Ants." For the pest group claim, EPA is proposing requiring testing data on one of the following carpenter ant species: black carpenter ant (*Camponotus pennsylvanicus*), or Florida carpenter ant (*Camponotus floridanus*), or Western carpenter ant (*Camponotus modoc*).

For bait treatment EPA is proposing a performance standard of 95% prevention of damage to wood for ≥ 3 years. For "Non-Structural: Wood Preservative Treatment," EPA is proposing a 100% performance standard of prevention of damage to wood for ≥2 years. And for structural protection, EPA is proposing a performance standard of 95% prevention of damage to wood ≥ 5 years.

For carpenter ants, the SAP suggested adding the carpenter ant (*Camponotus neracticus*) as a test species. The Panel also indicated that more test species might be needed on the list because laboratories may experience hardship obtaining and maintaining colonies of some of the species on the list provided. In response EPA notes that there are three carpenter ant options for testing and that testing would need to be done on only one of the species. EPA notes that the *Camponotus neracticus* is significantly smaller than any of the three options. Thus, EPA believes that the three proposed test species are better choices for representative species.

19. *Wood-destroying beetles*. For proposed 40 CFR 158.1784, EPA is proposing data requirements for wood destroying beetles. For products making a claim against wood-destroying beetles or wood-boring beetles, EPA is proposing to require testing on three species: anobiid

beetle (*Anobiidae* sp.), bostrichid beetle (*Bostrichidae* sp.), and old house borer (*Hylotrupes bajulus*). For products making a claim against true powderpost beetles, EPA is proposing to require testing on one species from the Lyctinae subfamily.

For bait treatment EPA is proposing a performance standard of 95% prevention of damage to wood for ≥ 3 years. For "Non-Structural: Wood Preservative Treatment," EPA is proposing a 100% performance standard of prevention of damage to wood for ≥2 years. And for structural protection, EPA is proposing a performance standard of 95% prevention of damage to wood ≥ 5 years.

One public commenter suggested that EPA consider adding a fourth genus also known as the lyctid beetles (Lyctinae spp.) to represent the major wood-destroying beetle genera while allowing flexibility to test three of the four. (Ref. 43). The EPA does not believe that substituting a lyctid beetle as a representative test species is appropriate, as these beetles are not likely to cause structural damage.

20. *Termites*. For proposed 40 CFR 158.1786, EPA is proposing data requirements for the subterranean termite, desert subterranean termite, Formosan subterranean termite, drywood termite, and dampwood termite. For products making a claim against termites, EPA is proposing testing on species from four genera of termites. EPA is proposing to require testing on:

• *Coptotermes formosanus*

• And one of the following *Reticulitermes* species: *Reticulitermes flavipes*, or *Reticulitermes hesperus*, or *Reticulitermes virginicus*

• And one of the following arboreal termite species: *Nasutitermes coringer* (Motschulsky)

• And one of the following drywood termite species: *Cryptotermes brevis*, or

Cryptotermes cavifrons, or *Incisitermes minor*, or *Incisitermes snyderi*

For a claim against arboreal termites, EPA is proposing testing of one arboreal termite species: *Nasutitermes coringer* (Motschulsky). For a claim against dampwood termites, EPA is proposing testing of the following dampwood termite: *Zootermopsis* sp. For a claim against drywood termites, EPA is proposing testing of one of the following drywood termites: *Cryptotermes brevis*, or *Cryptotermes cavifrons*, or *Incisitermes minor* or *Incisitermes snyderi*. For a claim against subterranean termites, including formosan subterranean termites, EPA is proposing testing in two genera of termites. Specifically, EPA is proposing testing on the following *Coptotermes* species: *Coptotermes formosanus*; and one of the following *Reticulitermes* species: *Reticulitermes flavipes*, or *Reticulitermes hesperus*, or *Reticulitermes virginicus*.

For bait treatment, EPA is proposing a performance standard of 95% prevention of damage to wood for ≥ 3 years. For "Non-Structural: Wood Preservative Treatment" EPA is proposing a 100% performance standard of prevention of damage to wood for ≥2 years. And for structural protection, EPA is proposing a performance standard of 95% prevention of damage to wood ≥ 5 years.

The SAP suggested adding drywood termite (*Incisitermes synderi*) as a test species. EPA is proposing to add *Incisitermes snyderi* to the list of representative species for drywood termites. Additionally, *Cryptotermes cavifrons*, a species endemic to Florida, would also be an acceptable representative test species and EPA is proposing to add this organism as well.

The SAP and other commenters questioned the standard of "100% prevention of damage to wood" and thought that the lesser 95% or 90% would be more acceptable. EPA agrees with the comment and is proposing a 95% prevention of damage to wood standard. However, EPA

notes that what constitutes a 95% standard is dependent on the type of study being performed. For example, for the standard U.S. Forest Service Concrete Slab field study, the 95% would be calculated such that any damage greater than nibbles to surface etching would be considered a failure; if a single plot had more than one instance of nibbles to surface etching in any of the standard five evaluation periods, this would also be a failure. A 95% success rate for the U.S. Forest Service Concrete Slab (CS) tests would be determined by the combined data for a product, by rate, in a given year. For non-structural wood preservative treatments, EPA is proposing a standard of 100% prevention of damage to wood for ≥ 2 years. Additionally, to be consistent with the majority of other pests, EPA is proposing the termite standards for direct applications to pests, surface applications, and spatial applications will be changed to a performance standard of 90%, consistent with proposed 40 CFR 158.1704.

21. *Invasive Species*. EPA believes treating invasive species quickly and appropriately is critical, and EPA does not intend to preclude use of a pesticide product pursuant to FIFRA 2(ee) to treat an invasive species. EPA believes that pesticide products are an important tool for managing the spread of an invertebrate invasive species and the related public health concerns or significant economic impacts. The availability of pesticide products with proven performance against an invasive species is important to slowing the spread of the invasive species.

Due to the sudden appearance and often rapid spread of invasive species, except for the pests noted, EPA does not presently intend to list the specific invasive species for which product performance data might be deemed necessary. Instead, the submission of product performance data to support claims for effectiveness against invasive invertebrate pests will be considered on a case-by-case basis. Given the expectation of infrequent submission of such an application, a "case-by-case" approach is the most suitable. EPA recommends that applicants consult with the

Agency when first considering a submission to place an invasive species on the label of a pesticide product. As part of the consultation, EPA would be able to provide information on protocol development and selection of test species. EPA generally expects to require product performance data for invasive species that are similar to the Asian longhorned beetle and emerald ash borer in that they have the potential to cause significant economic or ecological damage and the efficacy of products used against them cannot readily be determined at the time of application.

This proposal specifies that the Asian longhorned beetle and the emerald ash borer are two invasive pests for which product performance data must be submitted. The efficacy of the products used for their control typically cannot be determined until the season after application, and the EPA believes it appropriate to continue the practice of reviewing efficacy data for these invasive species.

VIII. Updates to Subparts U and V

In addition to the inclusion of product performance data requirements under the new subpart R, EPA is also proposing to revise and update the product performance data requirements language for biochemical and microbial pesticides in subpart U, 40 CFR 158.2070 and subpart V, 40 CFR 158.2160, in order to clarify the requirements for products that would be subject to both proposed subpart R and also subpart U or subpart V.

Subpart U (biochemical pesticides) and subpart V (microbial pesticides) currently require that product performance data be developed, and that each applicant must ensure through testing that the pesticide product is efficacious when used in accordance with label directions and commonly accepted pest control practices. Both subparts also state that EPA may require, on a case-by-case basis, submission of product performance data for any pesticide product registered

or proposed for registration or amendment (see, 40 CFR 158.2070 and 40 CFR 158.2160). These requirements would not be modified by this proposal.

Subpart U (biochemical pesticides) and subpart V (microbial pesticides) also currently require that product performance data be submitted for each biochemical and microbial pesticide product that bears a claim to control public health pests, as the term is used in subparts U and V. This requirement is followed by a non-exhaustive list of public health pests. This includes pest microorganisms infectious to humans in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans.

This proposal adds additional clarity by including a provision in subpart U (biochemical pesticides) and subpart V (microbial pesticides) stating that product performance data must be submitted for each product that bears a claim against an invertebrate pest that is covered by subpart R. This provision is intended to be coextensive with the requirements of subpart R, and broader than the currently existing requirements in subparts U and V related to "public health pests" in that it would also cover the wood-destroying beetles and invasive exotic species claims covered by subpart R.

Additionally, EPA notes that data requirements and the performance standards that determine the acceptability of data may be modified on a case-by-case pursuant to the provisions in 40 CFR 158.45 and 40 CFR 158.1707.

IX. Impact of this Proposal on Future and Existing Registrations

This action, if finalized, will have no immediate effect on existing registrations unless new information indicates an existing registration includes claims that are not sufficiently

supported. When an application for registration or amended registration requests to put a claim(s) on its pesticide product's labeling for effectiveness against an invertebrate species that is covered by this action, the application would generally include submission of product performance data to support those claims for effectiveness.

X. Peer Review

A. Human Studies Review Board

1. *Background*. Research with human subjects that is conducted or supported by the U.S. government is subject to regulations for the protection of human subjects. These regulations are referred to as the Common Rule. EPA's codification of the Common Rule appears at 40 CFR part 26, subpart A. On February 6, 2006 (71 FR 6138) (FRL-7759-8), EPA published a final rule amending part 26 by adding new subparts (B-Q). This amendment added, among other parts, Subpart K, which applies standards similar to those in the Common Rule to third parties (i.e., those other than federal agencies and federally-funded researchers) conducting research with human subjects. Additional amendments to part 26 have been made, most recently in 2019 (84 FR 35315, July 23, 2019) (FRL-9996-48-ORD). Under EPA's regulation, if the research involves intentional exposure of a human subject and if the sponsor or investigator intends to submit the results of the research to EPA in connection with any action that may be performed by EPA under the pesticide laws (FIFRA or FFDCA), then the research must comply with the provisions of 40 CFR part 26; the requirements of EPA's human studies rule also apply to any research involving intentional exposure of a human subject to a pesticide, when the results are intended to be submitted in connection with a regulatory action under any other statute EPA administers. In addition to establishing protections for human subjects of research, EPA established the Human Studies Review Board (HSRB or Board) to review both proposals for

new research and reports of covered human research on which EPA proposes to rely under the pesticide laws. The HSRB is a federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App.2, section 9).

The HSRB typically includes independent experts in toxicology, exposure assessment, industrial hygiene, statistics, and bioethics, as well as an entomologist consultant. The HSRB provides EPA with advice, information, and recommendations on issues related to both the scientific and ethical aspects of human subjects research. The major objectives are to provide review and recommendations on the scientific and ethical aspects of research proposals and protocols, and reports of completed research with human subjects; and, when requested, advise on how to strengthen EPA's programs for protection of human subjects of research. EPA considers all recommendations from the HSRB before finalizing its reviews of proposed or final research.

The HSRB reports to the EPA Administrator through EPA's Science Advisor. Since 2006, the rigorous independent reviews conducted by EPA and the HSRB, as mandated by part 26, have resulted in research protocols designed to result in scientifically-sound data and to ensure the protection of human subjects involved in the research. In providing for the establishment of the HSRB, the regulations have reassured the public that all pesticide research involving intentional exposure to human subjects undergoes thorough independent and expert review based on scientific and ethical standards.

Under 40 CFR part 26, subpart K, protocols for research subject to the regulation's requirements must be submitted to EPA for review and evaluation before initiation of the study. The relevant information that must be included in the proposed research protocol is specified in 40 CFR 26.1125. EPA then evaluates the protocol and makes a determination about the scientific

validity and reliability of the research as well as examining the ethical aspects of the research, in accordance with the conditions in 40 CFR 26.1603. EPA submits the protocol and supporting materials, as well as EPA's science and ethics reviews of the proposed research to the HSRB for review and comment. The members of the HSRB review the proposed research. Then in an open and transparent manner at a public meeting, members of the HSRB ask additional questions, provide their individual comments, and participate in a discussion which is documented in meeting minutes. Each final HSRB report contains the Board's responses to charge questions posed by EPA, as well as the final, approved advice of the HSRB. The research cannot be initiated until EPA approves the protocol, following its consideration of the HSRB's input and recommendations. The protocol will only be approved if EPA determines that the research conducted according to the protocol would meet the standards of 40 CFR 26, Subparts K and L. Information on the HSRB, including materials reviewed and recommendations can be found on the HSRB webpage. (Ref. 44).

Once the research has been conducted, then all of the records relevant to the research, including raw data and records of ethical review, are submitted to EPA. EPA examines all submitted materials, considers the scientific and ethical conduct of the research, and provides the completed research and its evaluation of the completed research to the HSRB. The HSRB reviews the documents and discusses them at a public meeting in the same open and transparent manner. The HSRB issues a report of their findings following the meeting. EPA may rely on the results of completed human research involving intentional exposure of human subjects only if the research meets the standards referenced in part 26, subpart Q.

2. *Review of EPA's draft guideline 810.3700.* In October 2008, EPA presented to the HSRB a draft guideline titled "Insect Repellents to be applied to Human Skin" for review and

evaluation. (Ref. 46). The HSRB final report (Ref. 46) for that October 2008 meeting included the HSRB's comments and concerns about the statistical analysis plan included in the draft guideline.

Based on the HSRB review and comments, EPA revised the guideline and presented the revised guideline to the HSRB on June 23, 2010. EPA's Senior Policy Advisor for the Pesticide Program made a presentation titled, "OPP Policy Decisions Regarding Insect Repellent Efficacy Testing." (Ref. 31).

The HSRB recommended several changes or clarifications for the revised guideline in its final report, (Ref. 47) including:

• Removal of the maximum-likelihood method requirement in the data analysis section;

• Clarification of recommendations regarding the use of positive controls, particularly with respect to the number of controls and the rationale for including them in the study;

• Careful consideration of recommendations regarding the recruitment and inclusion of so-called 'vulnerable' populations; and

• Encouraging the use of study designs that will enable investigators to collect data that will allow quantitative measurement of repellent efficacy in addition to determining the complete protection time (CPT).

On August 6, 2010 (75 FR 47592), EPA announced the availability of the final guideline for Insect Repellents to be Applied to Human Skin (Guideline 810.3700).

3. *Overall impact of HSRB review*. As required by 40 CFR part 26, the HSRB has reviewed and commented on all protocols for conducting skin-applied insect repellents as well as the completed studies conducted according to those protocols. In its final reports, the HSRB provided recommendations to strengthen EPA's statistical approaches for calculating CPTs.

Additionally, the HSRB's feedback has resulted in EPA's development of a model to calculate sample sizes for field and lab testing with mosquitoes and lab testing with ticks, to support results. At the recommendation of the HSRB, EPA also elected not to require positive controls.

B. FIFRA Scientific Advisory Panel

On March 19-20, 2013, EPA presented to the SAP a variety of issues for their consideration and response concerning the Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance. The meeting announcement, the Agency's presentations and support documents, public comments, and the comments by the SAP are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2012-0574. Unit VII of this proposal discusses how comments from the SAP and public comments informed the data requirements of proposed subpart R.

In separate actions EPA has developed and revised testing guidelines and continues to do so. While this rule refers to these guidelines, and recommends their use, they are not the subject of today's proposal. For informational purposes, EPA is providing a description of SAP meetings relevant to those guidelines.

1. *1994 meeting*. In 1994, EPA held a 2-day meeting of the SAP to review the Agency's proposed amendments to the data requirements for pesticide registrations contained in 40 CFR part 158. The SAP was asked to comment on each data requirement and identify, in their opinion, which ones were necessary to fully and thoroughly evaluate the potential hazard of a chemical compound and which ones were not intrinsically useful in providing practical scientific information. The review included both comparative product performance data requirements along with product performance data requirements for public health and non-public health data

requirements. A very complete discussion of the 1994 SAP was presented in the proposed rule for conventional pesticides (March 11, 2005; 70 FR 12310) (FRL-6811-2).

2. *April 2000 meeting*. In April 2000 the SAP was asked to comment on a draft guideline regarding insect repellents for human skin and outdoor premises. (Ref. 48).

3. *July 2002 meeting*. On July 30-31, 2002, the SAP was asked to review the design and scientific soundness of the draft guideline entitled "Termite Bait Testing." EPA's presentations, the draft guideline, the charge questions, and the Panel's review of the guideline are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2002-0125.

4. *March 2012 meeting*. On March 6-7, 2012, EPA presented to the SAP, a draft guideline regarding bed bugs. The meeting announcement, the Agency's presentations and support documents, public comments, and the comments by the SAP are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2011-1017. After taking the SAP's feedback into consideration, EPA announced the availability of the final test guideline, Laboratory Product Performance Testing Methods for Bed Bug Pesticide Products; OCSPP Test Guideline 810.3900, on June 14, 2017 (82 FR 27254) (FRL-9959-78).

5. *May 2018 meeting*. On May 8-10, 2018, EPA presented to the SAP for their consideration and response scientific issues associated with proposed revisions to two EPA Test Guidelines 810.3100 (Soil Treatment for Imported Fire Ants), and Guideline 810.3500 (Premises Treatment), for Red Imported Fire Ants (RIFA). These guidelines were originally published in March 1998.

The proposed premises treatment guideline revisions presented to the SAP contained recommended test methodologies for a wide range of products intended to kill, control, flush, and/or knockdown invertebrate premises pests, such as cockroaches, ticks, mosquitoes, flies, and

wasps. The guideline did not cover treatment of livestock or pets, wide area-mosquito control, or bed bug products. In addition to guidance for testing efficacy of direct pesticide application to pests, residual treatments, and cockroach and fly baits in the laboratory, the proposed guideline also included field testing methods for outdoor misting systems, Hymenoptera nest treatments, and outdoor foggers. Methods for resistance ratio determination and characterization of pest population strain susceptibility were also described.

The proposed RIFA treatment guideline revisions contained recommended test methodologies for evaluating the performance of pesticide products for the treatment and control of red imported fire ant colonies/mounds. The guideline did not cover premises treatments for RIFA workers/foragers, such as direct application to pests. Field tests for both mound- and area-applied pesticide products were proposed, along with accompanying laboratory studies for baits, barrier treatments, and insect growth regulators.

The meeting announcement, the Agency's presentations and support documents, and public comments are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2017-0693. In September of 2019, EPA published the final Product Performance Test Guidelines OCSPP 810.3500: Premises Treatments; Background information, the draft guideline, and charge questions developed by EPA are available at *https://archive.epa.gov/scipoly/sap/meetings/web/html/040500_mtg.html*.

7. *June 2019 meeting*. On June 11-14, 2019, the SAP reviewed EPA's proposed guidelines for Efficacy Testing of Topically Applied Pesticides Used Against Certain Ectoparasitic Pests on Pets. The meeting announcement, the Agency's presentations and support documents, public comments, and the comments by the SAP are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-20190161.

XI. Request for Comments

The Agency invites the public to provide comment on the proposed requirements and their basis. Specifically included within the Agency's requests for comments are suggestions which can be supported by scientific data for the Agency to consider during the development of the final rule. Specific comments are requested for:

1. *Definitions*. The Agency welcomes comment on the proposed definitions. The Agency also welcomes suggestions on additional definitions that may be needed to help clarify what is required in the regulations.

2. *Representative test species*. The proposed rule includes taxonomic categories of invertebrates which require more than one species to be tested to support a general claim for that pest group. The representative taxa were selected on the basis of vigor of the pest species and the likely ability of the species to serve as an adequate surrogate for other pests in the group. The selection of representative taxa was informed by the 2013 SAP.

3. *Performance standards*. The Agency welcomes specific comments on performance standards. The Agency would need to see scientifically sound data to support any recommendations for performance standards that differ from those proposed. The Agency believes requiring data showing the pesticide meets a specified threshold level (performance standard) of efficacy is the best means of addressing potential consequences which could occur through the use of ineffective pesticides intended for use against pests that transmit disease.

4. *Economic analysis*. The Agency also welcomes public comment on its economic analysis of the proposed rule, as well as on its underlying assumptions, economic data, and high and low-cost options and alternatives. Describe any assumptions and provide any technical information and data used in preparing your comments. Explain estimates in sufficient detail to

allow for it to be reproduced for validation. EPA's underlying principle in developing the proposed revisions has been to strike an appropriate balance between the need for adequate data to make the statutorily mandated determinations and informed risk management decisions, while minimizing data collection burdens on regulated community required to support product performance data requirements. In particular, EPA would appreciate public comment on the magnitude of the savings in discovery costs discussed on page 29 of the cost analysis.

XII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. US EPA. Cost Analysis of the Proposed Product Performance Rule, prepared by the Biological and Economic Analysis Division, Office of Pesticide Programs, available in docket: EPA-HQ-OPP-2020-0124.

2. US EPA. Pesticide Registration (PR Notice) Notice 2002-1, available at https://www.epa.gov/sites/production/files/2014-04/documents/pr2002-1.pdf at 2 (accessed March 6, 2020); *see also* Public Review Draft: Pesticide Registration (PR Notice) 2020-[X], Draft List of Pests of Significant Public Health Importance—Revised 2020, docket EPA-HQ-OPP-2020-0260.

3. US EPA. PRN 96-7 Termiticide Labeling, available at https://www.epa.gov/pesticide-registration/prn-96-7-termiticide-labeling (accessed March 13, 2020).

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6. Eisen, Lars. Pathogen transmission in relation to duration of attachment by Ixodes scapularis ticks, Ticks and Tick-borne Diseases.

7. US EPA. Bed Bugs, Get them out and Keep them Out, available at https://www.epa.gov/bedbugs (accessed March 6, 2020).

8. US EPA and CDC. Joint statement on bed bug control in the United States from the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Environmental Protection Agency (EPA); available at https://stacks.cdc.gov/view/cdc/21750/Email (accessed March 19, 2020).

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11. US EPA. Office of Pesticide Programs, Label Review Manual, available at *https://www.epa.gov/pesticide-registration/label-review-manual* (accessed March 13, 2020).

12. US EPA. Product Performance Guideline 810.1000, Overview, Definitions, and General Considerations, available at https://www.epa.gov/test-guidelines-pesticides-and-toxic-

substances/series-810-product-performance-test-guidelines (accessed March 6, 2020).

13. CDC. Division of Vector Borne Infectious Diseases: West Nile Virus Fact Sheet available at https://www.cdc.gov/westnile/resources/pdfs/wnvFactsheet_508.pdf, (accessed March 9, 2020).

14. CDC. Zika Virus, Statistics and Maps; available at https://www.cdc.gov/zika/reporting/index.html (accessed March 6, 2020); CDC, Zika Virus, available at https://www.cdc.gov/zika/index.html (accessed March 6, 2020).

15. CDC. Lyme Disease: Data and Surveillance, available at https://www.cdc.gov/lyme/datasurveillance/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Flyme%2Fstats%2Findex.html (accessed March 19, 2020).

16. M. L. Wilson, J. F. Levine, and A. Spielman. Effect of deer reduction on abundance of the deer tick (*Ixodes dammini*), [HYPERLINK "https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2589992/"]. 1984 Jul-Aug; 57(4): 697–705.

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22. CDC. Lyme Disease: Preventing Tick Bites on People, available at https://www.cdc.gov/lyme/prev/on_people.html (accessed March 6, 2020).

23. CDC. Division of Vector Borne Infectious Diseases: West Nile Virus (WNV) Fact Sheet https://www.cdc.gov/westnile/resources/pdfs/wnvFactsheet_508.pdf (accessed March 6, 2020).

24. Emerald Ash Borer Information Network, available at http://www.emeraldashborer.info/about-eab.php (accessed March 9, 2020)

25. USDA. Emerald Ash Borer, available at https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/pests-and-diseases/emerald-ash-borer (accessed March 9, 2020).

26. USDA. Asian Long-Horned Beetle, available at https://www.invasivespeciesinfo.gov/profile/asian-long-horned-beetle, (accessed March 9, 2020).

27. NRS. Economic Impacts of Non-Native Forest Insects in the Continental United States, available at https://www.nrs.fs.fed.us/pubs/38719 (accessed March 9, 2020).

28. US EPA. Technical Support Document Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance Submitted to the FIFRA Scientific Advisory

Panel for Review and Comment March 19-21, 2013 (Hereinafter "TSD"), available in docket: EPA-HQ-OPP-2012-0574-0002, Appendix 1, Tables I and II.

29. US EPA. FIFRA Scientific Advisory Panel, Meeting Minutes and Final Report for the March 19-21, 2013 Scientific Advisory Panel, available at https://www.epa.gov/sites/production/files/2015-06/documents/031913minutes.pdf (accessed April 9, 2020).

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31. US EPA. OPP Policy Decisions Regarding Insect Repellent Efficacy Testing, (prepared for June 23, 2010, Human Subjects Research Board Meeting.)

32. USDA. National Invasive Species Information Center, available at https://www.invasivespeciesinfo.gov/ (accessed April 29, 2020).

33. Consumer and Specialty Products Association (CSPA). Comment submitted by Beth Law, CSPA, March 15, 2013, EPA-HQ-OPP-2012-0574-0014.

34. USDA. Victor Borne Diseases: Cattle Fever Ticks, available at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/cattle-disease-information/cattle-vector-borne-diseases (accessed March 9, 2020).

35. Bovine Babesiosis, available at cfsph.iastate.edu/factsheets/pdfs/bovine_babesiosis.pdf (accessed March 24, 2020).

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37. UF IFAS. Featured Creatures: Human Bot Fly, available at http://entnemdept.ufl.edu/creatures/misc/flies/human_bot_fly.htm (accessed March 9, 2020).

38. USDA. National Agricultural Library, New World Screwworms, available at https://www.nal.usda.gov/exhibits/speccoll/exhibits/show/stop-screwworms--selections-fr/introduction (accessed March 9).

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41. Comment submitted by Beth Law, Consumer and Specialty Products Association, March 15, 2013, EPA-HQ-OPP-2012-0574-0014.

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43. Comment submitted by Brian Forschler, Termiticide Scientific Review Panel, March 19,2013, EPA-HQ-OPP-2012-0574-0016.

44. US EPA. Science Adviser Programs: Human Studies Review Board, available at https://www.epa.gov/osa/human-studies-review-board (accessed April 1, 2010).

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47. US EPA. EPA Human Studies Review Board Meeting Report, June 23, 2010. Available at https://archive.epa.gov/osa/hsrb/web/pdf/june2010finalreport090910.pdf (accessed April 14, 2020).

48. US EPA. Background Information, the Draft Guideline, and Charge Questions Developed by EPA, available at [HYPERLINK "https://archive.epa.gov/scipoly/sap/meetings/web/html/040500_mtg.html"].

49. US EPA. "Proposed Rule-related ICR Amendment for Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests" (RIN 2070-AJ49), EPA ICR No.: 0277.20 and OMB Control No.: 2070-[tbd]. November 2020.

XIII. FIFRA Review Requirements

Pursuant to FIFRA section 25(a), EPA submitted the draft proposed rule to the Secretary of Agriculture (USDA) and the FIFRA SAP for review. A draft of the proposed rule was also submitted to the appropriate Congressional Committees.

XIV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an analysis of the

potential costs and benefits associated with this action (Ref. 1) which is summarized in more detail in Unit I.E. This analysis is available in the docket.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is expected to be a deregulatory action under EO 13771 (82 FR 9339, February 3, 2017). Details on the estimated cost savings of this proposed rule can be found in EPA's cost analysis (Ref. 1).

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq*. The Information Collection Request (ICR) document that EPA prepared is assigned EPA ICR No. 0277.20 and OMB Control No.: 2070-[tbd] (Ref. 49). You can find a copy of the ICR in the docket and it is briefly summarized here.

The information collection activities in this proposed rule are associated with the codification of efficacy data requirements against certain invertebrate pests. These information collection activities are activities associated with the application for a new or amended registration of a pesticide and are currently approved by OMB under OMB Control No. 2070-0060 (EPA ICR No. 0277). As such, this ICR is intended to amend that existing ICR at the final rule stage, incorporating the information collection activities attributable to this proposed rule, including a reduction in transaction costs associated with a clear codification of the product performance data requirements for certain invertebrate pests.

Respondents/affected entities: There are three groups impacted by the rule. Chemical producers (NAICS 32532), colleges, universities, and professional schools (NAICS code 611310), and research and development labs and services (NAICS code 541712).

Respondent's obligation to respond: These data must be submitted for the applicant to receive the desired pesticide registration or label claim. Authorizing legislation is contained in Section 3 of FIFRA (7 U.S.C. 136). The implementing regulations specific to the product performance data requirements are contained in 40 CFR part 158.

Estimated number of respondents: EPA estimates that registrants submit 60 data packages to the Agency annually for efficacy review. Some registrants may submit multiple data packages per year. Under this rule the number of submissions may decline – and therefore the number of respondents may also decrease.

Frequency of response: On occasion

Total estimated burden: The proposed rule is expected to reduce burden hours by 4,683 annually, including 4,515 hours from reduced paperwork burden associated with data generation and 168 hours from reduced paperwork burden associated with the application process. Burden is defined at 5 CFR 1320.3(b). EPA already accounts for the activities associated with the proposed rule in the currently approved ICR, which covers most activities associated with new and amended registrations; EPA estimates a total annual respondent burden of 1.5 million hours for all these activities. As discussed in the Proposed Rule-related ICR Amendment (Ref. 49), 483,000 of those hours are paperwork burden from data generation for new products, and 102,000 of those hours are paperwork burden from application for new and amended products.

Total estimated cost: The estimated burden reduction is expected to reduce burden cost by $330,000 annually, including $315,000 from reduced paperwork burden associated with data generation and $15,000 from reduced paperwork burden associated with the application process, which includes $0 annualized capital or operation and maintenance costs. EPA already accounts for the activities associated with the proposed rule in the currently approved ICR, which covers

most activities associated with new and amended registrations; EPA estimates a total annual respondent burden of $109 million for all these activities. As discussed in the Proposed Rule ICR (Ref. 49), $33.7 million of that cost is paperwork burden from data generation for new products, and $9.3 million of that cost is paperwork burden from application for new and amended products.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov*, Attention: Desk Officer for the EPA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq*. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. EPA's small entity analysis suggests that the greatest impact, and the most potential cost savings, would accrue to small entities and new registrants. While large, established registrants have experience with the registration process and are aware of EPA's data requirements or have the means to determine the appropriate studies,

new and small registrants without that experience may bear significant costs of acquiring this information. The registrants would have easier access to the data requirements, and the reduction in information acquisition costs would be largest for those registrants with the greatest information acquisition needs. Thus, EPA anticipates that the proposed rule would result in cost savings, particularly for small and first-time registrants. While the affected NAICS codes contain up to 5,438 small entities, EPA does not expect all entities to experience cost savings in all years as a result of this proposed rule. As the cost analysis (Ref. 1) describes, a sample of 30 applications was selected at random. These applications were submitted by 16 different firms, four of which EPA was able to identify as small businesses according to the Small Business Administration Employees or Revenue Thresholds. About 60 packages are received annually by EPA for control claims. Therefore, EPA expects that, on average, approximately ten small entities will experience cost savings each year as a result of this proposed rule.

While not every element of the proposed rule would result in savings for registrants, EPA conservatively estimates that the rule would result in $1 million in annual reductions in registrant expenditures on the process of receiving label claims against public health, wood destroying, and invasive species pests, equivalent to about $17,000 in savings per data package submitted to the Agency and about $5,500 per registrant in annual savings I have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities. The basis for this determination is presented in the small entity analysis prepared as part of the cost analysis for the proposed rule (Ref. 1), which is summarized in Unit I.E, and a copy is available in the docket for this rulemaking. We have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and will not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments. The proposed rule would primarily affect the private sector, i.e., pesticide registrants. The rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this proposed rule is not subject to the requirements of sections 202, 203, or 205 of UMRA. The cost analysis for this action is summarized in Unit I.E. and is available in the docket.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. At present, no Tribal governments hold, or have applied for, a pesticide registration. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

Lists of Subjects in 40 CFR Part 158

Environmental protection, administrative practice and procedure, agricultural and non-agricultural, pesticides and pests, reporting and recordkeeping requirements.

Dated: _____.

Andrew Wheeler,

Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 158 as follows:

PART 158 - [AMENDED]

1. The authority citation for part 158 continues to read as follows:

Authority: 7 U.S.C. 136-136y; 21 U.S.C. 346(a)

PART 158 DATA REQUIREMENTS FOR PESTICIDES

2. In § 158.1, revise paragraph (c) to read as follows:

§ 158.1 Purpose and scope.

* * * * *

(c) *Scope of individual subparts*.

(1) *Conventional pesticides*. Subparts A, B, C, D, E, F, G, K, L, N, O, and R apply to conventional pesticides.

(2) *Biochemical pesticides*. Subparts A, B, E, R, and U apply to biochemical pesticides.

(3) *Microbial pesticides*. Subparts A, B, E, R, and V apply to microbial pesticides.

(4) *Antimicrobial pesticides*. Subparts A, B, C, D, E, R, and W of this part apply to antimicrobial pesticides.

3. Revise the heading for subpart E to read as follows:

Subpart E—Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion-related Claims, and Products for Control of Organisms Producing Mycotoxins

4. Add section subpart R to read as follows:

Subpart R—Product Performance for Products Claiming Effectiveness Against Invertebrate Pests

Sec.

158.1700 General requirements.
158.1701 Definitions.
158.1703 Application Categories.
158.1704 Performance standards for data acceptability.
158.1705 Test Guidelines.
158.1707 Data Requirement Modifications.
158.1708 Invasive species claims.
158.1709 Invertebrate disease vector claims.
158.1710 Structural and wood-destroying pest claims.
158.1712 Mites (excluding Chiggers).
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158.1722 Scorpions.
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158.1732 Centipedes.
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158.1748 Keds, Screwworms, and Bot Flies.
158.1752 Filth Flies.
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158.1768 Bed Bugs.
158.1772 Conenose Bugs and Kissing Bugs.
158.1776 Ants (excluding carpenter ants).
158.1780 Bees, Wasps, Yellowjackets, and Hornets.
158.1782 Carpenter Ants.
158.1784 Wood-destroying beetles.
158.1786 Termites.

Subpart R—Product Performance for Products Claiming Effectiveness Against Invertebrate Pests

§ 158.1700 General requirements.

(a) *General.* Each applicant must ensure through testing that their product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, as specified herein and on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(1) *Test substance*. All product performance testing is performed using the end-use product.

(2) *Test organism*. All product performance testing must report the species tested.

(3) *Testing*. All products are to be tested to support the claim(s) made on the labeling of the pesticide product.

(4) To determine the specific product performance data required to support the registration of each pesticide product, the applicant must refer to the applicable sections of this subpart.

(b) *Product performance data submission*. Each product that bears a claim subject to this subpart, must be supported by submission of product performance data, as listed in this subpart. This product performance data must be submitted with any application for registration or amended registration. For the pest-specific claims listed in this subpart, data must be for the species specified to support the claim.

§ 158.1701 Definitions.

Definitions. The following terms are defined for purposes of this subpart.

Complete protection time (CPT) means the time from application of a skin-applied insect repellent until efficacy failure, which is described in Product Performance Test Guideline 810.3700 – Insect Repellents to be Applied to Human Skin.

Introduction means the intentional or unintentional escape, release, dissemination, or placement of a species into an ecosystem as a result of human activity.

Invasive species means with respect to a particular ecosystem, any species that is not native to that ecosystem, and whose introduction does or is likely to cause economic or environmental harm or harm to human health. .

Performance standard means a benchmark or reference against which the efficacy of the pesticide is compared (including, but not limited to, the ability of the pesticide product to control, kill, or repel an invertebrate pest species).

Pest group labeling claim means a claim or statement on the labeling of the pesticide product that the product is effective against a group of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species for the entire assemblage of taxa.

Pest-specific labeling claim means a claim or statement on the labeling of the pesticide product that the product is effective against a particular arthropod species, such as German cockroach or house fly.

Pest sub-group labeling claim means a claim or statement on the labeling of the pesticide product that the product is effective against a set of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species and part of a larger identified taxonomic grouping (e.g., Biting flies) that includes other pest species, which may or may not have a proposed pest group.

Skin-applied insect repellent means a product intended to disrupt the host-seeking behavior of insects or other arthropods, driving or keeping them away from treated human skin. The repellent product, such as liquid, lotion, or spray, is intended to be applied directly to human skin. Efficacy of skin-applied insect repellents is expressed as complete protection time.

Species means a group of organisms all of which have a high degree of physical and genetic similarity, generally interbreed only among themselves, and show persistent differences from members of allied groups of organisms.

Wood-destroying applies to pests that feed on or nest in wood, and therefore are highly

destructive to wood buildings or structures, and stored lumber. The impact on the structural integrity of buildings can represent significant economic or safety concerns given the costs of remediation.

Vector means any organism capable of transmitting the causative agent of human and/or animal disease, including but not limited to mosquitoes and ticks

§ 158.1703 Application Categories.

Application Categories. The following terms are defined for purposes of this subpart.

Bait treatment means a pesticide product intended to be ingested by the target pest that kills or controls an invertebrate pest such as ants, cockroaches, or termites. This is normally through the insect feeding on the product directly, but may also include products which the target will contact and later ingest during grooming/cleaning. The attractiveness of these products is through the use of a palatable food base, however they may also incorporate an attractant (e.g. pheromone) which is intended to attract the target pests over a greater distance.

Soil-applied termiticides means pesticide products that are applied to the soil beneath and/or adjacent to the structure, pre- or post-construction, to kill or control termites. Treatments can be preventive (i.e., to provide structural protection before a termite infestation is present) or remedial (i.e., to kill and control a termite infestation when present).

Spatial repellents include treatments of both indoor and outdoor sites where the product is applied into the air rather than onto a surface or the skin in order to drive away insects or other arthropods from that space. They are intended to repel the target pest through the dispersal of pesticide into the atmosphere of a room or other open space.

Structural protection means the prevention of termite or other wood-destroying pest activity in an entire structure as the result of an application of a pesticide product.

§ 158.1704 Performance standards for data acceptability.

(a) *General.* The claim stated on the pesticide product labeling (such as knockdown, control, mortality, or repellency) determines the performance standard that must be met. In the absence of specific pest/labeling claims/performance standards specified in §§ 158.1708 through 158.1799, the performance standards of paragraphs (b) and (c) apply.

(b) *Skin-applied insect repellent labeling claims.* (1) For skin-applied insect repellent labeling claims, the performance standard must be greater than or equal to 2-hours complete protection time.

(2) Any testing required under 40 CFR part 158 which involves any human subjects must comply with all applicable requirements under 40 CFR part 26. For example, 40 CFR part 26 requirements are pertinent to the 40 CFR part 158 testing requirement if the testing involves intentional exposure of human subjects. Protocols for such testing must be submitted to EPA for review prior to study initiation. Those protocols determined by EPA to involve intentional exposure of human subjects also require review by EPA's Human Studies Review Board (HSRB)) prior to study initiation. If you are uncertain about the applicability of the 40 CFR part 26 requirements to this 40 CFR part 158 testing requirement or uncertain about the nature of your planned testing (such as, for example, whether the testing would involve intentional exposure of human subjects or whether the testing would be an observational study), you should contact the Agency prior to initiating the testing.

(c) *Labeling claims for products other than skin-applied insect repellents.* Unless otherwise specified in §§ 158.1710 through 158.1786, for pesticides other than skin-applied insect repellents, the performance standard for a product performance claim against a pest must be greater than or equal to 90 percent, except for non-wearable spatial repellents where the

performance standard is greater than or equal to 75 percent.

§ 158.1705 Test Guidelines.

EPA has published the Harmonized Test Guidelines, which set forth the recommended approach to generate the data required in this subpart. The Product Performance Guidelines (Series 810, Group C -- Invertebrate Control Agent Test Guidelines) are available on the Agency's website. These guidelines cover some, but not all, of the tests that would be used to generate data under this subpart. In instances where there is a conflict between one of the Harmonized Test Guidelines and the provisions of this subpart, this subpart will control.

§ 158.1707 Data Requirement Modifications.

The data requirements (including the performance standards associated with the data requirements) specified in this subpart as applicable to a category of products will not always be appropriate for every product in that category. Data requirements may, on a case-by-case basis, be adjusted by EPA in response to requests for novel technologies or products that have unusual physical, chemical, or biological properties or atypical use patterns which would make a particular data requirement, or data performance standard, inappropriate. Requests for such data requirement modifications must be submitted the same manner as waiver requests submitted under 40 CFR 158.45. EPA will respond in writing to those requests. The Agency may modify data requirements it finds are inappropriate for the pesticide in question, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

§ 158.1708 Invasive species claims.

(a) *General*. In addition to those species specified in paragraph (b) of this section, if an application for registration or amended registration requests a labeling claim for effectiveness

against an invasive invertebrate species, then on a case-by-case basis, EPA may require submission of product performance data and establish performance standards for those data to support those claims for effectiveness.

(b) *Specific*. Applications for registration or amended registration requests for a labeling claim for the emerald ash borer, *Agrilus planipennis*, or Asian longhorned beetle, *Anoplophora glabripennis*, must be accompanied by product performance data to support those claims for effectiveness.

§ 158.1709 Invertebrate disease vector claims.

If an application for registration or amended registration requests a labeling claim specific to a disease vector (such as repels mosquitoes that may carry West Nile virus), then submission of testing conducted with the species specific to the disease vector claim and subject to specific performance standards is required even if the test species is not specifically required in §§ 158.1712 through 158.1786.

§ 158.1710 Structural and wood-destroying pest claims.

If an application for registration or amended registration requests a labeling claim specific to a structural or wood-destroying pest not identified in §§ 158.1782 through 158.1786, EPA may require submission of product performance data, with testing on that specific pest and subject to specific performance standards, to support those claims for effectiveness.

§ 158.1712 Mites (excluding Chiggers).

(a) *General*. The tables and test notes in this section apply to dust, human itch or scabies, and dog follicle mites. The claim stated on the pesticide product labeling determines the required test species. The required test species for a specific type of mite claim appear in paragraph (b) of this section and the required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For pesticide products making a claim against mites, the required test species appear in the following table.

Table 1 of 158.1712—Required Test Species for Products Making a Claim Against Mites (excluding Chiggers)

Labeling Claim	Required Test Species
Dog Follicle Mite	Dog follicle mite (*Demodex canis*)
Dust Mite	Testing on one of the following species is required: American house dust mite (*Dermatophagoides farinae*) OR European house dust mite (*Dermatophagoides pteronyssinus*)
Human Itch or Scabies Mite	Human itch mite (*Sarcoptes scabiei*)

(c) *Performance standards*. (1) For the dog follicle mite, a performance standard of 100 percent is required.

(2) For the human itch or scabies mite, a performance standard of 100 percent is required.

§ 158.1714 Chiggers.

If the pesticide product labeling makes a claim against chiggers, then testing is required using the following test species: Chigger (*Trombicula alfreddugesi*).

§ 158.1718 Ticks.

(a) *General*. The table and test notes in this section apply to hard ticks (including cattle ticks) and soft ticks. The claim stated on the pesticide product labeling determines the required test species. The required test species for a specific type of tick claim appear in paragraph (b) of this section. Specific parameters that apply to individual tests appear in paragraph (c) of this section. For a claim against any specific species of "ticks" that individual species and all the listed representative species for "ticks" must be tested, but not the representative species for cattle ticks or soft ticks. Claims against ticks in association with tick borne diseases are also subject to the requirements in § 158.1709.

(b) *Test species*. For pesticide products making a claim against ticks, the required test

species appear in the following table.

Table 1 of 158.1718—Required Test Species for Products Making a Claim Against Ticks

Labeling Claim	Required Test Species
Ticks	Testing on a total of three hard tick species is required: Blacklegged tick (*Ixodes scapularis*) AND Lone star tick (*Amblyomma americanum*) AND One of the following three species: American dog tick (*Dermacentor variabilis*) OR Brown dog tick (*Rhipicephalus sanguineus*) OR Rocky Mountain wood tick (*Dermacentor andersoni*)
Cattle Ticks	Testing on one of the following species is required: Southern cattle tick (*Rhipicephalus microplus*) OR Cattle fever tick (*Rhipicephalus annulatus*)
Soft Ticks	Soft tick (*Ornithodoros hermsi*)

(c) *Specific parameters*. The following parameters are required.

1. For products applied to dogs, testing is required on three species: Blacklegged tick (*Ixodes scapularis*), American dog tick (*Dermacentor variabilis*), and Brown dog tick (*Rhipicephalus sanguineus*).

2. For products applied to cats, testing is required on three species: Blacklegged tick (*Ixodes scapularis*), Lone star tick (*Amblyomma americanum*), and American dog tick (*Dermacentor variabilis*).

§ 158.1722 Scorpions.

If the pesticide product labeling makes a claim against scorpions, then testing is required using the following test species: Striped bark scorpion (*Centruroides vittatus*).

§ 158.1726 Spiders.

(a) *General*. The table in this section applies to spiders. The product labeling claim determines the required test species. The required test species for spider labeling claims appear

in paragraph (b) of this section.

(b) *Test species*. For products making a claim against spiders, the test species for labeling claims appear in the following table.

Table 1 of 158.1726—Required Test Species for Products Making a Claim Against Spiders

Labeling Claim	**Required Test Species**
Pest Group Claim	
Spiders	Testing on two species is required: Brown recluse spider (*Loxosceles reclusa*) AND One of the following species is required: Northern black widow spider (*Latrodectus variolus*) OR Southern black widow spider (*Latrodectus mactans*) OR Western black widow spider (*Latrodectus hesperus*)
Pest Sub-Group Claims	
Black Widow Spiders	Testing on one of the following species is required: Northern black widow spider (*Latrodectus variolus*) OR Southern black widow spider (*Latrodectus mactans*) OR Western black widow spider (*Latrodectus hesperus*)
Pest-Specific Claims	
Brown recluse spider	Brown recluse spider (*Loxosceles reclusa*)
Brown widow spider	Brown widow spider (*Latrodectus geometricus*)
Northern black widow spider	Northern black widow spider (*Latrodectus variolus*)
Southern black widow spider	Southern black widow spider (*Latrodectus mactans*)
Western black widow spider	Western black widow spider (*Latrodectus hesperus*)

§ 158.1732 Centipedes.

(a) *General*. The table in this section applies to centipedes. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of the section.

(b) *Test species*. For products making a claim against centipedes, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1732—Required Test Species for Products Making a Claim Against Centipedes

Labeling Claim	Required Test Species
Centipedes	Testing on one of the following species is required: House centipede (*Scutigera coleoptrata*) OR Florida blue centipede (*Hemiscolopendra marginata*) OR *Scolopendra* sp.

§ 158.1736 Lice.

(a) *General*. The table in this section applies to human lice. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against lice, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1736—Required Test Species for Products Making a Claim Against Lice

Labeling Claim	Required Test Species
Lice	Testing on one of the following species is required: Head louse (*Pediculus humanus capitis*) OR Body louse (*Pediculus humanus humanus*)

(c) *Performance standards*. For labeling claims against lice, a performance standard of 100 percent is required.

§ 158.1740 Fleas.

(a) *General*. The table in this section applies to fleas. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section.

(b) *Test species*. For products making a claim against fleas, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1740—Required Test Species for Products Making a Claim Against Fleas

Labeling Claim	Required Test Species
Pest Group Claim	
Fleas	Testing on the following species is required: Cat flea (*Ctenocephalides felis*)
Pest-Specific Claims	
Cat flea	Cat flea (*Ctenocephalides felis*)
Chigoe flea	Chigoe flea (*Tunga penetrans*)
Dog flea	Dog Flea (*Ctenocephalides canis*)
Hen flea	Hen flea (*Ceratophyllus gallinae*)
Human flea	Human flea (*Pulex irritans*)
Oriental rat flea	Oriental rat flea (*Xenopsylla cheopis*)

§ 158.1744 Cockroaches.

(a) *General*. The table in this section applies to cockroaches. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section. Specific parameters that apply to individual tests and labeling claims appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against cockroaches, the required test species for a labeling claim for cockroaches and the test species for pest-specific label claims appear in the following table.

Table 1 of 158.1744—Required Test Species for Products Making a Claim Against Cockroaches

Labeling Claim	Required Test Species
Pest Group Claims	
Cockroaches	Testing on two species is required: American cockroach (*Periplaneta americana*) AND German cockroach (*Blattella germanica*)
Pest-Specific Claims	
American cockroach	American cockroach (*Periplaneta americana*)
Australian cockroach	Australian cockroach (*Periplaneta australasiae*)
Brown cockroach	Brown cockroach (*Periplaneta brunnea*)
Brownbanded cockroach	Brownbanded cockroach (*Supella longipalpa*)
German cockroach	German cockroach (*Blattella germanica*)
Oriental cockroach	Oriental cockroach (*Blatta orientalis*)
Smokybrown cockroach	Smokybrown cockroach (*Periplaneta fuliginosa)*
Turkestan cockroach	Turkestan cockroach (*Blatta lateralis*)

§ 158.1748 Keds, Screwworms, and Bot Flies.

(a) *General*. The table in this section applies to keds, screwworms, and bot flies. The product labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against keds, screwworms, and bot flies, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1748—Required Test Species for Products Making a Claim Against Keds, Screwworms, and Bot Flies

Labeling Claim	Required Test Species
Bot Flies (excluding Human bot fly)	Testing is required on one of the following species: Horse bot fly (*Gasterophilus intestinalis*) OR Throat bot fly (*Gasterophilus nasalis*) OR Nose bot fly (*Gasterophilus haemorrhoidalis*)
Human bot fly	Human bot fly (*Dermatobia hominis*)
Keds	Testing is required on the following species: Sheep ked (*Melophagus ovinus*)
Screwworms	Testing is required on one of the following species: Screwworm (*Cochliomyia hominivorax*) OR Secondary screwworm (*Cochliomyia macellaria*)

§ 158.1752 Filth Flies.

(a) *General*. The table in this section applies to filth flies. The product labeling claim determines the required test species. The required test species for a labeling claim against filth flies or specific species of filth flies appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against filth flies, the required test species for a labeling claim against filth flies appear in the following tables.

Table 1 of 158.1752—Required Test Species for Products Making a Claim Against Filth Flies

Labeling Claim	Required Test Species
Pest Group Claim	
Filth Flies	Testing on two species is required:

	House fly (*Musca domestica*) AND One of the following species is required: Flesh fly (*Sarcophaga* sp., *Wohlfahrtia* sp., and other *genera* of flesh flies) OR Blow fly (*Phaenicia* sp., *Calliphora* sp., and other *genera* of blow flies)
Pest-Specific Claims	
Blow fly	Blow fly (*Phaenicia* sp., *Calliphora* sp., and other *genera* of blow flies)
Cluster fly	Cluster fly (*Pollenia rudis*)
Face fly	Face fly (*Musca autumnalis*)
Flesh fly	Flesh fly (*Sarcophaga* sp., *Wohlfahrtia* sp., and other *genera* of flesh flies)
House fly	House fly (*Musca domestica*)
Little house fly	Little house fly (*Fannia canicularis*)

§ 158.1756 Mosquitoes.

(a) *General*. The tables and test notes in this section apply to mosquitoes. The required test species for a labeling claim against mosquitoes appears in paragraph (b) of this section. For a claim against any specific species of mosquito, that individual species and all the required test genera must be tested. Claims against mosquitos in association with mosquito-borne diseases are also subject to the requirements in § 158.1709.

(b) *Test species*. For products making a claim against mosquitoes, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1756—Required Test Species for Products Making a Claim Against Mosquitoes

Labeling Claim	Required Test Species
Mosquitoes	Testing in three genera (*Culex*, *Aedes*, and *Anopheles*) of mosquitoes is required. One of the following *Culex* species: *Culex pipiens* OR *Culex quinquefasciatus* OR *Culex tarsalis* AND one of the following *Aedes* species: *Aedes aegypti*

	OR *Aedes albopictus* AND one of the following *Anopheles* species: *Anopheles albimanus* OR *Anopheles freeborni* OR *Anopheles gambiae* OR *Anopheles punctipennis* OR *Anopheles quadrimaculatus* OR *Anopheles stephensi*

§ 158.1760 Biting Flies.

(a) *General*. The tables in this section apply to biting flies, which includes biting midges and black flies. The product labeling claim determines the required test species. The required test species for biting fly labeling claims and the test species for pest-specific labeling claims appear in paragraphs (b) of this section.

(b) *Test species*. For products making a claim against biting flies, the required test species for a labeling claim and the test species for pest-specific label claims appear in the following table.

Table 1 of 158.1760—Required Test Species for Products Making a Claim Against Biting Flies

Labeling Claim	**Required Test Species**
Pest Group Claim	
Biting flies (excluding Sand flies)	Testing is required on three species: Stable fly (*Stomoxys calcitrans*) AND one of the large biting fly species: Black horse fly (*Tabanus atratus*) OR Deer fly (*Chrysops* sp.) OR Striped horse fly (*Tabanus lineola*) AND one of the small biting fly species: Biting midge (punkie, granny nipper, no-see-um) (any

	Culicoides sp.) OR Black fly (any *Simulium* sp. or *Prosimulium* sp.) OR Black gnat (any *Leptoconops* sp.)
Pest Sub-Group Claims	
Large Biting Flies	Testing is required on two species: Stable fly (*Stomoxys calcitrans*) AND one of the following species: Black horse fly (*Tabanus atratus*) OR Deer fly (*Chrysops* sp.) OR Striped horse fly (*Tabanus lineola*)
Small Biting Flies (excluding Sand flies)	Testing is required on one of the following species: Biting midge (punkie, granny nipper, no-see-um) (*Culicoides* sp.) OR Black fly (*Simulium* sp. OR *Prosimulium* sp.) OR Black gnat (*Leptoconops* sp.)
Pest-Specific Claims	
Biting midges (punkie, granny nipper, no-see-um)	Biting midge (punkie, granny nipper, no-see-um) (*Culicoides* sp.)
Black flies	Testing on one of the following species is required: *Simulium* sp. OR *Prosimulium* sp.
Black gnats	Black gnat (*Leptoconops* sp.)
Deer flies	Deer fly (*Chrysops* sp.)
Greenhead	Greenhead (*Tabanus nigrovittatus*)
Horn fly	Horn fly (*Haematobia irritans*)
Horse flies	Testing on one of the following species is required: Black horse fly (*Tabanus atratus*), OR Striped horse fly (*Tabanus lineola*)
Sand flies	Testing on one of the following species is required: *Lutzomyia* sp. OR *Phlebotomus* sp.
Stable fly	Stable fly (*Stomoxys calcitrans*)

§ 158.1768 Bed Bugs.

(a) *General*. The table in this section applies to bed bugs. The product labeling claim

determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section.

(b) *Test species*. For products making a claim against bed bugs, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1768—Required Test Species for Products Making a Claim Against Bed Bugs

Labeling Claim	**Required Test Species**
Pest Group Claim	
Bed bugs	Common bed bug (*Cimex lectularius*)
Pest-Specific Claims	
Common bed bug	Common bed bug (*Cimex lectularius*)
Tropical bed bug	Tropical bed bug (*Cimex hemipterus*)

§ 158.1772 Conenose Bugs and Kissing Bugs.

(a) *General*. The table in this section applies to Conenose bugs and Kissing bugs. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section.

(b) *Test species*. For products making a claim against either the conenose and/or kissing bugs, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1772—Required Test Species for Products Making a Claim Conenose and Kissing Bugs

Labeling Claim	**Required Test Species**
Conenose bug	Conenose bug (*Triatoma sanguisuga*)
Kissing bug	Kissing bug (*Triatoma protracta*)

§ 158.1776 Ants (excluding carpenter ants).

(a) *General*. The table in this section applies to ants (excluding carpenter ants). The product labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against ants (excluding carpenter ants), the required test species for a labeling claim appear in the following table, unless otherwise specified

in paragraphs (c) or (d).

Table 1 of 158.1776—Required Test Species for Products Making a Claim Against Ants (excluding carpenter ants)

Labeling Claim	**Required Test Species**
Pest Group Claim	
Ants (excluding carpenter ants)	Testing is required on the following two species: Pharaoh ant (*Monomorium pharaonis*) AND Red imported fire ant (*Solenopsis invicta*)
Pest Sub-Group Claim	
Fire and Harvester	Testing is required on the following species: Red imported fire ant (*Solenopsis invicta*)
Fire ants	Testing is required on the following species: Red imported fire ant (*Solenopsis invicta*)
Pest-Specific Claims	
European fire ant	European fire ant (*Myrmica rubra*)
Harvester ant	Harvester ant (*Pogonomyrmex* sp.)
Pharaoh ant	Pharaoh ant (*Monomorium pharaonis*)
Red imported fire ant	Red imported fire ant (*Solenopsis invicta*)
Southern fire ant	Southern fire ant (*Solenopsis xyloni*)
Tropical fire ant	Tropical fire ant (*Solenopsis geminata*)
Black imported fire ant	Black imported fire ant (*Solenopsis richteri*)

(c) *Colony Claims*. For colony claims, testing must be done specific to the species listed. For colony claims against the red and/or black imported fire ants, testing may be done on, *S. invicta*, *S. richteri*, or their hybrid.

(d) *Bait products or claims involving outdoor use*. The group and sub-group claims in paragraph (b) are for direct kill and residual surface application claims against foraging ants only (excluding colony claims). For bait products or claims involving outdoor use, testing must be specific to the species listed.

§ 158.1780 Bees, Wasps, Yellowjackets, and Hornets.

(a) *General*. The table in this section applies to bees, wasps, yellowjackets, and hornets. The labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against bees, wasps, yellowjackets, and hornets, the required test species for a labeling claim appear in the following table, unless otherwise specified in paragraph (c).

Table 1 of 158.1780—Required Test Species for Products Making a Claim Against Bees, Wasps, Yellowjackets, and Hornets

Labeling Claim	Required Test Species
Pest Group Claims	
Bees, Wasps, Yellowjackets, and Hornets	Testing on three species is required: Two Yellowjacket species (one *Vespula* sp. AND the Bald-faced hornet (*Dolichovespula maculata*)) AND one Paper wasp (*Polistes* sp.)
Pest-Specific Claims	
Bald-faced hornet	Bald-faced hornet (*Dolichovespula maculata*)
Mud dauber wasp	Mud dauber wasp (*Sphecidae* sp.)
Paper wasp	Paper wasp (*Polistes* sp.)
Yellowjackets	Yellowjacket (*Vespula* sp.)

c) *Colony Claims*. For colony claims, except *Vespula* spp., testing must be specific to the species listed. Acceptable data for any *Vespula* species may support a yellowjacket colony claim for ground nesting *Vespula* species; however, species-specific claims need to be supported by data from testing of the specific species. Colony claims against *Vespula* spp. have a performance standard of 100%.

§ 158.1782 Carpenter Ants.

(a) *General*. The table in this section applies to carpenter ants. The product labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against carpenter ants, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1782—Required Test Species for Products Making a Claim Against Carpenter Ants

Labeling Claim	Required Test Species
Carpenter ants	Testing on one of the following carpenter ant species is required: Black carpenter ant (*Camponotus pennsylvanicus*) OR Florida carpenter ant (*Camponotus floridanus*) OR Western carpenter ant (*Camponotus modoc*)

(c) *Performance standards*. The performance standards for pesticide products making certain claims against carpenter ants appear in the following table. The performance standards for labeling claims that are not specifically provided in the following table appear in § 158.1704.

Table 2 of 158.1782—Performance Standards for Certain Claims Against Carpenter Ants

Application Category	Performance Standard
Bait Treatment	95% prevention of damage to wood for ≥ 3 years
Non-Structural: Wood Preservative Treatment	100% prevention of damage to wood for ≥ 2 years
Structural Protection	95% prevention of damage to wood ≥ 5 years

§ 158.1784 Wood-destroying beetles.

(a) *General*. The tables and test notes in this section apply to wood-destroying beetles. The labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against wood-destroying beetles, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1784—Required Test Species for Products Making a Claim Against Wood-Destroying Beetles

Labeling Claim	Required Test Species
True powderpost beetles	Testing on one species from the Lyctinae subfamily is required.

Wood-destroying or wood-boring beetles	Testing on three species is required: Anobiid beetle (*Anobiidae* sp.) AND Bostrichid beetle (*Bostrichidae* sp.) AND Old house borer (*Hylotrupes bajulus*)

(c) *Performance standards*. The performance standards for pesticide products making certain claims against wood-destroying beetles appear in the following table. The performance standards for labeling claims that are not specifically provided in the following table appear in § 158.1704.

Table 2 of 158.1784—Performance Standards for Certain Claims against Wood-Destroying Beetles

Application Category	Performance Standard
Bait Treatment	95% prevention of damage to wood ≥ 3 years
Non-Structural: Wood Preservative Treatment	100% prevention of damage to wood for ≥ 2 years
Structural Protection	95% prevention of damage to wood ≥ 5 years

§ 158.1786 Termites.

(a) *General*. The tables and test notes in this section apply to the subterranean termite, desert subterranean termite, Formosan subterranean termite, drywood termite, and dampwood termite. The labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against termites, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1786—Required Test Species for Products Making a Claim Against Termites

Labeling Claim	Required Test Species
Pest Group Claim	
Termites	Testing on species from four genera of termites is required: Testing is required on the following *Coptotermes* termite: *Coptotermes formosanus*

	AND one of the following *Reticulitermes* species: *Reticulitermes flavipes* OR *Reticulitermes hesperus* OR *Reticulitermes virginicus* AND one of the following arboreal termite species: *Nasutitermes coringer* (Motschulsky) AND one of the following drywood termite species: *Cryptotermes brevis* OR *Cryptotermes cavifrons* OR *Incisitermes minor* OR *Incisitermes snyderi*
Pest Sub-Group Claim	
Arboreal Termites	Testing of one arboreal termite species is required: *Nasutitermes coringer* (Motschulsky)
Dampwood Termites	Testing of the following dampwood termite is required: *Zootermopsis* sp.
Drywood Termites	Testing of one of the following drywood termites is required: *Cryptotermes brevis* OR *Cryptotermes cavifrons* OR *Incisitermes minor* OR *Incisitermes snyderi*
Subterranean Termites, including Formosan Subterranean Termites	Testing in two genera of termites is required: Testing on the following *Coptotermes* species is required: *Coptotermes formosanus* AND one of the following *Reticulitermes* species: *Reticulitermes flavipes* OR *Reticulitermes hesperus* OR *Reticulitermes virginicus*

(c) *Performance standards*. The performance standards for pesticide products making certain claims against termites appear in the following table. The performance standards for labeling claims not provided in the following table appear in § 158.1704.

Table 2 of 158.1786—Performance Standards for Certain Claims Against Termites

Application Category	Performance Standard
Bait Treatment	95% prevention of damage to wood ≥3 years
Non-Structural: Wood Preservative Treatment	100% Prevention of damage to wood for ≥ 2 years
Structural Protection	95% prevention of damage to wood ≥ 5 years

5. Revise § 158.2070 in subpart U to read as follows:

§ 158.2070 Biochemical Pesticides Product Performance Data Requirements.

(a) *General*. Product performance data must be developed for all biochemical pesticides. Each applicant must ensure through testing that the product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(b) *Product performance data for each product that bears a claim against an invertebrate pest that is covered by subpart R of this Part*. The product performance data requirements of subpart R of this part apply to biochemical products covered by this subpart. Product performance data must be submitted with any application for registration or amended registration. The performance standards required in subpart R of this part also apply to biochemical pesticide products. However, data requirements and the performance standards that determine the acceptability of data may be modified on a case-by-case basis pursuant to the waiver provisions in 40 CFR 158.45 and the provisions in 40 CFR 158.1707.

(c) *Product performance data for each product that bears a public health claim, excluding those covered under paragraph (b)*. Product performance data must be submitted with any application for registration or amended registration, if the product bears a claim to control public health pests, such as pest microorganisms infectious to humans in any area of the inanimate environment, or a claim to control vertebrates, including but not limited to, rodents,

birds, bats, canids, and skunks.

6. Revise § 158.2160 in subpart V to read as follows:

§ 158.2160 Microbial Pesticides Product Performance Data Requirements.

(a) *General*. Product performance data must be developed for all microbial pesticides. Each applicant must ensure through testing that the product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(b) *Product performance data for each product that bears a claim against an invertebrate pest that is covered by subpart R of this part*. The product performance data requirements of subpart R of this part apply to microbial products covered by this subpart. Product performance data must be submitted with any application for registration or amended registration. However, data requirements and the performance standards that determine the acceptability of data may be modified on a case-by-case basis pursuant to the waiver provisions in 40 CFR 158.45 and the provisions in 40 CFR 158.1707.

(c) *Product performance data for each product that bears a public health claim, excluding those covered under paragraph (b)*. Product performance data must be submitted with any application for registration or amended registration, if the product bears a claim to control public health pests, such as pest microorganisms infectious to humans in any area of the inanimate environment, or a claim to control vertebrates, including but not limited to, rodents, birds, bats, canids, and skunks.

7. In § 158.2200, revise paragraph (b) in subpart W to read as follows:

§ 158.2200 Applicability.

* * * * *

(b) *A product that bears both antimicrobial and non-antimicrobial uses or claims*. Such a product is subject to the data requirements for pesticides in subparts C through O, R, and U or V of this part with respect to its non-antimicrobial uses and claims, and to the requirements of this subpart with respect to its antimicrobial uses and claims.

* * * * *

Message

From: HQ_Facilities_Updates [HQ_Facilities_Updates@epa.gov]
Sent: 1/6/2021 10:16:15 PM
To: All HQ Feds-nonFeds [All_HQ_Feds-nonFeds@epa.gov]
Subject: Mandatory City-Wide Curfew Schedule to Begin 6:00 PM Today -- Revised Draft

EPA

Office of Mission Support

This email message is being sent to HQ EPA employees

DC Mayor Browser has instituted a city-wide curfew beginning at 6:00PM this evening. All entrances to EPA buildings at the Federal Triangle will be locked at that time. We encourage all EPA staff and contractors to exit the facilities before 6:00pm.

If you are still in the building after 6pm and require assistance, please contact the HQ Guard Command Center at 202-564-1120. For all other inquiries, please send an email to HQSECURITY@epa.gov.

Please monitor news outlets for further information on the DC operational status.

Message

From: Staff Secretary [Ex. 6]
Sent: 1/6/2021 8:21:22 PM
To: Lair, Kate E. EOP/WHO [Ex. 6]; Philbin, Patrick F. EOP/WHO [Ex. 6]; Eisenberg, John A. EOP/WHO [Ex. 6]; DL OMB ExecSec [Ex. 6]; Gilmartin, Kayleigh M. EOP/WHO [Ex. 6]; Hahn, Julia A. EOP/WHO [Ex. 6]; Liddell, Christopher P. EOP/WHO [Ex. 6]; Butterfield, Nicholas W. EOP/WHO [Ex. 6]; DL Chief of Staff Office [Ex. 6]; Hicks, Hope C. EOP/WHO [Ex. 6]; Luna, Cassidy M. EOP/WHO [Ex. 6]; Boyd, Charlton J. EOP/WHO [Ex. 6]; Lahasky, Rosemary A. EOP/WHO [Ex. 6]; Radford, Julie T. EOP/WHO [Ex. 6]; Wiggins, Jeremy G. EOP/WHO [Ex. 6]; Willens, Todd D [todd_willens@ios.doi.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Droegemeier, Kelvin K. EOP/OSTP [Ex. 6]; Kratsios, Michael J. EOP/OSTP [Ex. 6]; Parry, Preston J. EOP/WHO [Ex. 6]; Chalkey, Richard J. EOP/WHO [Ex. 6]; Pataki, Tim A. EOP/WHO [Ex. 6]; Veletsis, Alexandra E. EOP/WHO [Ex. 6]; Parnitzke, Kate L. EOP/WHO [Ex. 6]
CC: Staff Secretary [Ex. 6]
Subject: For Review: Draft CEQ Accomplishments Document and Blog Post
Attachments: 20210105 Draft Condensed Environmental Accomplishments Document CLEAN.docx; 210105 - DRAFT Accomplishments Blog CLEAN.docx

Attached for your review is a draft CEQ accomplishments document and a draft accomplishments blog that highlights the Administration's work over the past four years. These are intended for posting on CEQ's website.

Affirmative clearances are requested from **WHCO, NEC, and EPA**. All others are also welcome to comment.

Please review and send all edits and clearances to STAFF SEC **by 3 p.m. on Friday, January 8**.

Thank you,

STAFF SEC

The Trump Administration's Environmental Accomplishments

Ex. 5 Deliberative Process (DP)

January 2021

DRAFT

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

67265 (October 22, 2020).

Ex. 5 Deliberative Process (DP)

White House Council on Environmental Quality Highlights Trump Administration Environmental Accomplishments

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Message

From: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
Sent: 1/6/2021 10:48:30 PM
To: Bolen, Brittany [bolen.brittany@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: Cyanide
Attachments: FRN Cyanide RTR Proposal 4Jan21_Admin.docx

Done, and done

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2020-0532; FRL-10018-49-OAR]

RIN 2060-AU64

National Emission Standards for Hazardous Air Pollutants: Cyanide Chemicals Manufacturing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing the results of the residual risk and technology review (RTR) for the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Cyanide Chemicals Manufacturing source category as required under the Clean Air Act (CAA). We are proposing to find that risk from emissions of air toxics from this source category is acceptable, and that the current standards provide an ample margin of safety to protect public health. We are also proposing to find that there are no developments in practices, processes, and control technologies, and, as such, we are not proposing any development-based changes to the current standards pursuant to the technology review. The EPA is, however, proposing new emissions standards to address emissions from process wastewater at existing sources. We are proposing to amend provisions addressing startup, shutdown, and malfunction (SSM), to add electronic reporting, and to update the reporting and recordkeeping requirements. We do not expect these proposed amendments to result in changes in emissions from the source category but anticipate improved monitoring, compliance, and implementation of the existing standards.

DATES:.Comments must be received on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Public hearing: If anyone contacts us requesting a public hearing on or before **[INSERT DATE 5 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OAR-2020-0532, by any of the following methods:

- Federal eRulemaking Portal: *https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- Email: *a-and-r-docket@epa.gov*. Include Docket ID No. EPA-HQ-OAR-2020-0532 in the subject line of the message.
- Fax: (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2020-0532.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2020-0532, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

- Hand/Courier Delivery: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. – 4:30 p.m., Monday – Friday (except federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/*, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Nathan Topham, Sector Policies and Programs Division (D243-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-0483; fax number: (919) 541-4991; and email address: *topham.nathan@epa.gov*. For specific information regarding the risk modeling methodology, contact James Hirtz, Health and Environmental Impacts Division (C539-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research

Triangle Park, North Carolina 27711; telephone number: (919) 541-0881; fax number: (919) 541-0840; and email address: *Hirtz.James@epa.gov*.

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. Please note that the EPA is deviating from its typical approach for public hearings because the President has declared a national emergency. Due to the current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID-19, the EPA cannot hold in-person public meetings at this time.

To request a virtual public hearing, contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov*. If requested, the virtual hearing will be held on **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The hearing will convene at 9:00 a.m. Eastern Time (ET) and will conclude at 3:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*.

The EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**, if a hearing is requested. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen* or contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov*. The last day to pre-register to speak at the hearing will be **[INSERT DATE 12 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Prior to the hearing, the EPA will

post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*.

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *topham.nathan@epa.gov*. The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*. While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372-8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or a special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your

needs by **[INSERT DATE 7 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA-HQ-OAR-2020-0532. All documents in the docket are listed in *https://www.regulations.gov*. Although listed, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. With the exception of such material, publicly available docket materials are available electronically in Regulations.gov.

Instructions. Direct your comments to Docket ID No. EPA-HQ-OAR-2020-0532. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/*, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia

submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets*.

The EPA is temporarily suspending its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* as there may be a delay in processing mail and faxes. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets*.

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID-19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404-02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA-HQ-OAR-2020-0532. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

AEGL	acute exposure guideline level
AERMOD	air dispersion model used by the HEM-3 model
CAA	Clean Air Act
CalEPA	California EPA
CBI	Confidential Business Information
CFR	Code of Federal Regulations
EPA	Environmental Protection Agency
ERPG	emergency response planning guideline
ERT	Electronic Reporting Tool
HAP	hazardous air pollutant(s)
HCl	hydrochloric acid
HEM-3	Human Exposure Model, Version 1.5.5
HF	hydrogen fluoride
HI	hazard index
HQ	hazard quotient
IRIS	Integrated Risk Information System
km	kilometer
MACT	maximum achievable control technology
mg/kg-day	milligrams per kilogram per day
mg/m^3	milligrams per cubic meter
MIR	maximum individual risk
NAAQS	National Ambient Air Quality Standards
NAICS	North American Industry Classification System
NESHAP	national emission standards for hazardous air pollutants
NRC	National Research Council
OAQPS	Office of Air Quality Planning and Standards
OMB	Office of Management and Budget
PAH	polycyclic aromatic hydrocarbons
PB-HAP	hazardous air pollutants known to be persistent and bio-accumulative in the environment
PM	particulate matter
POM	polycyclic organic matter
ppm	parts per million
REL	reference exposure level
RFA	Regulatory Flexibility Act
RfC	reference concentration
RfD	reference dose
RTR	residual risk and technology review

SAB	Science Advisory Board
SBA	Small Business Administration
SSM	startup, shutdown, and malfunction
SV	screening value
TOSHI	target organ-specific hazard index
tpy	tons per year
TRIM.FaTE	Total Risk Integrated Methodology.Fate, Transport, and Ecological Exposure model
UF	uncertainty factor
$\mu g/m^3$	microgram per cubic meter
URE	unit risk estimate
VCS	voluntary consensus standards

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
II. Background
A. What is the statutory authority for this action?
B. What is this source category and how does the current NESHAP regulate its HAP emissions?
C. What data collection activities were conducted to support this action?
D. What other relevant background information and data are available?
III. Analytical Procedures and Decision-Making
A. How do we consider risk in our decision-making?
B. How do we perform the technology review?
C. How do we estimate post-MACT risk posed by the source category?
IV. Analytical Results and Proposed Decisions
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J. National Technology Transfer and Advancement Act (NTTAA)
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I. General Information

A. Does this action apply to me?

The source category that is the subject of this proposal is cyanide chemicals manufacturing major sources regulated under 40 CFR 63, subpart YY. The North American Industry Classification System (NAICS) codes for the cyanide chemicals manufacturing industry are 325188 and 325199. This list of categories and NAICS codes is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, state, local, and tribal government entities would not be affected by this proposed action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576, July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (see EPA-450/3-91-030, July 1992), the Cyanide Chemicals Manufacturing source category is any facility engaged in the production of hydrogen cyanide or sodium cyanide. Hydrogen cyanide production includes, but is not limited to, production of hydrogen cyanide using any of the following

methods: reaction of methane and ammonia over a platinum catalyst, reaction of methane and ammonia over a platinum-rhodium catalyst, co-production with acrylonitrile (via Sohio process), or pyrolysis of formaldehyde. Sodium cyanide production includes, but is not limited to, production of sodium cyanide via the neutralization process, or so-called wet process. In this process, hydrogen cyanide reacts with sodium hydroxide solution usually in a reactor that involves evaporation of water and crystallization of the product, commonly called white cyanide.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website. Information on the overall RTR program is available at *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html*.

The proposed changes to the CFR that would be necessary to incorporate the changes proposed in this action are set out in an attachment to the memorandum titled *Proposed Regulation Edits for 40 CFR Part 63, Subpart YY*, available in the docket for this action (Docket ID No. EPA-HQ-OAR-2020-0532). The document includes the specific proposed amendatory language for revising the CFR and, for the convenience of interested parties, a redline version of the regulation. Following signature by the EPA Administrator, the EPA will also post a copy of this memorandum and the attachments to *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*.

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the CAA, as amended (42 U.S.C. 7401 *et seq.*). Section 112 of the CAA establishes a two-stage regulatory process to develop standards for emissions of hazardous air pollutants (HAP) from stationary sources. Generally, the first stage involves establishing technology-based standards and the second stage involves evaluating those standards that are based on maximum achievable control technology (MACT) to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the "residual risk review." In addition to the residual risk review, the CAA also requires the EPA to review standards set under CAA section 112 every 8 years and revise the standards as necessary taking into account any "developments in practices, processes, or control technologies." This review is commonly referred to as the "technology review." When the two reviews are combined into a single rulemaking, it is commonly referred to as the "risk and technology review." The discussion that follows identifies the most relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology*, in the docket for this rulemaking.

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. "Major sources" are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any

combination of HAP. All other sources are "area sources." For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT "floor." In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as beyond-the-floor standards. For area sources, CAA section 112(d)(5) gives the EPA discretion to set standards based on generally available control technologies or management practices (GACT standards) in lieu of MACT standards.

The second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.,* "residual") risk pursuant to CAA section 112(f). For source categories subject to MACT standards, section 112(f)(2) of the CAA requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. Section 112(d)(5) of the CAA provides that this residual risk review is not required for categories of area sources subject to GACT standards. Section 112(f)(2)(B) of the CAA further expressly preserves the EPA's use of the two-step approach for developing standards to address any residual risk and the Agency's interpretation of "ample margin of safety" developed in the National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP) (54 FR 38044, September 14, 1989). The EPA notified Congress in the

Residual Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA–453/R–99–001, p. ES–11). The EPA subsequently adopted this approach in its residual risk determinations and the United States Court of Appeals for the District of Columbia Circuit (the court) upheld the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. See *NRDC v. EPA*, 529 F.3d 1077, 1083 (D.C. Cir. 2008).

The approach incorporated into the CAA and used by the EPA to evaluate residual risk and to develop standards under CAA section 112(f)(2) is a two-step approach. In the first step, the EPA determines whether risks are acceptable. This determination "considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR)[1] of approximately 1 in 10 thousand." (54 FR 38045). If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health "in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision." *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety

[1] Although defined as "maximum individual risk," MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime.

analysis, we consider whether a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

CAA section 112(d)(6) separately requires the EPA to review standards promulgated under CAA section 112 and revise them "as necessary (taking into account developments in practices, processes, and control technologies)" no less often than every 8 years. In conducting this review, which we call the "technology review," the EPA is not required to recalculate the MACT floor. *Natural Resources Defense Council (NRDC) v. EPA*, 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc. v. EPA*, 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6). The EPA is required to address regulatory gaps, such as missing standards for listed air toxics known to be emitted from the source category. *Louisiana Environmental Action Network (LEAN) v. EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

B. What is this source category and how does the current NESHAP regulate its HAP emissions?

The MACT standards for the Cyanide Chemicals Manufacturing source category are contained in the Generic Maximum Achievable Control Technology (GMACT) NESHAP which also includes MACT standards for several other source categories. The cyanide chemicals manufacturing standards were promulgated on July 12, 2002, (67 FR 46258) and codified at 40 CFR part 63, subpart YY. As promulgated in 2002, the cyanide chemicals manufacturing standards regulate HAP emissions from cyanide chemicals manufacturing units located at major sources. The HAP emitted from the source category include cyanide compounds (hydrogen cyanide and sodium cyanide), acetonitrile, and acrylonitrile.

The NESHAP defines the affected source as each cyanide chemicals manufacturing process unit (CCMPU). The rule states that the CCMPU is the equipment assembled and

connected by hard-piping or duct work to process raw materials to manufacture, store, and transport a cyanide chemicals product. A CCMPU shall be limited to any one of the following: an Andrussow process unit, a Blausaure Methane Anlage process unit, a sodium cyanide process unit, or a Sohio hydrogen cyanide process unit. For the purpose of this subpart, a CCMPU includes reactors and associated unit operations, associated recovery devices, and any feed, intermediate and product storage vessels, product transfer racks, and connected ducts and piping. A CCMPU also includes pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, and control devices or systems.

The NESHAP established emissions standards for process vents, storage vessels, transfer racks, and equipment leaks. Cyanide process vents are subject to a 98 weight-percent reduction of total HAP[2] performance standard or 20 parts per million by volume (ppmv) total HAP outlet exit concentration limit. For storage vessels in the Cyanide Chemicals Manufacturing source category, sources may either choose to comply with a 98 weight-percent reduction of hydrogen cyanide performance standard, a 20 ppmv hydrogen cyanide exit outlet concentration limit, or equipment standards (*e.g.*, use a flare). Transfer racks are subject to equipment standards or the same performance standard or concentration limit[3] as cyanide process vents. Equipment leaks are subject to work practice standards required by either 40 CFR part 63, subpart TT or subpart UU.

C. *What data collection activities were conducted to support this action?*

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[2] "Dry end" process vents at sodium cyanide units must meet a 98 percent reduction performance standard for emissions of sodium cyanide since this is the form of cyanide compounds emitted from these emission points. The HAP emitted from other process vents that make up the "total HAP" emitted from these sources are hydrogen cyanide, acetonitrile, and acrylonitrile.

[3] Transfer racks emissions limits are expressed in terms of hydrogen cyanide as this is the only HAP emitted from these sources.

The EPA used a variety of resources to obtain data about facilities and their emissions for use in our risk assessment. We used the EPA's Enforcement and Compliance History Online (ECHO) database to develop a list of potentially subject facilities. Using this list, we searched state environmental agency websites and correspondence with industry to obtain copies of title V permits to confirm whether facilities have cyanide chemicals manufacturing subject to the NESHAP. Once the facility list was finalized, the EPA used the 2017 National Emissions Inventory (NEI) to get emissions data for each facility. We compared the NEI data to title V permits to provide additional information regarding the applicability of the Cyanide Chemicals Manufacturing NESHAP. Further discussion of the methodology used to develop the emissions dataset for the risk assessment can be found in the memorandum titled *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, which is available in the docket for this action.

D. What other relevant background information and data are available?

We searched for information from the Reasonably Available Control Technology, Best Available Control Technology, and Lowest Achievable Emission Rate Clearinghouse (RBLC) database, reviewed title V permits for each cyanide chemicals manufacturing facility, and reviewed regulatory actions related to emissions controls at similar sources that could be applicable to cyanide chemicals manufacturing. We reviewed the RBLC to identify potential additional control technologies. No additional control technologies applicable to cyanide chemicals manufacturing were found using the RBLC. Additional information related to the promulgation and subsequent amendments of the NESHAP is available in docket ID: No. EPA-HQ-OAR-2004-0041.

III. Analytical Procedures and Decision-Making

In this section, we describe the analyses performed to support the proposed decisions for the RTR and other issues addressed in this proposal.

A. How do we consider risk in our decision-making?

As discussed in section II.A of this preamble and in the Benzene NESHAP, in evaluating and developing standards under CAA section 112(f)(2), we apply a two-step approach to determine whether or not risks are acceptable and to determine if the standards provide an ample margin of safety to protect public health. As explained in the Benzene NESHAP, "the first step judgment on acceptability cannot be reduced to any single factor" and, thus, "[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information." (54 FR at 38046). Similarly, with regard to the ample margin of safety determination, "the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors." *Id.*

The Benzene NESHAP approach provides flexibility regarding factors the EPA may consider in making determinations and how the EPA may weigh those factors for each source category. The EPA conducts a risk assessment that provides estimates of the MIR posed by emissions of HAP that are carcinogens from each source in the source category, the hazard index (HI) for chronic exposures to HAP with the potential to cause noncancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause noncancer health effects.[4] The assessment also provides estimates of the distribution of cancer risk within the

[4] The MIR is defined as the cancer risk associated with a lifetime of exposure at the highest concentration of HAP where people are likely to live. The HQ is the ratio of the potential HAP

exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The scope of the EPA's risk analysis is consistent with the explanation in EPA's response to comments on our policy under the Benzene NESHAP:

> The policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of non-cancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the *Vinyl Chloride* mandate that the Administrator ascertain an acceptable level of risk to the public by employing his expertise to assess available data. It also complies with the Congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and thereby implicitly permits consideration of any and all measures of health risk which the Administrator, in his judgment, believes are appropriate to determining what will "protect the public health.

(54 FR at 38057). Thus, the level of the MIR is only one factor to be weighed in determining acceptability of risk. The Benzene NESHAP explained that "an MIR of approximately one in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes an MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors." *Id.* at 38045. In other words, risks that include an MIR above 100-in-1 million may be determined to be acceptable, and risks with an MIR below that level may be determined to be unacceptable, depending on all of the available health information. Similarly, with regard to the ample margin of safety analysis, the EPA stated in the Benzene NESHAP that: "EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of

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exposure concentration to the noncancer dose-response value; the HI is the sum of HQs for HAP that affect the same target organ or organ system.

safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category." *Id.* at 38061. We also consider the uncertainties associated with the various risk analyses, as discussed earlier in this preamble, in our determinations of acceptability and ample margin of safety.

The EPA notes that it has not considered certain health information to date in making residual risk determinations. At this time, we do not attempt to quantify the HAP risk that may be associated with emissions from other facilities that do not include the source category under review, mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in the category.

The EPA understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. We recognize that such consideration may be particularly important when assessing noncancer risk, where pollutant-specific exposure health reference levels (*e.g.*, reference concentrations (RfCs)) are based on the assumption that thresholds exist for adverse health effects. For example, the EPA recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk of adverse noncancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (*e.g.*, other facilities) to which an individual is exposed may be sufficient to result in an increased risk of adverse noncancer health effects. In May 2010, the Science Advisory Board (SAB) advised the EPA "that RTR assessments will be most useful to decision makers and communities if results are presented in

the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area."[5]

In response to the SAB recommendations, the EPA incorporates cumulative risk analyses into its RTR risk assessments. The Agency (1) conducts facility-wide assessments, which include source category emission points, as well as other emission points within the facilities; (2) combines exposures from multiple sources in the same category that could affect the same individuals; and (3) for some persistent and bioaccumulative pollutants, analyzes the ingestion route of exposure. In addition, the RTR risk assessments consider aggregate cancer risk from all carcinogens and aggregated noncancer HQs for all noncarcinogens affecting the same target organ or target organ system.

Although we are interested in placing source category and facility-wide HAP risk in the context of total HAP risk from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. Estimates of total HAP risk from emission sources other than those that we have studied in depth during this RTR review would have significantly greater associated uncertainties than the source category or facility-wide estimates. Such aggregate or cumulative assessments would compound those uncertainties, making the assessments too unreliable.

B. How do we perform the technology review?

Our technology review primarily focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the

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[5] Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, which is available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf.*

MACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions associated with applying each development. This analysis informs our decision of whether it is "necessary" to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a "development":

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT standards) that could result in additional emissions reduction;
- Any work practice or operational procedure that was not identified or considered during development of the original MACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT standards; and
- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed (or last updated) the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls. We also

review the NESHAP and the available data to determine if there are any unregulated emissions of HAP within the source category and evaluate this data for use in developing new emission standards. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

C. How do we estimate post-MACT risk posed by the source category?

In this section, we provide a complete description of the types of analyses that we generally perform during the risk assessment process. In some cases, we do not perform a specific analysis because it is not relevant. For example, in the absence of emissions of HAP known to be persistent and bioaccumulative in the environment (PB-HAP), we would not perform a multipathway exposure assessment. Where we do not perform an analysis, we state that we do not and provide the reason. While we present all of our risk assessment methods, we only present risk assessment results for the analyses actually conducted (see section IV.B of this preamble).

The EPA conducts a risk assessment that provides estimates of the MIR for cancer posed by the HAP emissions from each source in the source category, the HI for chronic exposures to HAP with the potential to cause noncancer health effects, and the HQ for acute exposures to HAP with the potential to cause noncancer health effects. The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The seven sections that follow this paragraph describe how we estimated emissions and conducted the risk assessment. The docket for this rulemaking contains the following document which provides more information on the risk assessment inputs and models: *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the 2020 Risk and Technology Review Proposed*

Rule. The methods used to assess risk (as described in the seven primary steps below) are consistent with those described by the EPA in the document reviewed by a panel of the EPA's SAB in 2009;[6] and described in the SAB review report issued in 2010. They are also consistent with the key recommendations contained in that report.

1. How did we estimate actual emissions and identify the emissions release characteristics?

The list of facilities subject to the NESHAP was created through searching the EPA's ECHO database, the 2017 NEI, and state databases of title V permits. The list of facilities is available in the memorandum titled *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*. Once the facility list was finalized, available emissions data were obtained from the NEI. Title V permits were used to determine which emission points at each facility are subject to the Cyanide Chemicals Manufacturing NESHAP.

We compared the NEI data to title V permits to confirm that the NEI included all emission points listed as subject to the NESHAP according to the permit. We evaluated latitudes and longitudes listed in the NEI to ensure their accuracy using satellite imagery. All of the latitudes and longitudes used in our dispersion modeling are in the modeling file used for the proposed rule, which is available in Docket ID No. EPA-HQ-OAR-2020-0532. Corrections were made to emission point characteristics for one non-category emission point that appeared to have erroneous stack velocity entered into the NEI. This emission point's stack velocity was corrected

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[6] U.S. EPA. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing*, June 2009. EPA-452/R-09-006. *https://www3.epa.gov/airtoxics/rrisk/rtrpg.html*.

to a default maximum value. All corrections made to emission point parameters are documented in the modeling file, available in Docket ID No. EPA-HQ-OAR-2020-0532.

2. How did we estimate MACT-allowable emissions?

The available emissions data in the RTR emissions dataset include estimates of the mass of HAP emitted during a specified annual time period. These "actual" emission levels are often lower than the emission levels allowed under the requirements of the current MACT standards. The emissions allowed under the MACT standards are referred to as the "MACT-allowable" emissions. We discussed the consideration of both MACT-allowable and actual emissions in the final Coke Oven Batteries RTR (70 FR 19992, 19998 and 19999, April 15, 2005) and in the proposed and final Hazardous Organic NESHAP RTR (71 FR 34421, 34428, June 14, 2006, and 71 FR 76603, 76609, December 21, 2006, respectively). In those actions, we noted that assessing the risk at the MACT-allowable level is inherently reasonable since that risk reflects the maximum level facilities could emit and still comply with national emission standards. We also explained that it is reasonable to consider actual emissions, where such data are available, in both steps of the risk analysis, in accordance with the Benzene NESHAP approach. (54 FR 38044).

We have determined that the actual emissions data are reasonable estimates of the MACT-allowable emissions levels for the Cyanide Chemicals Manufacturing source category. The ability to estimate MACT-allowable emissions from the actual emissions dataset is largely dependent on the format of the standard for a given emissions source as well as the types of controls employed for the source. With respect to the various types of controls used within the Cyanide Chemicals Manufacturing source category, the most prevalent is the use of a flare as a combustion control device. A flare can be used to control emissions for a single emissions source, or, as is generally the case, to control emissions from multiple emission sources/emission

source types. Flares are designed to handle a wide range of flowrates and compositions of combustible waste gases. Within the Cyanide Chemicals Manufacturing source category, flares generally control emissions from multiple emission source types. Consideration of this, along with not having a specific limit on how much gas can be combusted in a flare (given that in many cases multiple emissions sources are being controlled by this control device), means that it is extremely difficult to determine an allowable emission rate for flares. We have determined that flares in the Cyanide Chemicals Manufacturing source category are currently complying with design and operational requirements that are generally expected to achieve 98 percent destruction efficiencies or control, which is the level of control required by the NESHAP. HAP emissions inventories for flares in the Cyanide Chemicals Manufacturing source category are developed using engineering knowledge and, in many instances, presume this 98 percent level of control. The Agency is unaware of any data that suggest that flares used as controls in the Cyanide Chemicals Manufacturing source category are consistently overcontrolling HAP emissions beyond 98 percent control. Thus, weighing all of these factors for flares, we determined that the actual emission levels are a reasonable estimation of the MACT-allowable emissions levels where the performance standards allow the use of a flare as an air pollution control device (*e.g.*, storage vessels, process vents, and transfer racks).

For equipment leaks, which are currently subject to work practice standards, there would be no difference between actual and MACT-allowable emissions for facilities in the Cyanide Chemicals Manufacturing source category, provided the facilities are complying with the MACT standards as well as not conducting additional work practices that would reduce emissions beyond those required by the rule. We are aware of only one rule in the state of Texas, the Texas Commission of Environmental Quality (TCEQ) Highly Reactive Volatile Organic Compounds

(HRVOC) Rule (*i.e.*, 30 TAC Chapter 115, Subchapter H, Division 3), that may contain more stringent leak definitions and/or monitoring frequencies for certain pieces of equipment for the three facilities located in Texas that might be subject to this rule. However, based on our review of the Texas rule, we note the following: (1) specific facilities located in the Houston-Galveston-Brazoria area still conduct a leak detection and repair (LDAR) program using EPA Method 21; (2) the vast majority of equipment, including almost all pieces of equipment in gas and vapor service that would tend to contribute considerably to the overall equipment leak air emissions, are complying with the same leak definition as in the MACT standards; and (3) the TCEQ HRVOC Rule generally requires quarterly monitoring while the MACT standards have varying monitoring frequencies depending on the percentage of leaking equipment that could lead to more stringent, the same, or less stringent frequencies that would require an EPA Method 21 measurement and repair of a leaking component (if measured). Therefore, considering these factors for equipment leaks, we determined that the actual emission levels for equipment leaks are a reasonable estimation of the MACT-allowable emissions levels.

3. How do we conduct dispersion modeling, determine inhalation exposures, and estimate individual and population inhalation risk?

Both long-term and short-term inhalation exposure concentrations and health risk from the source category addressed in this proposal were estimated using the Human Exposure Model (HEM-3).[7] The HEM-3 performs three primary risk assessment activities: (1) conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 kilometers (km) of the

[7] For more information about HEM-3, go to *https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem.*

modeled sources, and (3) estimating individual and population-level inhalation risk using the exposure estimates and quantitative dose-response information.

a. Dispersion Modeling

The air dispersion model AERMOD, used by the HEM-3 model, is one of the EPA's preferred models for assessing air pollutant concentrations from industrial facilities.[8] To perform the dispersion modeling and to develop the preliminary risk estimates, HEM-3 draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes 1 year (2016) of hourly surface and upper air observations from 826 meteorological stations, selected to provide coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block[9] internal point locations and populations provides the basis of human exposure calculations (U.S. Census, 2010). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant-specific dose-response values is used to estimate health risk. These are discussed below.

b. Risk from Chronic Exposure to HAP

In developing the risk assessment for chronic exposures, we use the estimated annual average ambient air concentrations of each HAP emitted by each source in the source category. The HAP air concentrations at each nearby census block centroid located within 50 km of the facility are a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. A distance of 50 km is consistent with both the analysis supporting

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[8] U.S. EPA. Revision to the *Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions* (70 FR 68218, November 9, 2005).

[9] A census block is the smallest geographic area for which census statistics are tabulated.

the 1989 Benzene NESHAP (54 FR 38044) and the limitations of Gaussian dispersion models, including AERMOD.

For each facility, we calculate the MIR as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, 52 weeks per year, 70 years) exposure to the maximum concentration at the centroid of each inhabited census block. We calculate individual cancer risk by multiplying the estimated lifetime exposure to the ambient concentration of each HAP (in micrograms per cubic meter ($\mu g/m^3$)) by its unit risk estimate (URE). The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use UREs from the EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using California EPA (CalEPA) UREs, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate. The pollutant-specific dose-response values used to estimate health risk are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants*.

No data are available on the carcinogenic effects of cyanide compounds in humans via inhalation. Under the U.S. EPA (2005a) *Guidelines for Carcinogen Risk Assessment*, there is "inadequate information to assess the carcinogenic potential" of cyanide compounds.

To estimate individual lifetime cancer risks associated with exposure to HAP emissions from each facility in the source category, we sum the risks for each of the carcinogenic HAP[10] emitted by the modeled facility. We estimate cancer risk at every census block within 50 km of every facility in the source category. The MIR is the highest individual lifetime cancer risk estimated for any of those census blocks. In addition to calculating the MIR, we estimate the distribution of individual cancer risks for the source category by summing the number of individuals within 50 km of the sources whose estimated risk falls within a specified risk range. We also estimate annual cancer incidence by multiplying the estimated lifetime cancer risk at each census block by the number of people residing in that block, summing results for all of the census blocks, and then dividing this result by a 70-year lifetime.

To assess the risk of noncancer health effects from chronic exposure to HAP, we calculate either an HQ or a target organ-specific hazard index (TOSHI). We calculate an HQ when a single noncancer HAP is emitted. Where more than one noncancer HAP is emitted, we sum the HQ for each of the HAP that affects a common target organ or target organ system to obtain a TOSHI. The HQ is the estimated exposure divided by the chronic noncancer dose-

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[10] The EPA's 2005 *Guidelines for Carcinogen Risk Assessment* classifies carcinogens as: "carcinogenic to humans," "likely to be carcinogenic to humans," and "suggestive evidence of carcinogenic potential." These classifications also coincide with the terms "known carcinogen, probable carcinogen, and possible carcinogen," respectively, which are the terms advocated in the EPA's *Guidelines for Carcinogen Risk Assessment*, published in 1986 (51 FR 33992, September 24, 1986). In August 2000, the document, *Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (EPA/630/R-00/002), was published as a supplement to the 1986 document. Copies of both documents can be obtained from *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533&CFID=70315376&CFTOKEN=71597944*. Summing the risk of these individual compounds to obtain the cumulative cancer risk is an approach that was recommended by the EPA's SAB in their 2002 peer review of the EPA's National Air Toxics Assessment (NATA) titled *NATA - Evaluating the National-scale Air Toxics Assessment 1996 Data -- an SAB Advisory*, available at *https://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/$File/ecadv02001.pdf*.

response value, which is a value selected from one of several sources. The preferred chronic noncancer dose-response value is the EPA RfC, defined as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime" (*https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary*). In cases where an RfC from the EPA's IRIS is not available or where the EPA determines that using a value other than the RfC is appropriate, the chronic noncancer dose-response value can be a value from the following prioritized sources, which define their dose-response values similarly to the EPA: (1) the Agency for Toxic Substances and Disease Registry (ATSDR) Minimum Risk Level (*https://www.atsdr.cdc.gov/mrls/index.asp*); (2) the CalEPA Chronic Reference Exposure Level (REL) (*https://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0*); or (3) as noted above, a scientifically credible dose-response value that has been developed in a manner consistent with the EPA guidelines and has undergone a peer review process similar to that used by the EPA. The pollutant-specific dose-response values used to estimate health risks are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants*.

Cyanide is extremely toxic to humans. Acute (10-minute) inhalation exposure to 579 milligrams per cubic meter (mg/m^3) of hydrogen cyanide will cause death in 50 percent of exposed humans. Nonlethal exposures to hydrogen cyanide gas will cause a variety of effects in humans, such as headache, dizziness, upper respiratory irritation, cough, altered sense of smell, nasal congestion, nosebleed, and difficulty breathing. Chronic (long-term) inhalation exposure of

humans to cyanide results primarily in effects on the central nervous system. Other effects in humans include cardiovascular and respiratory effects, effects to the endocrine system (*e.g.*, thyroid enlargement, altered iodine uptake), and irritation to the eyes and skin. However, short term exposure levels below the acute REL and chronic exposures below the RfC are not likely to cause adverse effects.

c. Risk from Acute Exposure to HAP that May Cause Health Effects Other Than Cancer

For each HAP for which appropriate acute inhalation dose-response values are available, the EPA also assesses the potential health risks due to acute exposure. For these assessments, the EPA makes conservative assumptions about emission rates, meteorology, and exposure location. As part of our efforts to continually improve our methodologies to evaluate the risks that HAP emitted from categories of industrial sources pose to human health and the environment,[11] we revised our treatment of meteorological data to use reasonable worst-case air dispersion conditions in our acute risk screening assessments instead of worst-case air dispersion conditions. This revised treatment of meteorological data and the supporting rationale are described in more detail in *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the 2020 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Technical Support Document for Acute Risk Screening Assessment.* This revised approach has been used in this proposed rule and in all other RTR rulemakings proposed on or after June 3, 2019.

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[11] See, *e.g.*, U.S. EPA. *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis* (Draft Report, May 2017. *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html*).

To assess the potential acute risk to the maximally exposed individual, we use the peak hourly emission rate for each emission point,[12] reasonable worst-case air dispersion conditions (*i.e.*, 99th percentile), and the point of highest off-site exposure. Specifically, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions co-occur and that a person is present at the point of maximum exposure.

To characterize the potential health risks associated with estimated acute inhalation exposures to a HAP, we generally use multiple acute dose-response values, including acute RELs, acute exposure guideline levels (AEGLs), and emergency response planning guidelines (ERPG) for 1-hour exposure durations, if available, to calculate acute HQs. The acute HQ is calculated by dividing the estimated acute exposure concentration by the acute dose-response value. For each HAP for which acute dose-response values are available, the EPA calculates acute HQs.

An acute REL is defined as "the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration."[13] Acute RELs are based on the most sensitive, relevant, adverse health effect reported in the peer-reviewed medical and toxicological literature. They are designed to protect the most sensitive individuals in the population through

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[12] In the absence of hourly emission data, we develop estimates of maximum hourly emission rates by multiplying the average actual annual emissions rates by a factor (either a category-specific factor or a default factor of 10) to account for variability. This is documented in *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the 2020 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Technical Support Document for Acute Risk Screening Assessment*. Both are available in the docket for this rulemaking.

[13] CalEPA issues acute RELs as part of its Air Toxics Hot Spots Program, and the 1-hour and 8-hour values are documented in *Air Toxics Hot Spots Program Risk Assessment Guidelines, Part I, The Determination of Acute Reference Exposure Levels for Airborne Toxicants*, which is available at *https://oehha.ca.gov/air/general-info/oehha-acute-8-hour-and-chronic-reference-exposure-level-rel-summary*.

the inclusion of margins of safety. Because margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact. AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to 8 hours.[14] They are guideline levels for "once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals." *Id.* at 21. The AEGL–1 is specifically defined as "the airborne concentration (expressed as ppm (parts per million) or mg/m^3 (milligrams per cubic meter)) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure." The document also notes that "Airborne concentrations below AEGL–1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects." *Id.* AEGL–2 are defined as "the airborne concentration (expressed as parts per million or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape." *Id.*

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[14] National Academy of Sciences, 2001. *Standing Operating Procedures for Developing Acute Exposure Levels for Hazardous Chemicals*, page 2. Available at *https://www.epa.gov/sites/production/files/2015-09/documents/sop_final_standing_operating_procedures_2001.pdf*. Note that the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances ended in October 2011, but the AEGL program continues to operate at the EPA and works with the National Academies to publish final AEGLs (*https://www.epa.gov/aegl*).

ERPGs are "developed for emergency planning and are intended as health-based guideline concentrations for single exposures to chemicals."[15] *Id.* at 1. The ERPG–1 is defined as "the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor." *Id.* at 2. Similarly, the ERPG–2 is defined as "the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action." *Id.* at 1.

An acute REL for 1-hour exposure durations is typically lower than its corresponding AEGL–1 and ERPG–1. Even though their definitions are slightly different, AEGL–1s are often the same as the corresponding ERPG–1s, and AEGL–2s are often equal to ERPG–2s. The maximum HQs from our acute inhalation screening risk assessment typically result when we use the acute REL for a HAP. In cases where the maximum acute HQ exceeds 1, we also report the HQ based on the next highest acute dose-response value (usually the AEGL–1 and/or the ERPG–1).

For this source category, we used acute factors between 2 and 10, depending on the type of source, to estimate peak hourly emissions from annual emissions estimates for input into the risk assessment modeling analysis. Specifically, we used a factor of 2 for process vents and equipment leaks, a factor of 4 for storage vessels, and a factor of 10 for transfer racks. A further

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[15] *ERPGS Procedures and Responsibilities*. March 2014. American Industrial Hygiene Association. Available at: *https://www.aiha.org/get-involved/AIHAGuidelineFoundation/EmergencyResponsePlanningGuidelines/Documents/ERPG%20Committee%20Standard%20Operating%20Procedures%20%20-%20March%202014%20Revision%20%28Updated%2010-2-2014%29.pdf.*

discussion of why these factors were chosen can be found in the memorandum, *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, available in the docket for this rulemaking.

In our acute inhalation screening risk assessment, acute impacts are deemed negligible for HAP for which acute HQs are less than or equal to 1, and no further analysis is performed for these HAP. In cases where an acute HQ from the screening step is greater than 1, we assess the site-specific data to ensure that the acute HQ is at an off-site location. For this source category, no data were conducted.

4. How do we conduct the multipathway exposure and risk screening assessment?

The EPA conducts a tiered screening assessment examining the potential for significant human health risks due to exposures via routes other than inhalation (*i.e.*, ingestion). We first determine whether any sources in the source category emit any HAP known to be persistent and bioaccumulative in the environment, as identified in the EPA's Air Toxics Risk Assessment Library (see Volume 1, Appendix D, at *https://www.epa.gov/fera/risk-assessment-and-modeling-air-toxics-risk-assessment-reference-library)*.

For the Cyanide Chemicals Manufacturing source category, we identified potential PB-HAP emissions of arsenic, cadmium, lead, mercury, and polycyclic organic matter (POM) based on entries in the NEI. We note that for the Cyanide Chemicals Manufacturing source category, we modeled these pollutants to provide a conservative assessment of risks because these pollutants are included in the NEI. However, we do not believe these HAP are emitted from the cyanide chemicals manufacturing process. Very small amounts of these HAP are included in the NEI as byproducts of fuel combustion and are unrelated to cyanide chemicals manufacturing.

After identifying potential PB-HAP emissions, the next step of the evaluation is a tiered screening assessment. Except for lead, the human health risk screening assessment for PB-HAP consists of three progressive tiers. In a Tier 1 screening assessment, we determine whether the magnitude of the facility-specific emissions of PB-HAP warrants further evaluation to characterize human health risk through ingestion exposure. To facilitate this step, we evaluate emissions against previously developed screening threshold emission rates for several PB-HAP that are based on a hypothetical upper-end screening exposure scenario developed for use in conjunction with the EPA's Total Risk Integrated Methodology.Fate, Transport, and Ecological Exposure (TRIM.FaTE) model. The PB-HAP with screening threshold emission rates are arsenic compounds, cadmium compounds, chlorinated dibenzodioxins and furans, mercury compounds, and POM. Based on the EPA estimates of toxicity and bioaccumulation potential, these pollutants represent a conservative list for inclusion in multipathway risk assessments for RTR rules. (See Volume 1, Appendix D at *https://www.epa.gov/sites/production/files/2013-08/documents/volume_1_reflibrary.pdf.*) In this assessment, we compare the facility-specific emission rates of these PB-HAP to the screening threshold emission rates for each PB-HAP to assess the potential for significant human health risks via the ingestion pathway. We call this application of the TRIM.FaTE model the Tier 1 screening assessment. The ratio of a facility's actual emission rate to the Tier 1 screening threshold emission rate is a "screening value (SV)."

We derive the Tier 1 screening threshold emission rates for these PB-HAP (other than lead compounds) to correspond to a maximum excess lifetime cancer risk of 1-in-1 million (*i.e.*, for arsenic compounds, polychlorinated dibenzodioxins and furans, and POM) or, for HAP that cause noncancer health effects (*i.e.*, cadmium compounds and mercury compounds), a maximum HQ of 1. If the emission rate of any one PB-HAP or combination of carcinogenic PB-HAP in the

Tier 1 screening assessment exceeds the Tier 1 screening threshold emission rate for any facility (*i.e.*, the SV is greater than 1), we conduct a second screening assessment, which we call the Tier 2 screening assessment. The Tier 2 screening assessment separates the Tier 1 combined fisher and farmer exposure scenario into fisher, farmer, and gardener scenarios that retain upper-bound ingestion rates.

In the Tier 2 screening assessment, the location of each facility that exceeds a Tier 1 screening threshold emission rate is used to refine the assumptions associated with the Tier 1 fisher and farmer exposure scenarios at that facility. A key assumption in the Tier 1 screening assessment is that a lake and/or farm is located near the facility. As part of the Tier 2 screening assessment, we use a U.S. Geological Survey (USGS) database to identify actual waterbodies within 50 km of each facility and assume the fisher only consumes fish from lakes within that 50 km zone. We also examine the differences between local meteorology near the facility and the meteorology used in the Tier 1 screening assessment. We then adjust the previously-developed Tier 1 screening threshold emission rates for each PB-HAP for each facility based on an understanding of how exposure concentrations estimated for the screening scenario change with the use of local meteorology and the USGS lakes database.

In the Tier 2 farmer scenario, we maintain an assumption that the farm is located within 0.5 km of the facility and that the farmer consumes meat, eggs, dairy, vegetables, and fruit produced near the facility. We may further refine the Tier 2 screening analysis by assessing a gardener scenario to characterize a range of exposures, with the gardener scenario being more plausible in RTR evaluations. Under the gardener scenario, we assume the gardener consumes home-produced eggs, vegetables, and fruit products at the same ingestion rate as the farmer. The Tier 2 screen continues to rely on the high-end food intake assumptions that were applied in Tier

1 for local fish (adult female angler at 99th percentile fish consumption[16]) and locally grown or raised foods (90th percentile consumption of locally grown or raised foods for the farmer and gardener scenarios[17]). If PB-HAP emission rates do not result in a Tier 2 SV greater than 1, we consider those PB-HAP emissions to pose risks below a level of concern. If the PB-HAP emission rates for a facility exceed the Tier 2 screening threshold emission rates, we may conduct a Tier 3 screening assessment.

There are several analyses that can be included in a Tier 3 screening assessment, depending upon the extent of refinement warranted, including validating that the lakes are fishable, locating residential/garden locations for urban and/or rural settings, considering plume-rise to estimate emissions lost above the mixing layer, and considering hourly effects of meteorology and plume-rise on chemical fate and transport (a time-series analysis). If necessary, the EPA may further refine the screening assessment through a site-specific assessment.

In evaluating the potential multipathway risk from emissions of lead compounds, rather than developing a screening threshold emission rate, we compare maximum estimated chronic inhalation exposure concentrations to the level of the current National Ambient Air Quality Standard (NAAQS) for lead.[18] Values below the level of the primary (health-based) lead NAAQS are considered to have a low potential for multipathway risk.

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[16] Burger, J. 2002. *Daily consumption of wild fish and game: Exposures of high end recreationists. International Journal of Environmental Health Research,* 12:343–354.

[17] U.S. EPA. *Exposure Factors Handbook 2011 Edition (Final)*. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–09/052F, 2011.

[18] In doing so, the EPA notes that the legal standard for a primary NAAQS – that a standard is requisite to protect public health and provide an adequate margin of safety (CAA section 109(b)) – differs from the CAA section 112(f) standard (requiring, among other things, that the standard provide an "ample margin of safety to protect public health"). However, the primary lead NAAQS is a reasonable measure of determining risk acceptability (*i.e.*, the first step of the Benzene NESHAP analysis) since it is designed to protect the most susceptible group in the

For further information on the multipathway assessment approach, see the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this action.

5. How do we conduct the environmental risk screening assessment?

a. Adverse Environmental Effect, Environmental HAP, and Ecological Benchmarks

The EPA conducts a screening assessment to examine the potential for an adverse environmental effect as required under section 112(f)(2)(A) of the CAA. Section 112(a)(7) of the CAA defines "adverse environmental effect" as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

The EPA focuses on eight HAP, which are referred to as "environmental HAP," in its screening assessment: six PB-HAP and two acid gases. The PB-HAP included in the screening assessment are arsenic compounds, cadmium compounds, dioxins/furans, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. The acid gases included in the screening assessment are hydrochloric acid (HCl) and hydrogen fluoride (HF).

HAP that persist and bioaccumulate are of particular environmental concern because they accumulate in the soil, sediment, and water. The acid gases, HCl and HF, are included due to their well-documented potential to cause direct damage to terrestrial plants. In the environmental risk screening assessment, we evaluate the following four exposure media: terrestrial soils,

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human population – children, including children living near major lead emitting sources. 73 FR 67002/3; 73 FR 67000/3; 73 FR 67005/1. In addition, applying the level of the primary lead NAAQS at the risk acceptability step is conservative, since that primary lead NAAQS reflects an adequate margin of safety.

surface water bodies (includes water-column and benthic sediments), fish consumed by wildlife, and air. Within these four exposure media, we evaluate nine ecological assessment endpoints, which are defined by the ecological entity and its attributes. For PB-HAP (other than lead), both community-level and population-level endpoints are included. For acid gases, the ecological assessment evaluated is terrestrial plant communities.

An ecological benchmark represents a concentration of HAP that has been linked to a particular environmental effect level. For each environmental HAP, we identified the available ecological benchmarks for each assessment endpoint. We identified, where possible, ecological benchmarks at the following effect levels: probable effect levels, lowest-observed-adverse-effect level, and no-observed-adverse-effect level. In cases where multiple effect levels were available for a particular PB-HAP and assessment endpoint, we use all of the available effect levels to help us to determine whether ecological risks exist and, if so, whether the risks could be considered significant and widespread.

For further information on how the environmental risk screening assessment was conducted, including a discussion of the risk metrics used, how the environmental HAP were identified, and how the ecological benchmarks were selected, see Appendix 9 of the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this action.

b. Environmental Risk Screening Methodology

For the environmental risk screening assessment, the EPA first determined whether any facilities in the Cyanide Chemicals Manufacturing source category emitted any of the environmental HAP. For the Cyanide Chemicals Manufacturing source category, we identified

potential emissions of arsenic, cadmium, lead, mercury, POM, and one acid gas, HCl, based on entries in the NEI. Because one or more of the environmental HAP evaluated may be emitted by at least one facility in the source category, we proceeded to the second step of the evaluation. As noted above, we modeled these emissions to err on the side of an overly conservative analysis because they are included in the NEI; however, we do not believe these HAP are emitted from the Cyanide Chemicals Manufacturing source category. The NEI entries for these HAP from these sources are likely the result of emissions factors that are used for fuel combustion and are unrelated to cyanide chemicals manufacturing.

c. PB-HAP Methodology

The environmental screening assessment includes six PB-HAP, arsenic compounds, cadmium compounds, dioxins/furans, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. With the exception of lead, the environmental risk screening assessment for PB-HAP consists of three tiers. The first tier of the environmental risk screening assessment uses the same health-protective conceptual model that is used for the Tier 1 human health screening assessment. TRIM.FaTE model simulations were used to back-calculate Tier 1 screening threshold emission rates. The screening threshold emission rates represent the emission rate in tons of pollutant per year that results in media concentrations at the facility that equal the relevant ecological benchmark. To assess emissions from each facility in the category, the reported emission rate for each PB-HAP was compared to the Tier 1 screening threshold emission rate for that PB-HAP for each assessment endpoint and effect level. If emissions from a facility do not exceed the Tier 1 screening threshold emission rate, the facility "passes" the screening assessment, and, therefore, is not evaluated further under the screening approach. If

emissions from a facility exceed the Tier 1 screening threshold emission rate, we evaluate the facility further in Tier 2.

In Tier 2 of the environmental screening assessment, the screening threshold emission rates are adjusted to account for local meteorology and the actual location of lakes in the vicinity of facilities that did not pass the Tier 1 screening assessment. For soils, we evaluate the average soil concentration for all soil parcels within a 7.5-km radius for each facility and PB-HAP. For the water, sediment, and fish tissue concentrations, the highest value for each facility for each pollutant is used. If emission concentrations from a facility do not exceed the Tier 2 screening threshold emission rate, the facility "passes" the screening assessment and typically is not evaluated further. If emissions from a facility exceed the Tier 2 screening threshold emission rate, we evaluate the facility further in Tier 3.

As in the multipathway human health risk assessment, in Tier 3 of the environmental screening assessment, we examine the suitability of the lakes around the facilities to support life and remove those that are not suitable (*e.g.*, lakes that have been filled in or are industrial ponds), adjust emissions for plume-rise, and conduct hour-by-hour time-series assessments. If these Tier 3 adjustments to the screening threshold emission rates still indicate the potential for an adverse environmental effect (*i.e.*, facility emission rate exceeds the screening threshold emission rate), we may elect to conduct a more refined assessment using more site-specific information. If, after additional refinement, the facility emission rate still exceeds the screening threshold emission rate, the facility may have the potential to cause an adverse environmental effect.

To evaluate the potential for an adverse environmental effect from lead, we compared the average modeled air concentrations (from HEM-3) of lead around each facility in the source category to the level of the secondary NAAQS for lead. The secondary lead NAAQS is a

reasonable means of evaluating environmental risk because it is set to provide substantial protection against adverse welfare effects which can include "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."

d. Acid Gas Environmental Risk Methodology

The environmental screening assessment for acid gases evaluates the potential phytotoxicity and reduced productivity of plants due to chronic exposure to HF and HCl. The environmental risk screening methodology for acid gases is a single-tier screening assessment that compares modeled ambient air concentrations (from AERMOD) to the ecological benchmarks for each acid gas. To identify a potential adverse environmental effect (as defined in section 112(a)(7) of the CAA) from emissions of HF and HCl, we evaluate the following metrics: the size of the modeled area around each facility that exceeds the ecological benchmark for each acid gas, in acres and square kilometers; the percentage of the modeled area around each facility that exceeds the ecological benchmark for each acid gas; and the area-weighted average SV around each facility (calculated by dividing the area-weighted average concentration over the 50-km modeling domain by the ecological benchmark for each acid gas). For further information on the environmental screening assessment approach, see Appendix 9 of the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this action.

6. How do we conduct facility-wide assessments?

To put the source category risks in context, we typically examine the risks from the entire "facility," where the facility includes all HAP-emitting operations within a contiguous area and

under common control. In other words, we examine the HAP emissions not only from the source category emission points of interest, but also emissions of HAP from all other emission sources at the facility for which we have data. For this source category, we conducted the facility-wide assessment using a dataset compiled from the 2017 NEI. The source category records of that NEI dataset were removed, evaluated, and updated as described in section II.C of this preamble: What data collection activities were conducted to support this action? Once a quality assured source category dataset was available, it was placed back with the remaining records from the NEI for that facility. The facility-wide file was then used to analyze risks due to the inhalation of HAP that are emitted "facility-wide" for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, the modeled source category risks were compared to the facility-wide risks to determine the portion of the facility-wide risks that could be attributed to the source category addressed in this proposal. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

For this source category, we conducted the facility-wide assessment using a dataset that the EPA compiled from the 2017 NEI. We used the NEI data for the facility and did not adjust any category or "non-category" data. Therefore, there could be differences in the dataset from that used for the source category assessments described in this preamble. We analyzed risks due

to the inhalation of HAP that are emitted "facility-wide" for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, we made a reasonable attempt to identify the source category risks, and these risks were compared to the facility-wide risks to determine the portion of facility-wide risks that could be attributed to the source category addressed in this proposal. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

7. How do we consider uncertainties in risk assessment?

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health and environmentally protective. A brief discussion of the uncertainties in the RTR emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. Also included are those uncertainties specific to our acute screening assessments, multipathway screening assessments, and our environmental risk screening assessments. A more thorough discussion of these uncertainties is included in the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this action. If a multipathway site-specific assessment was performed for this source category, a full discussion of the

uncertainties associated with that assessment can be found in Appendix 11 of that document, *Site-Specific Human Health Multipathway Residual Risk Assessment Report*.

a. Uncertainties in the RTR Emissions Dataset

Although the development of the RTR emissions dataset involved quality assurance/quality control processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, errors in emission estimates, and other factors. The emission estimates considered in this analysis generally are annual totals for certain years, and they do not reflect short-term fluctuations during the course of a year or variations from year to year. The estimates of peak hourly emission rates for the acute effects screening assessment were based on an emission adjustment factor applied to the average annual hourly emission rates, which are intended to account for emission fluctuations due to normal facility operations.

b. Uncertainties in Dispersion Modeling

We recognize there is uncertainty in ambient concentration estimates associated with any model, including the EPA's recommended regulatory dispersion model, AERMOD. In using a model to estimate ambient pollutant concentrations, the user chooses certain options to apply. For RTR assessments, we select some model options that have the potential to overestimate ambient air concentrations (*e.g.*, not including plume depletion or pollutant transformation). We select other model options that have the potential to underestimate ambient impacts (*e.g.*, not including building downwash). Other options that we select have the potential to either under- or overestimate ambient levels (*e.g.*, meteorology and receptor locations). On balance, considering the directional nature of the uncertainties commonly present in ambient concentrations estimated

by dispersion models, the approach we apply in the RTR assessments should yield unbiased estimates of ambient HAP concentrations. We also note that the selection of meteorology dataset location could have an impact on the risk estimates. As we continue to update and expand our library of meteorological station data used in our risk assessments, we expect to reduce this variability.

c. Uncertainties in Inhalation Exposure Assessment

Although every effort is made to identify all of the relevant facilities and emission points, as well as to develop accurate estimates of the annual emission rates for all relevant HAP, the uncertainties in our emission inventory likely dominate the uncertainties in the exposure assessment. Some uncertainties in our exposure assessment include human mobility, using the centroid of each census block, assuming lifetime exposure, and assuming only outdoor exposures. For most of these factors, there is neither an under nor overestimate when looking at the maximum individual risk or the incidence, but the shape of the distribution of risks may be affected. With respect to outdoor exposures, actual exposures may not be as high if people spend time indoors, especially for very reactive pollutants or larger particles. For all factors, we reduce uncertainty when possible. For example, with respect to census-block centroids, we analyze large blocks using aerial imagery and adjust locations of the block centroids to better represent the population in the blocks. We also add additional receptor locations where the population of a block is not well represented by a single location.

d. Uncertainties in Dose-Response Relationships

There are uncertainties inherent in the development of the dose-response values used in our risk assessments for cancer effects from chronic exposures and noncancer effects from both chronic and acute exposures. Some uncertainties are generally expressed quantitatively, and

others are generally expressed in qualitative terms. We note, as a preface to this discussion, a point on dose-response uncertainty that is stated in the EPA's *2005 Guidelines for Carcinogen Risk Assessment*; namely, that "the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective" (the EPA's *2005 Guidelines for Carcinogen Risk Assessment*, pages 1 through 7). This is the approach followed here as summarized in the next paragraphs.

Cancer UREs used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk.[19] That is, they represent a "plausible upper limit to the true value of a quantity" (although this is usually not a true statistical confidence limit). In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater.[20] Chronic noncancer RfC and reference dose (RfD) values represent chronic exposure levels that are intended to be health-protective levels. To derive dose-response values that are intended to be "without appreciable risk," the methodology relies upon an uncertainty factor (UF) approach,[21] which considers uncertainty, variability, and gaps in the available data. The UFs are applied to derive dose-response values that are intended to protect against appreciable risk of deleterious effects.

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[19] IRIS glossary (*https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary*).

[20] An exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

[21] See *A Review of the Reference Dose and Reference Concentration Processes*, U.S. EPA, December 2002, and *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*, U.S. EPA, 1994.

Many of the UFs used to account for variability and uncertainty in the development of acute dose-response values are quite similar to those developed for chronic durations. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (*e.g.*, 4 hours) to derive an acute dose-response value at another exposure duration (*e.g.*, 1 hour). Not all acute dose-response values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health effects relative to the dose-response value or values being exceeded. Where relevant to the estimated exposures, the lack of acute dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

Uncertainty also exists in the selection of ecological benchmarks for the environmental risk screening assessment. We established a hierarchy of preferred benchmark sources to allow selection of benchmarks for each environmental HAP at each ecological assessment endpoint. We searched for benchmarks for three effect levels (*i.e.*, no-effects level, threshold-effect level, and probable effect level), but not all combinations of ecological assessment/environmental HAP had benchmarks for all three effect levels. Where multiple effect levels were available for a particular HAP and assessment endpoint, we used all of the available effect levels to help us determine whether risk exists and whether the risk could be considered significant and widespread.

For a group of compounds that are unspeciated (*e.g.*, glycol ethers), we conservatively use the most protective dose-response value of an individual compound in that group to estimate risk. Similarly, for an individual compound in a group (*e.g.*, ethylene glycol diethyl ether) that does not have a specified dose-response value, we also apply the most protective dose-response value from the other compounds in the group to estimate risk.

e. Uncertainties in Acute Inhalation Screening Assessments

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that the EPA conducts as part of the risk review under section 112 of the CAA. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates, meteorology, and the presence of a person. In the acute screening assessment that we conduct under the RTR program, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions (*i.e.*, 99th percentile) co-occur. We then include the additional assumption that a person is located at this point at the same time. Together, these assumptions represent a reasonable worst-case actual exposure scenario. In most cases, it is unlikely that a person would be located at the point of maximum exposure during the time when peak emissions and reasonable worst-case air dispersion conditions occur simultaneously.

f. Uncertainties in the Multipathway and Environmental Risk Screening Assessments

For each source category, we generally rely on site-specific levels of PB-HAP or environmental HAP emissions to determine whether a refined assessment of the impacts from multipathway exposures is necessary or whether it is necessary to perform an environmental screening assessment. This determination is based on the results of a three-tiered screening assessment that relies on the outputs from models – TRIM.FaTE and AERMOD – that estimate environmental pollutant concentrations and human exposures for five PB-HAP (dioxins, POM, mercury, cadmium, and arsenic) and two acid gases (HF and HCl). For lead, we use AERMOD to determine ambient air concentrations, which are then compared to the secondary NAAQS standard for lead. Two important types of uncertainty associated with the use of these models in

RTR risk assessments and inherent to any assessment that relies on environmental modeling are model uncertainty and input uncertainty.[22]

Model uncertainty concerns whether the model adequately represents the actual processes (*e.g.*, movement and accumulation) that might occur in the environment. For example, does the model adequately describe the movement of a pollutant through the soil? This type of uncertainty is difficult to quantify. However, based on feedback received from previous EPA SAB reviews and other reviews, we are confident that the models used in the screening assessments are appropriate and state-of-the-art for the multipathway and environmental screening risk assessments conducted in support of RTRs.

Input uncertainty is concerned with how accurately the models have been configured and parameterized for the assessment at hand. For Tier 1 of the multipathway and environmental screening assessments, we configured the models to avoid underestimating exposure and risk. This was accomplished by selecting upper-end values from nationally representative datasets for the more influential parameters in the environmental model, including selection and spatial configuration of the area of interest, lake location and size, meteorology, surface water, soil characteristics, and structure of the aquatic food web. We also assume an ingestion exposure scenario and values for human exposure factors that represent reasonable maximum exposures.

In Tier 2 of the multipathway and environmental screening assessments, we refine the model inputs to account for meteorological patterns in the vicinity of the facility versus using upper-end national values, and we identify the actual location of lakes near the facility rather

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[22] In the context of this discussion, the term "uncertainty" as it pertains to exposure and risk encompasses both ***variability*** in the range of expected inputs and screening results due to existing spatial, temporal, and other factors, as well as ***uncertainty*** in being able to accurately estimate the true result.

than the default lake location that we apply in Tier 1. By refining the screening approach in Tier 2 to account for local geographical and meteorological data, we decrease the likelihood that concentrations in environmental media are overestimated, thereby increasing the usefulness of the screening assessment. In Tier 3 of the screening assessments, we refine the model inputs again to account for hour-by-hour plume-rise and the height of the mixing layer. We can also use those hour-by-hour meteorological data in a TRIM.FaTE run using the screening configuration corresponding to the lake location. These refinements produce a more accurate estimate of chemical concentrations in the media of interest, thereby reducing the uncertainty with those estimates. The assumptions and the associated uncertainties regarding the selected ingestion exposure scenario are the same for all three tiers.

For the environmental screening assessment for acid gases, we employ a single-tiered approach. We use the modeled air concentrations and compare those with ecological benchmarks.

For all tiers of the multipathway and environmental screening assessments, our approach to addressing model input uncertainty is generally cautious. We choose model inputs from the upper end of the range of possible values for the influential parameters used in the models, and we assume that the exposed individual exhibits ingestion behavior that would lead to a high total exposure. This approach reduces the likelihood of not identifying high risks for adverse impacts.

Despite the uncertainties, when individual pollutants or facilities do not exceed screening threshold emission rates (*i.e.*, screen out), we are confident that the potential for adverse multipathway impacts on human health is very low. On the other hand, when individual pollutants or facilities do exceed screening threshold emission rates, it does not mean that impacts are significant, only that we cannot rule out that possibility and that a refined assessment

for the site might be necessary to obtain a more accurate risk characterization for the source category.

The EPA evaluates the following HAP in the multipathway and/or environmental risk screening assessments, where applicable: arsenic, cadmium, dioxins/furans, lead, mercury (both inorganic and methyl mercury), POM, HCl, and HF. These HAP represent pollutants that can cause adverse impacts either through direct exposure to HAP in the air or through exposure to HAP that are deposited from the air onto soils and surface waters and then through the environment into the food web. These HAP represent those HAP for which we can conduct a meaningful multipathway or environmental screening risk assessment. For other HAP not included in our screening assessments, the model has not been parameterized such that it can be used for that purpose. In some cases, depending on the HAP, we may not have appropriate multipathway models that allow us to predict the concentration of that pollutant. The EPA acknowledges that other HAP beyond these that we are evaluating may have the potential to cause adverse effects and, therefore, the EPA may evaluate other relevant HAP in the future, as modeling science and resources allow.

IV. Analytical Results and Proposed Decisions

A. What actions are we taking pursuant to CAA sections 112(d)(2) and 112(d)(3)?

We are proposing standards pursuant to CAA section 112(d)(2) for process wastewater from existing cyanide chemical manufacturing process units, which was previously unregulated[23]. During development of the initial MACT standards, we identified process

[23] The EPA not only has authority under CAA section 112(d)(2) and (3) to set MACT standards for previously unregulated HAP emissions at any time, but is required to address any previously unregulated HAP emissions as part of its periodic review of MACT standards under CAA section 112(d)(6). *LEAN v. EPA*, 955 F3d at 1091-1099.

wastewater at existing sources as a potential source of emissions of hydrogen cyanide, acetonitrile, and acrylonitrile. See 65 FR 76408, 76411, and 76413, December 6, 2000, for a discussion of the HAP emitted from cyanide chemicals manufacturing. At that time, we identified measures undertaken at cyanide chemicals manufacturing facilities to comply with other NESHAP as the "MACT floor," but we did not include these measures in 40 CFR part 63, subpart YY for existing cyanide chemical manufacturing process units. Based on our review, we are proposing to find that these measures reflect the best performing sources in the source category. The results and proposed decisions based on the analyses performed pursuant to CAA section 112(d)(2) and (3) are presented below.

For this proposal, we reviewed title V permits for facilities subject to the Cyanide Chemicals Manufacturing NESHAP and determined that all cyanide chemicals manufacturing facilities are co-located with processes subject to the Hazardous Organic NESHAP (HON) or substantively similar requirements. In the 2000 NESHAP proposal, we stated that wastewater treatment units at cyanide chemicals manufacturing facilities are typical of synthetic organic chemicals manufacturing facilities subject to the HON. The wastewater requirements of the HON are already an approved means of compliance for wastewater emission sources subject to 40 CFR part 63, subpart YY as stated in 40 CFR 63.1100(g)(5). We are proposing to require compliance with HON wastewater requirements for process wastewater at existing sources, which will ensure all affected sources at cyanide chemicals manufacturing facilities are subject to MACT standards. We are proposing these requirements for cyanide chemicals manufacturing existing sources because such requirements represent: (1) the measures employed by the best performing sources in the category; and (2) an already acceptable means of compliance for wastewater emissions at sources subject to subpart YY. We believe that these requirements will

not require additional controls or emissions reductions since existing sources we have identified as subject to the Cyanide Chemicals Manufacturing NESHAP are already subject to the HON or substantively identical wastewater requirements in another NESHAP.

We are also adding the HON requirements for waste management units upstream of an open or closed biological treatment process to the new source standard to ensure demonstrable compliance measures are in place for these sources; however, we believe these measures would already be employed by any new sources to achieve the combined 93 percent capture and control of HAP emissions from wastewater required for process wastewater emissions at new sources subject to the Cyanide Chemicals Manufacturing NESHAP.

We have identified three HAP that may be present in process wastewater streams at cyanide chemicals manufacturing facilities: hydrogen cyanide, acetonitrile, and acrylonitrile. We are proposing to include hydrogen cyanide in the calculations required to determine compliance with the wastewater standard for the Cyanide Chemicals Manufacturing source category to ensure all HAP potentially present in process wastewater are subject to MACT standards. The other two HAP that may be present in cyanide chemicals manufacturing wastewater (acetonitrile and acrylonitrile) are already included in the list of compounds subject to the HON wastewater provisions. We do not expect significant amounts of hydrogen cyanide to be present in these process wastewater streams. When developing the 2002 NESHAP, facilities that were surveyed reported very low levels of hydrogen cyanide in their wastewaters with one exception. The only facility that had high levels of hydrogen cyanide in its wastewater used add-on controls to remove the hydrogen cyanide prior to discharge. That facility was the basis for the "new source" MACT floor. We expect any facilities with high levels of hydrogen cyanide in their wastewater would already possess add-on controls similar to those present at the single existing source with

high levels of hydrogen cyanide in order to meet effluent discharge limits and protect the biological wastewater treatment systems used at these facilities. We are including hydrogen cyanide in these calculations to ensure that all HAP emitted by the source category are subject to MACT standards.

Nevertheless, we are seeking comment on whether facilities would need to install additional controls, achieve additional emissions reductions, or incur significant costs as a result of the proposed standards for process wastewater. For this proposed rule, we did not identify any new control technologies or developments in existing technologies to evaluate as "beyond-the-floor" controls other than the controls evaluated during the initial MACT standards. We did not find any data to support changing the conclusion that application of the new source MACT limit for process wastewater emissions to existing sources is unreasonable (See 65 FR 76419 and Docket Item No. EPA-HQ-OAR-2004-0041-0003).

B. What are the results of the risk assessment and analyses?

1. Chronic Inhalation Risk Assessment Results

The EPA estimated inhalation risk based on actual and allowable emissions, which we determined are the same for this category. The estimated baseline inhalation MIR posed by the source category is 5-in-1 million based on actual emissions and MACT-allowable emissions. The total estimated cancer incidence based on actual or allowable emission levels is 0.004 excess cancer cases per year, or one case every 250 years. Emissions of acrylonitrile from process vents account for 95 percent of the cancer incidence. Approximately 61,653 people are exposed to cancer risk greater than or equal to 1-in-1 million based upon actual and allowable emissions (see Table 1 of this preamble).

The maximum chronic noncancer TOSHI values for the source category were estimated to be 1 for neurological effects based on actual and allowable emissions. For both actual and allowable emissions, risk was driven by hydrogen cyanide emissions from process vents, wastewater, and equipment leaks.

TABLE 1: INHALATION RISK ASSESSMENT SUMMARY FOR CYANIDE CHEMICALS MANUFACTURING[1] SOURCE CATEGORY (40 CFR PART 63, SUBPART YY)

Risk Assessment	Number of Facilities[2]	Maximum Individual Cancer Risk (1-in-1 million)[3]	Estimated Population at Increased Risk of Cancer ≥ 1-in-1 Million	Estimated Annual Cancer Incidence (cases per year)	Maximum Chronic Noncancer TOSHI[4]	Maximum Screening Acute Noncancer HQ[5]
Baseline Actual Emissions						
Source Category	13	5	61,653	0.004	1 (neurological)	1 (REL)
Facility-Wide	13	200	266,532	0.04	1 (neurological)	-
Baseline Allowable Emissions						
Source Category	13	5	61,653	0.004	1 (neurological)	-

[1] Based on actual and allowable emissions.
[2] Number of facilities evaluated in the risk assessment. Includes 13 operating facilities subject to 40 CFR part 63, subpart YY.
[3] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[4] Maximum TOSHI. The target organ with the highest TOSHI for the Cyanide Chemicals Manufacturing source category is the neurological system.
[5] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of HQ values. The acute HQ shown was based upon the lowest acute 1-hour dose-response value, the REL for hydrogen cyanide. When an HQ exceeds 1, we also show the HQ using the next lowest available acute dose-response value.

2. Screening Level Acute Risk Assessment Results

Based on our screening analysis of reasonable worst-case acute exposure to actual emissions from the category, no HAP exposures result in an HQ greater than 1 based upon the 1-hour REL. As discussed in section III.C.3.c of this preamble, for this source category, we used acute factors between 2 and 10, depending on the type of source. Specifically, we used a factor of 2 for process vents and equipment leaks, a factor of 4 for storage vessels, and a factor of 10 for transfer racks. A further discussion of why these factors were chosen can be found in the memorandum, *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, available in the docket for this rulemaking.

3. Multipathway Risk Screening Results

Three of the 13 facilities in this source category reported emissions of PB-HAP in the NEI which include POM (of which polycyclic aromatic hydrocarbons is a subset), lead compounds, arsenic compounds, cadmium compounds, and mercury compounds. We note that for the Cyanide Chemicals Manufacturing source category, while we modeled these emissions, none of these HAP are expected to be emitted from the source category and they were only modeled to provide a conservative estimate of risk because they were included in the NEI. To identify potential multipathway health risks from PB-HAP other than lead, we first performed a tiered screening assessment (Tiers 1, 2, and 3) based on emissions of PB-HAP emitted from each facility in the source category. Arsenic emissions from a single facility exceeded the Tier 1 cancer screening threshold emission rate with a maximum SV of 2. No facilities had POM emissions exceeding the Tier 1 cancer screening threshold emission rate. Mercury emissions from a single facility exceeded the Tier 1 noncancer screening threshold emission rate with a maximum SV of 2. No facilities had cadmium emissions exceeding the Tier 1 noncancer screening threshold emission rate. For the facilities and HAP for which the Tier 1 threshold

emissions rates were exceeded (*i.e.*, SV greater than 1), we conducted a Tier 2 screening analysis. In the Tier 2 screening analysis, no facilities had an SV greater than 1. Specifically, the maximum Tier 2 cancer SV was less than 1 for both the farmer scenario for arsenic (0.4) and the fisher scenario for mercury (0.3).

Further facility details on the multipathway screening analysis can be found in Appendix 10 of the *Residual Risk Assessment for the Cyanide Chemical Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule.*

An SV in any of the tiers is not an estimate of the cancer risk or a noncancer HQ. Rather, an SV represents a high-end estimate of what the risk or HQ may be. For example, facility emissions resulting in an SV of 2 for a non-carcinogen can be interpreted to mean that we are confident that the HQ would be lower than 2. Similarly, facility emissions resulting in a cancer SV of 20 for a carcinogen means that we are confident that the cancer risk is lower than 20-in-1 million. Our confidence comes from the health-protective assumptions that are incorporated into the screens: we choose inputs from the upper end of the range of possible values for the influential parameters used in the screens and we assume food consumption behaviors that would lead to high total exposure. This risk assessment estimates the maximum hazard for mercury and cadmium through fish consumption based on upper bound screens and the maximum excess cancer risks from POM and arsenic through ingestion of fish and farm produce.

In evaluating the potential for adverse health effects from emissions of lead, the EPA compared modeled annual lead concentrations to the secondary NAAQS level for lead (0.15 $\mu g/m^3$, arithmetic mean concentration over a 3-month period). The highest annual average lead concentration, 0.00000065 $\mu g/m^3$, is orders of magnitude below the NAAQS level for lead, indicating a low potential for adverse health impacts.

4. Environmental Risk Screening Results

As described in section III.A of this preamble, we conducted an environmental risk screening assessment for the Cyanide Chemical Manufacturing source category for the following pollutants: arsenic, cadmium, HCl, lead, mercury (methyl mercury and mercuric chloride), and POM. As noted in our discussion of the multipathway risk assessment results, these HAP are not associated with cyanide chemicals manufacturing and are not emitted from the source category. There were NEI entries for small amounts of these pollutants and we chose to model these emissions to err on the side of an overly conservative assessment.

In the Tier 1 screening analysis for the above PB-HAP (other than lead, which was evaluated differently), the maximum Tier 1 SV was less than or equal to 1 for all PB-HAP.

For lead, we did not estimate any exceedances of the secondary lead NAAQS. For HCl, the average modeled concentration around each facility (*i.e.,* the average concentration of all off-site data points in the modeling domain) did not exceed any ecological benchmark. In addition, for the one facility that reported HCl emissions, each individual modeled concentration of HCl (*i.e.,* each off-site data point in the modeling domain) was below the ecological benchmarks for HCl.

Based on the results of the environmental risk screening analysis, we do not expect an adverse environmental effect as a result of HAP emissions from this source category.

5. Facility-Wide Risk Results

The EPA estimated inhalation risk based on facility-wide emissions. The estimated maximum individual excess lifetime cancer risk based on facility-wide emissions was 200-in-1 million, with 0.04 excess cancer cases per year, or one case every 25 years. This cancer risk is driven by emissions sources that are not in the Cyanide Chemicals Manufacturing source

category; specifically, emissions of ethylene oxide and coke oven emissions from non-category sources account for 95 percent of the cancer incidence. Approximately 150 people are exposed to an excess cancer risk greater than or equal to 100-in-1 million, with 266,532 people exposed to an excess cancer risk above 1-in-1 million (see Table 1 of this preamble). The estimated maximum chronic noncancer TOSHI values for the facility-wide assessment was the same as estimated based on actual and allowable emissions from the source category -- a TOSHI equal to 1 for neurological effects driven by hydrogen cyanide emissions from process vents, wastewater, and equipment leaks.

Regarding the facility-wide risks due to ethylene oxide, which are emitted by sources that are not part of the Cyanide Chemicals Manufacturing source category, we intend to continue to evaluate those facility-wide estimated emissions and risks further and may address these in separate actions, as appropriate. In particular, the EPA is addressing ethylene oxide in response to the results of the latest NATA released in August 2018, which identified the chemical as a potential concern in several areas across the country (NATA is the Agency's nationwide air toxics screening tool, designed to help the EPA and state, local, and tribal air agencies identify areas, pollutants, or types of sources for further examination). The latest NATA estimates that ethylene oxide significantly contributes to potential elevated cancer risks in some census tracts across the U.S. (less than 1 percent of the total number of tracts). These elevated risks are largely driven by an EPA risk value that was updated in late 2016. The EPA will work with industry and state, local, and tribal air agencies as the EPA takes a two-pronged approach to address ethylene oxide emissions by: (1) reviewing and, as appropriate, revising CAA regulations for facilities that emit ethylene oxide – starting with air toxics emissions standards for miscellaneous organic chemical manufacturing facilities (85 FR 49084, August 12, 2020) and commercial sterilizers;

and (2) conducting site-specific risk assessments and, as necessary, implementing emission control strategies for targeted high-risk facilities. The EPA will post updates on its work to address ethylene oxide on its website at: *https://www.epa.gov/ethylene-oxide*.

6. What demographic groups might benefit from this regulation?

To examine the potential for any environmental justice issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risk to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risk from the Cyanide Chemicals Manufacturing source category across different demographic groups within the populations living near facilities.[24]

The results of the demographic analysis are summarized in Table 2 below. These results, for various demographic groups, are based on the estimated risk from actual emissions levels for the population living within 50 km of the facilities.

TABLE 2. CYANIDE CHEMICALS MANUFACTURING DEMOGRAPHIC RISK ANALYSIS RESULTS

	Nationwide	Population with Cancer Risk at or Above 1-in-1 Million Due to Cyanide Chemicals Manufacturing	Population with Chronic HI Above 1 Due to Cyanide Chemicals Manufacturing
Total Population	317,746,049	61,653	0
Race by Percent			
White	62	73	
All Other Races	38	27	
Race by Percent			
White	62	73	

[24] Demographic groups included in the analysis are: White, African American, Native American, other races and multiracial, Hispanic or Latino, children 17 years of age and under, adults 18 to 64 years of age, adults 65 years of age and over, adults without a high school diploma, people living below the poverty level, people living two times the poverty level, and linguistically isolated people.

African American	12	19	
Native American	0.8	0.4	
Other and Multiracial	7	4	
Ethnicity by Percent			
Hispanic	18	3	
Non-Hispanic	82	97	
Income by Percent			
Below Poverty Level	14	16	
Above Poverty Level	86	84	
Education by Percent			
Over 25 and without High School Diploma	14	16	
Over 25 and with a High School Diploma	86	84	

The results of the Cyanide Chemicals Manufacturing source category demographic analysis indicate that emissions from the source category expose approximately 61,653 people to a cancer risk at or above 1-in-1 million and nobody to a chronic noncancer TOSHI greater than 1. The percentages of the at-risk population in the White, African American, Below Poverty, and Over 25 without High School Diploma demographic groups are greater than their respective nationwide percentages.

The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review – Analysis of Demographic Factors for Populations Living Near Cyanide Chemicals Manufacturing*, available in the docket for this action.

C. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?

1. Risk Acceptability

As explained in section II.A of this preamble, the EPA sets standards under CAA section 112(f)(2) using "a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual risk (MIR) of approximately 1-in-10 thousand." (54 FR 38045, September 14, 1989). The EPA weighed all health risk measures and information, including science policy assumptions and estimation uncertainties, in determining whether risk posed by emissions from the source category is acceptable.

The estimated maximum cancer risk for inhalation exposure to actual and allowable emissions from the Cyanide Chemicals Manufacturing source category was 5-in-1 million, 20 times below 100-in-1 million, which is the presumptive upper limit of acceptable risk. The EPA estimates emissions from the category would result in a cancer incidence of 0.004 excess cancer cases per year, or one case every 250 years. Inhalation exposures to HAP associated with chronic noncancer health effects result in a TOSHI of 1 based on actual and allowable emissions, an exposure level that the EPA has determined is without appreciable risk of adverse health effects. Exposures to HAP associated with acute noncancer health effects also are below levels of health concern with no HAP exposures resulting in an HQ greater than 1 based upon the 1-hour REL.

Maximum cancer risk due to ingestion exposures, estimated using health-protective risk screening assumptions, is below 1-in-1 million for the Tier 2 farmer exposure scenario. Tier 2 screening analyses of mercury exposure due to fish ingestion determined that the maximum HQ for mercury would be less than 1 as explained in section III.C.4 of this preamble.

Considering all of the health risk information and factors discussed above, as well as the uncertainties discussed in section III of this preamble, we propose that the risks posed by emissions from the Cyanide Chemicals Manufacturing source category are acceptable.

2. Ample Margin of Safety Analysis

As directed by CAA section 112(f)(2), we conducted an analysis to determine whether the current emissions standards provide an ample margin of safety to protect public health. Under the ample margin of safety analysis, we evaluated the cost and feasibility of available control technologies and other measures (including the controls, measures, and costs reviewed under the technology review) that could be applied to this source category to further reduce the risks (or potential risks) due to emissions of HAP from the source category. In light of the low cancer and noncancer risk posed to individuals exposed to HAP emitted from this source category and lack of additional control technologies, we are proposing to conclude that the existing standards under the NESHAP provide an ample margin of safety to protect public health.

3. Adverse Environmental Effect

Based on the results of our environmental risk screening analysis, we do not anticipate an adverse environmental effect as a result of HAP emissions from this source category. Therefore, the EPA is proposing that it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

D. What are the results and proposed decisions based on our technology review?

As part of the technology review, we identified a previously unregulated process, and are proposing a MACT standard for the process under CAA section 112(d)(2) and (3), as described in Section IV.A of this preamble, above. We did not identify any developments in processes, practices, or control technologies for cyanide chemicals manufacturing facilities during our analysis for this proposal. Facilities subject to this NESHAP use flares to control emissions from point sources and LDAR programs to address emissions from equipment leaks. As discussed in

the memorandum titled *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, we did not identify any developments in these technologies during our technology review.

E. What other actions are we proposing?

In addition to the proposed actions described above, we are proposing additional revisions to the NESHAP. We are proposing revisions to the SSM provisions of the MACT rule in order to ensure that they are consistent with the decision in *Sierra Club v. EPA*, 551 F. 3d 1019 (D.C. Cir. 2008), in which the court vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We note that for the Cyanide Chemicals Manufacturing source category, the NESHAP currently does not include an exemption for SSM events, and already includes standards that apply at all times, including periods of SSM. Therefore, we have determined that the NESHAP is already consistent with the court decision mentioned above. However, we are making revisions to the MACT rule at 40 CFR 63.1108 through 40 CFR 63.1112 to ensure this is clearly and consistently communicated throughout and no confusion results from referenced subparts associated with the GMACT that may contain SSM exemptions for other source categories. We also are proposing other changes to add electronic reporting. Our analyses and proposed changes related to these issues are discussed below.

Electronic Reporting. The EPA is proposing that owners and operators of cyanide chemicals manufacturing facilities submit electronic copies of required notifications of compliance, performance test reports, and periodic reports through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum, *Electronic*

Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules, available in the docket for this action. The proposed rule requires that performance test results collected using test methods that are supported by the EPA's Electronic Reporting Tool (ERT) as listed on the ERT website[25] at the time of the test be submitted in the format generated through the use of the ERT or an electronic file consistent with the xml schema on the ERT website, and other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. The proposed rule requires that Notification of Compliance Status (NOCS) be submitted as a PDF upload in CEDRI.

For periodic reports, the proposed rule requires that owners and operators use the appropriate spreadsheet template to submit information to CEDRI. A draft version of the proposed template for these reports is included in the docket for this action.[26] The EPA specifically requests comment on the content, layout, and overall design of the template. Additionally, the EPA has identified two broad circumstances in which electronic reporting extensions may be provided. These circumstances are (1) outages of the EPA's CDX or CEDRI which preclude an owner or operator from accessing the system and submitting required reports and (2) *force majeure* events, which are defined as events that will be or have been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevent an owner or operator from complying with the requirement to submit a report electronically. Examples of *force majeure* events are acts of nature, acts of war or

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[25] *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*
[26] See Draft Form_5900-485_Subpart_YY_Cyanide_Draft_Periodic_Report_Template_Proposal.xlsm , available at Docket ID No. EPA-HQ-OAR-2020-0532.

terrorism, or equipment failure or safety hazards beyond the control of the facility. The EPA is providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible.

The electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA's plan[27] to implement Executive Order 13563 and is in keeping with the EPA's Agency-wide policy[28] developed in

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[27] EPA's Final Plan for Periodic Retrospective Reviews, August 2011. Available at: *https://www.regulations.gov/document?D=EPA-HQ-OA-2011-0156-0154.*

[28] E-Reporting Policy Statement for EPA Regulations, September 2013. Available at: *https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf.*

response to the White House's Digital Government Strategy.[29] For more information on the benefits of electronic reporting, see the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules*, referenced earlier in this section.

F. What compliance dates are we proposing?

The EPA is proposing that existing affected sources and affected sources that commenced construction or reconstruction on or before **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, must comply with the proposed process wastewater standards no later than 365 days after the effective date of the final rule and all of the other amendments no later than 180 days after the effective date of the final rule. The final action is not expected to be a ''major rule'' as defined by 5 U.S.C. 804(2), so the effective date of the final rule will be the promulgation date as specified in CAA section 112(d)(10). For existing sources, we are proposing a change that would impact ongoing compliance requirements for 40 CFR part 63, subpart YY. As discussed elsewhere in this preamble, we are proposing to change the requirements for SSM by removing references to exemptions in other subparts. Our experience with similar industries shows that this sort of regulated facility generally requires a time period of 180 days to read and understand the amended rule requirements; to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; and to update their operations to reflect the revised requirements.

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[29] Digital Government: Building a 21st Century Platform to Better Serve the American People, May 2012. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html*.

From our assessment of the timeframe needed for compliance with the revised requirements, the EPA considers a period of 180 days to be the most expeditious compliance period practicable, and, thus, is proposing that existing affected sources be in compliance with this regulation's revised requirements within 180 days of the regulation's effective date. We solicit comment on this proposed compliance period, and we specifically request submission of information from sources in this source category regarding specific actions that would need to be undertaken to comply with the proposed amended requirements, including the proposed amendments related to recordkeeping and reporting and the time needed to make the adjustments for compliance with them. We note that information provided may result in changes to the proposed compliance date; however, we expect the proposed compliance time to be sufficient given that cyanide chemicals manufacturing facilities are already subject to standards during these periods. We are proposing that facilities will have 1 year to comply with the proposed process wastewater standards for existing sources. We note that we do not expect the proposed wastewater standards for existing sources to require installation of any additional controls. We believe that all affected sources are already complying with the proposed wastewater requirements or requirements that are substantively identical. We are proposing that facilities must comply within 365 days in order to provide time to evaluate wastewater operations, perform compliance calculations, and adjust plans and reports as necessary. We are seeking comment on the assumption that facilities will not need to install additional add-on controls and whether facilities would require more or less time to comply with the proposed process wastewater requirements. Affected sources that commence construction or reconstruction after **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, must comply with all requirements of the subpart, including the amendments being proposed, no later than the

effective date of the final rule or upon startup, whichever is later. All affected facilities would have to continue to meet the current requirements of 40 CFR part 63, subpart YY, until the applicable compliance date of the amended rule.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

There are 13 cyanide chemicals manufacturing facilities currently operating as major sources of HAP subject to the proposed amendments. A list of facilities that are currently subject to the MACT standards is available in the memorandum titled *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal*, available in Docket ID No. EPA-HQ-OAR-2020-0532.

B. What are the air quality impacts?

We do not anticipate that the proposed amendments to this subpart will impact air quality. We are not proposing changes to the standard that will result in additional emission reductions beyond the levels already achieved by the NESHAP.

C. What are the cost impacts?

The proposed amendments will have a limited cost impact on affected facilities. Total estimated costs are $47,527 based on a $3,656 per facility cost for all 13 facilities. The costs result from reading and understanding rule requirements and adjusting compliance plans based on the rule proposal. All costs are one-time expenses expected to occur in the first year after the rule is finalized. Costs are based on Agency knowledge and experience with the NESHAP program, related ICRs, and Bureau of Labor Statistics data.

D. What are the economic impacts?

Economic impact analyses focus on changes in market prices and output levels. If changes in market prices and output levels in the primary markets are significant enough, impacts on other markets may also be examined. Both the magnitude of costs associated with the proposed requirements and the distribution of these costs among affected facilities can have a role in determining how the market will change in response to a proposed rule.

Economic costs to owners of cyanide chemicals manufacturing facilities were measured in present value (PV) total costs and equivalent annual value (EAV) costs. All cyanide chemicals manufacturing facilities were estimated to have similar costs. All costs are presented in 2019 dollars. See section V.C of this preamble for additional information on costs.

PV total costs and EAV costs were measured at the 3 percent and 7 percent discount rates. The duration of analysis was 8 years. Per facility PV total cost estimate is $3,656 at the 3 percent and 7 percent discount rates. The similarity in both discount rates is due to the costs all occuring in the first year after the rule is finalized. EAV costs per facility are measured to be $521 and $612 at the 3 percent and 7 percent discount rates, respectively. Combined total PV cost of the proposed requirements for all facilities is measured to be $47,527 at the 3 percent and 7 percent discount rates. The similarity in both discount rates is due to the costs all coming in the first year that the rule will be finalized. Combined EAV costs of the proposed requirements for all facilities are measured to be $6,771 and $7,959 at the 3 percent and 7 percent discount rates, respectively.

As required by the Regulatory Flexibility Act (RFA), we performed an analysis to determine if any small entities would be unduly burdened by the proposed amendments. We determined that all facilities subject to the NESHAP are owned by large parent entities based on Small Business Administration standards. No significant economic impacts from the proposed

amendments are anticipated because the PV and EAV costs associated with the proposed revisions are minimal.

E. What are the benefits?

As discussed in section V.B of this preamble, we do not anticipate the proposed amendments to this subpart to impact air quality. The electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements, and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public.

VI. Request for Comments

We solicit comments on this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the risk assessments and other analyses. We are specifically interested in receiving any improvements to the data used in the site-specific emissions profiles used for risk modeling. Such data should include supporting documentation in sufficient detail to allow characterization of the quality and representativeness of the data or information. Section VII of this preamble provides more information on submitting data.

VII. Submitting Data Corrections

The site-specific emissions profiles used in the source category risk and demographic analyses and instructions are available for download on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*. The data files include detailed information for each HAP emissions release point for the facilities in the source category.

If you believe that the data are not representative or are inaccurate, please identify the data in question, provide your reason for concern, and provide any "improved" data that you have, if available. When you submit data, we request that you provide documentation of the basis for the revised values to support your suggested changes. To submit comments on the data downloaded from the RTR website, complete the following steps:

1. Within this downloaded file, enter suggested revisions to the data fields appropriate for that information.

2. Fill in the commenter information fields for each suggested revision (*i.e.*, commenter name, commenter organization, commenter email address, commenter phone number, and revision comments).

3. Gather documentation for any suggested emissions revisions (*e.g.*, performance test reports, material balance calculations).

4. Send the entire downloaded file with suggested revisions in Microsoft® Access format and all accompanying documentation to Docket ID No. EPA-HQ-OAR-2020-0532 (through the method described in the **ADDRESSES** section of this preamble).

5. If you are providing comments on a single facility or multiple facilities, you need only submit one file for all facilities. The file should contain all suggested changes for all sources at

that facility (or facilities). We request that all data revision comments be submitted in the form of updated Microsoft® Excel files that are generated by the Microsoft® Access file. These files are provided on the project website at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen*.

VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted to the OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2678.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The EPA is proposing amendments that revise provisions pertaining to emissions during periods of SSM, add requirements for electronic reporting of NOCS, periodic reports, and performance test results, and make other minor clarifications and corrections. This information will be collected to assure compliance with the Cyanide Chemicals Manufacturing NESHAP.

Respondents/affected entities: Owners or operators of cyanide chemicals manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart YY).

Estimated number of respondents: 13 (assumes no new respondents over the next 3 years).

Frequency of response: Initially, occasionally, and annually.

Total estimated burden: 160 hours (per year) to comply with all of the requirements in the NESHAP. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $15,800 (per year), including no annualized capital or operation and maintenance costs, to comply with all of the requirements in the NESHAP.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments n later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. There are no small entities among the eight ultimate parent companies impacted by this proposed action given the Small Business Administration small business size definition for this industry (1,000 employees or greater for NAICS 325180 – Other Basic Inorganic Chemical Manufacturing), and no significant economic impact on any of these entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. None of the cyanide chemicals manufacturing production facilities that have been identified as being affected by this proposed action are owned or operated by tribal governments or located within tribal lands. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section IV.B of this preamble and the document, *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2020 Proposed Rule*, which is available in the docket for this rulemaking.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards. Therefore, the EPA conducted a search to identify potentially applicable voluntary consensus standards. However, the Agency identified no such standards. A thorough summary of the search and results are included in the memorandum titled *Voluntary Consensus Standard Results for Cyanide Chemicals Manufacturing Residual Risk and Technology Review*, which is available in the docket for this action.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in section IV.B of this preamble and in the technical report, *Risk and Technology Review—Analysis of Demographic Factors for*

Populations Living Near Cyanide Chemicals Manufacturing Facilities, available in the docket for this action.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Andrew Wheeler,

Administrator.

Message

From: Kasper, Amanda [Kasper.Amanda@epa.gov]
Sent: 1/7/2021 12:25:50 AM
To: Wheeler, Andrew [wheeler.andrew@epa.gov]
CC: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Meadowcroft, Micah [Meadowcroft.Micah@epa.gov]
Subject: Resignation Letter
Attachments: Amanda Kasper Resignation_01062021.pdf

Administrator Wheeler,

After serious consideration today, I have attached my letter of resignation. While it is stated in the letter, I want to reaffirm just how much I have valued your leadership and all that I have learned from the opportunity to serve with you and the entire team.

Again, thank you for your trust and confidence throughout my time with the EPA. I will always be grateful.

Best,

Amanda Kasper
Senior Advisor to the Administrator
Office of the Administrator (AO/IO)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
O: 202-564-1524 I M: 202-302-7765

January 6, 2021

Dear Administrator Wheeler:

The intent of this letter is to submit my resignation as your Senior Advisor at the U.S. Environmental Protection Agency (EPA) effective Wednesday, January 13, 2021 to allow for proper administrative offboarding.

Since joining the EPA in July 2019, I have greatly admired and respected your leadership and how you inspired true belief in the fundamental importance of our agency's mission and workforce. However, following today's events, I cannot, in good faith or conscience, continue to uphold my duties on behalf of the Administration.

Please know that I am thankful for the opportunity to have served under your strong leadership and will always reflect on my time in service as one of the most rewarding experiences of my professional career.

It is my sincere hope that our paths will cross again.

Respectfully,

Ex. 6

Amanda Kasper
Senior Advisor to the Administrator
U.S. Environmental Protection Agency
Personal email: Ex. 6
Mobile: Ex. 6

CC: Mandy Gunasekara
Michael Molina
Micah Meadowcroft

Message

From: Soltani, Beth [Soltani.Beth@epa.gov]
on behalf of Lopez, Peter [lopez.peter@epa.gov]
Sent: 1/6/2021 5:23:08 PM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
CC: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Meadowcroft, Micah [Meadowcroft.Micah@epa.gov]
Subject: Letter on behalf of Peter D. Lopez
Attachments: LTR to Administrator Wheeler 1-6-21.pdf

Beth Soltani
Executive Assistant to the Regional Administrator
U.S. Environmental Protection Agency, Region 2
290 Broadway
New York, NY 10007
Office: 212.637.5038
Mobile: 646.531.2763

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

January 6, 2021

The Honorable Andrew R. Wheeler
Administrator - US EPA
William Jefferson Clinton Building
1200 Pennsylvania Avenue
Washington, DC 20004

Dear Administrator Wheeler,

With a heavy heart, I am respectfully reaching out to advise that I will be resigning from my role as EPA Region 2 Administrator effective Wednesday, January 20, 2021.

This has been an incredible journey, and it has been my privilege to faithfully serve with you and our colleagues throughout the Agency to protect public health and the environment.

I know we both share the strong belief that we should always leave a place better than how we found it, and that we have a sacred responsibility to manage our natural resources wisely to ensure they are available to those who follow us.

With your leadership, support and guidance, we have demonstrated that protecting the environment is not mutually exclusive to achieving other priorities and that, if we are patient with each other as a society, we can achieve environmental objectives even as we strengthen communities, as well promote the viability of our family farms and small businesses.

While firm in our resolve to fulfill our mission, I am especially proud of our compassionate, collaborative and community-centered problem-solving focus; the emphasis on aiding those in need, including our urban environmental justice populations, rural areas, Indian Nations and other underserved communities, speaks to who we are as individuals and as an organization.

In closing, it has been an honor to offer my experience, energy and servant's heart in support of EPA and its critical mission. Thank you for this incredible opportunity, and for your friendship.

Wishing you the best in the years ahead.

Respectfully,

Peter D. Lopez
Administrator – USEPA R2

cc: Mandy Gunasekara
Micha Meadowcroft

ED_005879_00000269-00001

Message

From: Walters, Ben [Walters.Ben@epa.gov]
Sent: 1/6/2021 8:11:22 PM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Benevento, Douglas [benevento.douglas@epa.gov]; Brazauskas, Joseph [brazauskas.joseph@epa.gov]; Coxen, Carrie [coxen.carrie@epa.gov]; Johnson, Taylor [Johnson.Taylor.C@epa.gov]; McFaul, Jessica [mcfaul.jessica@epa.gov]; Rodriguez, Alejandra (Allie) [rodriguez.alejandra@epa.gov]; Walters, Ben [Walters.Ben@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Block, Molly [block.molly@epa.gov]
Subject: 1.6.20 Daily Media Brief
Attachments: 1.6.20 Daily Media Report.docx

Sir,

Please see attached/below for today's media brief.

Daily Media Brief 1/6/20

Most common and notable inquiry topic
1. David Ross

Inside EPA/Lara Beaven
Topic: David Ross departure
Status: Referred to email that went out
- Additional Inquiries: Politico (Annie Snider)

AP/Travis Loller
Topic: Civil rights enforcement
Status: Developing Response

Bloomberg Green/Margaret Rhodes
Topic: Furniture waste
Status: Developing Response

E&E News/Hannah M. Northey
Topic: David Ross interview request
Status: Developing Response

E&E News/Jeremy Jacobs
Topic: Changes to Title VI of the Civil Rights Act
Status: Developing Response

EE News/Kelsey Brugger
Topic: Guidance documents
Status: Developing Response

EE News/Sean Reilly
Topic: Pivotal science rule
Status: Developing Response

KSWT/Jose A. Teposte

Topic: Lung Cancer prevention
Status: Developing Response

MinnPost/Gregg Aamot
Topic: Clean Water Act
Status: Developing Response

Mississippi Today/Alex Rozier
Topic: ECHO data
Status: Developing Response

National Journal/Brian Dabbs
Topic: DRA
Status: Developing Response

Slade.com/Nitish Pahwa
Topic: Greenhouse Gases Equivalencies Calculator
Status: Developing Response

Texas Standard radio/Michael Marks
Topic: Register aldicarb in Texas
Status: Developing Response

E&E News/Pamela King
Topic: Denver smog ruling
Status: Referred to DOJ

The Hill/Rebecca Beitsch
Topic: Nancy Beck
Status: Did Not Respond

NPR/Jeff Brady
Topic: Biden transition response
Status: Did Not Respond

Ben Walters
Special Advisor for Digital Media
Office of the Administrator – OPA
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460
M: 202-923-5203

Daily Media Brief 1/6/20

Most common and notable inquiry topic

1. David Ross

Inside EPA/Lara Beaven
Topic: David Ross departure
Status: Referred to email that went out

- Additional Inquiries: Politico (Annie Snider)

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Topic: Lung Cancer prevention
Status: Developing Response

MinnPost/Gregg Aamot
Topic: Clean Water Act
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Mississippi Today/Alex Rozier
Topic: ECHO data
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National Journal/Brian Dabbs
Topic: DRA
Status: Developing Response

Slade.com/Nitish Pahwa
Topic: Greenhouse Gases Equivalencies Calculator
Status: Developing Response

Texas Standard radio/Michael Marks
Topic: Register aldicarb in Texas
Status: Developing Response

E&E News/Pamela King
Topic: Denver smog ruling
Status: Referred to DOJ

The Hill/Rebecca Beitsch
Topic: Nancy Beck
Status: Did Not Respond

NPR/Jeff Brady
Topic: Biden transition response
Status: Did Not Respond

Message

From: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
Sent: 1/7/2021 1:08:34 AM
To: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
CC: Wallace, Ryan [Wallace.Ryan@epa.gov]; Gillespie, Andrew [Gillespie.Andrew@epa.gov]
Subject: CORRECTED: OCSPP Job Opportunity: Supervisory Biologist/Toxicologist/Environmental Engineer/Physical Scientist/Chemist; GS-0401/0415/0819/1301/1320-15; OCSPP/OPPT/ECRAD/RAB5

CORRECTION: THE LOCATION OF THIS POSITION HAS BEEN CORRECTED TO WASHINGTON, DC

The vacancy announcement for this position is currently open and is scheduled to close on Thursday, January 15, 2021. If you are interested in applying for this position, please make sure to read the entire vacancy announcement and instructions for submitting all required/necessary documentation to ensure your application is complete and acceptable for review and consideration.

The following job opportunity is being announced within the Office of Chemical Safety and Pollution Prevention **(OCSPP)**, Office of Pollution Prevention and Toxics **(OPPT)**, Existing Chemicals Risk Assessment Division **(ECRAD)**, Risk Assessment Branch 5 **(RAB5)**.

To view the specifics of this announcement, please click the following link:
https://www.usajobs.gov/GetJob/ViewDetails/588696100

Announcement Number: R-OCSPP-MP-2021-0022

Title:	Supervisory Biologist/Toxicologist/Environmental Engineer/Physical Scientist/Chemist
Series and Grade Announced:	GS-0401/0415/0819/1301/1320-15
Location of Position:	Washington, DC
Area of Consideration:	Current permanent EPA employees with competitive status or EPA Career Transition Assistance Program (CTAP) eligibles.
Position Type:	Full time, permanent
Opening Date:	January 6, 2021
Closing Date:	January 15, 2021
Number of Vacancies:	1
Position Risk Designation:	This position is designated as Moderate Risk and requires a background investigation.

To be considered for this position, applicants must apply on-line at the USAJOBS.gov website by the closing date of the announcement and follow the vacancy announcement instructions for providing any applicable supplemental information.

Please share this announcement with anyone that you feel may be interested and meets the eligibility requirements.

Please do not respond to this email. For questions regarding this job opportunity, please contact Gloria Ashley Gaines on 919-541-0990 or gaines.gloria@epa.gov

Message

From: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
Sent: 1/7/2021 1:01:07 AM
To: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
CC: Wallace, Ryan [Wallace.Ryan@epa.gov]; Gillespie, Andrew [Gillespie.Andrew@epa.gov]
Subject: CORRECTED: OCSPP Job Opportunity: Supervisory Biologist/Toxicologist/Environmental Engineer/Physical Scientist/Chemist; GS-0401/0415/0819/1301/1320-15; OCSPP/OPPT/ECRAD/RAB5

CORRECTION: THE LOCATION OF THIS POSITION HAS BEEN CORRECTED TO WASHINGTON, DC

The vacancy announcement for this position is currently open and is scheduled to close on Thursday, January 15, 2021. If you are interested in applying for this position, please make sure to read the entire vacancy announcement and instructions for submitting all required/necessary documentation to ensure your application is complete and acceptable for review and consideration.

The following job opportunity is being announced within the Office of Chemical Safety and Pollution Prevention **(OCSPP)**, Office of Pollution Prevention and Toxics **(OPPT)**, Existing Chemicals Risk Assessment Division **(ECRAD)**, Risk Assessment Branch 5 **(RAB5)**.

To view the specifics of this announcement, please click the following link:
https://www.usajobs.gov/GetJob/ViewDetails/588696100

Announcement Number: R-OCSPP-MP-2021-0022

Title:	Supervisory Biologist/Toxicologist/Environmental Engineer/Physical Scientist/Chemist
Series and Grade Announced:	GS-0401/0415/0819/1301/1320-15
Location of Position:	Washington, DC
Area of Consideration:	Current permanent EPA employees with competitive status or EPA Career Transition Assistance Program (CTAP) eligibles.
Position Type:	Full time, permanent
Opening Date:	January 6, 2021
Closing Date:	January 15, 2021
Number of Vacancies:	1
Position Risk Designation:	This position is designated as Moderate Risk and requires a background investigation.

To be considered for this position, applicants must apply on-line at the USAJOBS.gov website by the closing date of the announcement and follow the vacancy announcement instructions for providing any applicable supplemental information.

Please share this announcement with anyone that you feel may be interested and meets the eligibility requirements.

Please do not respond to this email. For questions regarding this job opportunity, please contact Gloria Ashley Gaines on 919-541-0990 or gaines.gloria@epa.gov

HOWARD BARNETT
CHIEF, HUMAN CAPITAL BRANCH
OCSPP/OPS/MSD
S-9913 POTOMAC YARDS SOUTH
ARLINGTON, VA

(703) 347-0311

Message

From: Bolen, Brittany [bolen.brittany@epa.gov]
Sent: 1/7/2021 1:03:16 AM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]; Ross, David P [ross.davidp@epa.gov]
CC: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]
Subject: RE: Nutrient Trading Policy Document & OMB

Got it

From: adm15.arwheeler.email <adm15.arwheeler.email@epa.gov>
Sent: Wednesday, January 6, 2021 8:02 PM
To: Ross, David P <ross.davidp@epa.gov>
Cc: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Wildeman, Anna <wildeman.anna@epa.gov>
Subject: Re: Nutrient Trading Policy Document & OMB

Put it through

Sent from my iPhone

On Jan 6, 2021, at 4:46 PM, Ross, David P <ross.davidp@epa.gov> wrote:

Confidential/Deliberative

Administrator,

Anna and I have one last nutrient trading policy document that we'd like to get on the street, further advancing our Feb. 2019 trading policy mentioned in the water subcab EO. The final document was developed with the benefit of public comment (prior to the new guidance rule taking effect). As the

Ex. 5 Deliberative Process (DP)

But, this document was inadvertently left off our priorities list for you (as was getting UCMR5 out of OMB, which cleared this week!), so Brittany needs your approval to communicate to OMB that this final policy document can get processed to and through OMB. We'd appreciate that approval so that we can get this processed and posted to our nutrients website.

Dave

David P. Ross
Assistant Administrator
Office of Water, EPA
ross.davidp@epa.gov

Message

From: Bolen, Brittany [bolen.brittany@epa.gov]
Sent: 1/6/2021 11:34:39 PM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
CC: Molina, Michael [molina.michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Scott, Corey [scott.corey@epa.gov]; Idsal, Anne [idsal.anne@epa.gov]
Subject: Ready to Sign - 111(b) New Sources EGU Final Rule
Attachments: 111(b) EGU Preamble and Rule 01_06_2021_Admin.docx

Administrator –

Attached for your electronic signature is the Pollutant-Specific Significant Contribution Finding for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units, and Process for Determining Significance of Other New Source Performance Standards Source Categories.

Please digitally sign this file using Word then email it back to me.

Thanks,

Brittany

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA-HQ-OAR-2013-0495; FRL-10019-30-OAR]

RIN 2060-AT56

Pollutant-Specific Significant Contribution Finding for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units, and Process for Determining Significance of Other New Source Performance Standards Source Categories

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this final action, the U.S. Environmental Protection Agency (EPA) is finalizing a significant contribution finding (SCF) for purposes of regulating source categories for greenhouse gas (GHG) emissions, under section 111(b) of the Clean Air Act (CAA) for electric generating units (EGUs), and in doing so, reaffirming that EGUs remain a listed source category. The EPA has reached that conclusion by articulating a framework under which source categories are considered to contribute significantly to dangerous air pollution due to their GHG emissions if the amount of those emissions exceeds 3 percent of total U.S. GHG emissions. The EPA is applying the 3-percent threshold to the EGU source category to demonstrate that GHG emissions from the EGU source category would contribute significantly to dangerous air pollution. While EGU GHG emissions exceed this threshold by a sufficient magnitude to warrant an SCF without more ado, the EPA has also, for completeness, analyzed EGU emissions under a secondary criteria framework, which also demonstrates the propriety of the SCF.

DATES: The final rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2013-0495. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. With the exception of such material, publicly available docket materials are available electronically through *https://www.regulations.gov/*. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Mr. Christopher Werner, Sector Policies and Programs Division (D243-01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5133; fax number: (919) 541-4991; and email address: *werner.christopher@epa.gov*.

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. The EPA uses multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

AEO	Annual Energy Outlook
BSER	best system of emission reduction
°C	degrees Celsius
CAA	Clean Air Act
CFR	Code of Federal Regulations
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
D.C. Cir.	United States Court of Appeals for the District of Columbia Circuit
DOE	Department of Energy
EGU	electric utility generating unit
EIA	U.S. Energy Information Administration
EPA	Environmental Protection Agency
°F	degrees Fahrenheit
GHG	greenhouse gas
HAP	hazardous air pollutant(s)
HFC	hydrofluorocarbon
km	kilometers
M	million
N_2O	nitrous oxide
NAICS	North American Industry Classification System
NGCC	natural gas combined cycle
NOx	nitrogen oxides
NSPS	new source performance standards
OMB	Office of Management and Budget
PC	pulverized coal
PFC	perfluorocarbon
PM	particulate matter
SF_6	sulfur hexafluoride
SO_2	sulfur dioxide
U.S.	United States
U.S.C.	United States Code

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
C. Judicial Review
II. Executive Summary
A. What is the purpose of this regulatory action?
B. What is the summary of the major provisions in this action?
C. What are the costs and benefits?
III. Summary of Previous Rulemaking Actions
IV. Pollutant-Specific Significant Contribution Finding (SCF)
A. Background

B. What is a Significant Contribution Finding (SCF)?
C. Primary Criteria for Determining Significance
D. Secondary Criteria for Determining Significance
E. Significant Contribution Finding for EGUs
V. Summary of Cost, Environmental, and Economic Impacts
A. What are the affected facilities?
B. What are the air quality impacts?
C. What are the energy impacts?
D. What are the cost impacts?
E. What are the economic impacts?
F. What are the benefits?
VI. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs
C. Paperwork Reduction Act (PRA)
D. Regulatory Flexibility Act (RFA)
E. Unfunded Mandates Reform Act (UMRA)
F. Executive Order 13132: Federalism
G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
I. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act (NTTAA)
K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
L. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Categories and entities potentially impacted by this rule include sources subject to new source performance standards (NSPS) requirements under section 111 of the CAA. While this rule informs all NSPS source categories, the EPA is finalizing a SCF specific to electric generating units regulated under 40 CFR part 60, subpart TTTT. The North American Industry Classification System (NAICS) code for the industrial, federal government, and state/local government electric generating units is 221112. The NAICS code for tribal government electric generating units is 921150.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action is available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at *https://www.epa.gov/stationary-sources-air-pollution/nsps-ghg-emissions-new-modified-and-reconstructed-electric-utility*. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the final rule and key technical documents at this same website.

C. Judicial Review

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the D.C. Circuit) by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Moreover, under section 307(b)(2) of the CAA, the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce these requirements. The Administrator has determined that this action is subject to section 307(d) of the CAA (42 U.S.C. 7607(d)(1)(V)). Section 307(d)(7)(B) of the CAA further provides that "[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review." This section also provides a mechanism for the EPA to convene a proceeding for reconsideration "[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment, (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule." Any person seeking to make such a demonstration

to us should submit a Petition for Reconsideration to the Office of the Administrator, U.S. Environmental Protection Agency, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

II. Executive Summary

A. What is the purpose of this regulatory action?

In Executive Order 13783 (Promoting Energy Independence and Economic Growth), all executive departments and agencies, including the EPA, were directed to "immediately review existing regulations that potentially burden the development or use of domestically produced energy resources and appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources beyond the degree necessary to protect the public interest or otherwise comply with the law."[1] Moreover, the Executive Order directed the EPA to undertake this process of review with regard to the "Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units," 80 FR 64510 (October 23, 2015) (2015 Rule).

In a document signed the same day as Executive Order 13783 and published in the **Federal Register** at 82 FR 16330 (April 4, 2017), the EPA announced that, consistent with the Executive Order, it was initiating a review of the 2015 Rule and providing notice of a forthcoming proposed rulemaking consistent with the Executive Order. After due deliberation, the EPA issued a proposed rulemaking, "Review of Standards of Performance for Greenhouse

[1] Executive Order 13783, Section 1(c), 82 FR 16093, March 31, 2017.

Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units—Proposed Rule," 83 FR 65424 (December 20, 2018) (2018 Proposal). Here the EPA is finalizing a rulemaking with respect to whether GHG emissions from EGUs contribute significantly to dangerous air pollution, in reliance on a methodology articulated herein for determining whether GHG emissions from other NSPS source categories contribute significantly to dangerous air pollution. Any action regarding the proposal to revise the standards of performance, including the underlying determinations of the BSER, for new, reconstructed, and modified coal-fired EGUs, including certain technical issues, is beyond the scope of this final rule and comments received on the 2018 Proposal will be addressed in a separate future action.

B. What is the summary of the major provisions in this action?

The EPA is finalizing a pollutant-specific SCF for GHG emissions from EGUs. That finding is based on an emissions threshold framework for determining significance, as well as secondary criteria to be applied in certain circumstances, for other NSPS source categories.

C. What are the costs and benefits?

In 2015, the EPA promulgated "Standards of Performance for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units," 80 FR 64510 (October 23, 2015) (2015 Rule). When the EPA promulgated the 2015 Rule, it took note of both utility announcements and U.S. Energy Information Administration (EIA) modeling and, based on that information, concluded that even in the absence of this rule, (1) existing and anticipated economic conditions are such that few, if any, coal-fired EGUs will be built in the foreseeable future, and that (2) utilities and project developers are expected to choose new generation technologies (primarily natural gas combined cycle (NGCC)) that would meet the

final standards and also renewable generating sources that are not affected by these final standards. *See* 80 FR 64515 (October 23, 2015). The EPA, therefore, projected that the 2015 Rule would "result in negligible CO_2 emission changes, quantified benefits, and costs by 2022 as a result of the performance standards for newly constructed EGUs." *Id.* The Agency went on to say that it had been "notified of few power sector new source performance standards (NSPS) modifications or reconstructions." Based on that additional information, the EPA said it "expects that few EGUs will trigger either the modification or the reconstruction provisions" of the 2015 Rule. *Id.* at 64516.

The EPA has concluded that the projections described in the 2015 Rule remain generally correct.[2] In the period of analysis,[3] the EPA expects there to be few, if any, newly constructed, reconstructed, or modified sources that will trigger the provisions the EPA is promulgating in this action. Consequently, the EPA projects that there will be no significant changes in carbon dioxide (CO_2) emissions or in compliance costs as a result of this final rule.

III. Summary of Previous Rulemaking Actions

On December 20, 2018, the EPA published a proposal to revise certain parts of the 2015 Rule; "Review of Standards of Performance for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units." 83 FR 65424 (2018 Proposal). The majority of that proposal was dedicated to the issue of the best system of emission reduction (BSER) for newly constructed, modified, and reconstructed coal-fired EGUs. Comments received on that issue are not being addressed in this rule and will be addressed in any future EPA action. In that proposal, the EPA solicited comment on whether to

[2] In the reference case for the most recent Annual Energy Outlook (AEO2020), the EIA projected no additions of new planned or unplanned coal capacity through 2050 (*www.eia.gov/aeo2020*; Table 9. Electricity Generating Capacity).
[3] Standards developed under the NSPS program must, by statutory requirement, be reviewed, at least, every 8 years.

make a pollutant-specific significant contribution determination for GHG emissions from EGUs, 83 FR 65432 n. 25, which is the subject of this action.

IV. Pollutant-Specific Significant Contribution Finding (SCF)

A. Background

CAA section 111(b)(1)(A) states that "[The Administrator] shall include a category of sources in such list if in his judgment it causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare."

In the 2015 Rule, the EPA promulgated standards for GHG (measured CO_2 emissions) from fossil fuel-fired steam generating EGUs and combustion turbines, a pollutant that the Administrator had not considered when he listed the categories of those sources - fossil fuel-fired steam generators[4] and stationary gas turbines.[5] *See* 80 FR 64510. Similarly, in 2016, the EPA promulgated an NSPS for GHG (measured by methane (CH_4) emissions) from oil and gas sources, a pollutant that the Administrator had not considered when he listed the category for those sources - the Crude Oil and Natural Gas Production source category.[6] *See* 81 FR 35824 (June 3, 2016) (2016 Oil & Gas Rule).

In each rule, the EPA interpreted CAA section 111(b) to require that an SCF and endangerment finding be made only with respect to the source category, at the time the EPA lists the category, and to authorize the EPA to promulgate NSPS for GHG, as long as the EPA

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[4] *See* "List of Categories of Stationary Sources," 36 FR 5931 (March 31, 1971) (listing source category); "Standards of Performance for New Stationary Sources," 36 FR 24376 (December 31, 1971) (promulgating NSPS for source category).

[5] *See* "Standards of Performance for New Stationary Sources; Gas Turbines," 44 FR 52792 (September 10, 1979) (listing and promulgating NSPS for source category).

[6] *See* "Priority List and Additions to the List of Categories of Stationary Sources," 49 FR 49222 (August 21, 1979) (listing source category); "Standards of Performance for New Stationary Sources; Equipment Leaks of VOC From Onshore Natural Gas Processing Plants," 50 FR 26124 (June 23, 1985), and "Standards of Performance for New Stationary Sources; Onshore Natural Gas Processing SO_2 Emissions," 50 FR 40160 (October 1, 1985) (promulgating standards of performance).

provides a rational basis for doing so. However, in each rule, the EPA acknowledged that some stakeholders had argued that the EPA first needed to make a pollutant-specific SCF, that is, a finding that GHG from the source category contributes significantly to dangerous air pollution. In each rule, the EPA stated that it disagreed with those stakeholders, but nevertheless, in the alternative, did make a pollutant-specific SCF for GHG, supported by the same reasons that the EPA had used to determine that it had a rational basis to regulate GHG. *See* 80 FR 64529 through 64531 (2015 EGU Rule); 81 FR 35840 through 35843 (2016 Oil & Gas Rule).

In the 2018 Proposal, in which the EPA proposed to revise the 2015 Rule, the EPA solicited comment on whether to adopt the interpretation that it was required to make an SCF for GHG from the EGU source category before it could promulgate an NSPS for CO_2. Some commenters stated that the EPA must make pollutant-specific findings of endangerment and significant contribution in order to establish an NSPS for that pollutant. These commenters explained that in their view, CAA section 111(b)(1)(A) requires the EPA to make two specific findings: (1) the specific "air pollution" to be regulated is "reasonably … anticipated to endanger public health or welfare;" and (2) the specific source category "causes or contributes significantly to" that air pollution. Commenters asserted that CAA section 111(b)(1)(A) is not ambiguous in this respect, and, therefore, the Agency's interpretation in the 2015 Rule directly contradicts the plain language of that section.

Other commenters stated that the EPA's approach in the 2015 Rule, that it needs to determine only that it has a rational basis to regulate GHGs emitted by this source category as a prerequisite to regulation, is sound. They said in the context of CAA section 111, the SCF and endangerment finding are made with respect to the source category, and not as to specific pollutants. These commenters supported the conclusion in the 2015 Rule that the EPA possesses

authority to regulate GHG emissions from fossil fuel-fired EGUs under CAA section 111 because there was no new evidence calling into question its determination that GHG air pollution may reasonably be anticipated to endanger public health and welfare and fossil fuel-fired EGUs have a high level of GHG emissions. The commenters stated that these considerations hew closely to the statutory factors that inform the decision whether to list a source category in the first place—namely, whether the category "causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare," under CAA section 111(b)(1)(A). The commenters added that this approach, which closely parallels the listing analysis but does not require a formal endangerment finding or SCF, is legally sound. They also added that the statute is clear that a formal endangerment finding is required to initially list a sector to be regulated under CAA section 111; but it is also clear that such a finding is not required before regulating additional harmful pollutants from a previously-listed sector.[7]

[7] Some commenters on the 2018 Proposal also said that, in the 2009 Endangerment Finding, the EPA specifically defined air pollution, as referred to in section 202(a) of the CAA, to be the mix of six well-mixed, long-lived, and directly emitted GHGs: CO_2, CH_4, N_2O, HFCs, PFCs, and SF_6. 74 FR 66497. They commented that the EPA needs to make, but has never made, a separate finding that CO_2 alone is reasonably anticipated to endanger the public health or welfare. The Agency disagrees with commenters. The air pollutant that the 2015 Rule regulates is GHG, and that air pollutant contributes to the same GHG air pollution that was addressed by the Endangerment Finding. The standards of performance adopted in the 2015 Rule take the form of an emission limitation on only one constituent gas of this air pollutant, CO_2. *See* 40 CFR 60.5515(a) ("The pollutants regulated by this subpart are greenhouse gases. The greenhouse gas standard in this subpart is in the form of a limitation on emission of carbon dioxide."). This is reasonable, given that CO_2 is the constituent gas emitted in the largest volume by the source category and for which there are available controls that are technically feasible and cost effective. There is no requirement that standards of performance address each component of an air pollutant. CAA section 111(b)(1)(B) requires the EPA to establish "standards of performance" for listed source categories, and the definition of "standard of performance" in CAA section 111(a)(1) does not specify which air pollutants must be controlled. Moreover, as the EPA noted in the 2015 Rule, the information considered in the 2009 Endangerment Finding and its supporting record, together with additional discussion of GHG impacts in the 2015 Rule, makes clear that GHG air pollution may reasonably be anticipated to endanger public health or welfare. *See* 80 FR 64517, 64530 and 31. Because the 2015 Rule followed the same approach as in the 2009 findings and regulated the same pollutant as contributing to the same air pollution (to reiterate, both the air pollutant and the air pollution are GHG as the group of six well-mixed gases, including CO_2), it was not necessary to evaluate CO_2 separately. The EPA took the same position in the 2016 Oil & Gas Rule in response to a similar comment concerning CH_4. *See* 81 FR 35843.

Similarly, in a 2019 proposal to revise the 2016 Oil & Gas Rule, the EPA solicited comment on whether to adopt the interpretation that it was required to make an SCF for GHG from the Oil and Gas source category before it could promulgate a CH_4 NSPS. Recently, the EPA completed the final rule to revise the 2016 Oil & Gas Rule, "Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review: Final Rule," 85 FR 57018 (September 14, 2020) (2020 Oil & Gas Rule). There, the EPA determined that a pollutant-specific SCF is required. In addition, the EPA further determined that the pollutant-specific SCF in the 2016 Oil & Gas Rule was invalid on grounds, in part, that the EPA had not established a threshold or criteria by which to determine whether an amount of emissions contributes significantly to dangerous air pollution, and to distinguish from an amount of emissions that simply contributes to dangerous air pollution. The EPA stated that section 111(b) of the CAA requires, or at least authorizes, a pollutant-specific SCF, and such an SCF must be based on defined criteria or thresholds. *Id.* at 57033-40.

B. What is a Significant Contribution Finding (SCF)?

1. Significant Contribution Finding and Key Comments Received

CAA section 111 directs the EPA to regulate, through a multi-step process, air pollutants from categories of stationary sources. CAA section 111(b)(1)(A) requires the initial action, which is that the Administrator must "publish … a list of categories of stationary sources. He shall include a category of sources in such list if in his judgment it causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare." Therefore, the first action that the EPA must take, specified in CAA section 111(b)(1)(A), is to list a source category for regulation on the basis of a determination that the category contributes significantly to dangerous air pollution. This provision makes clear that

although Congress designed CAA section 111 to apply broadly to source categories of all types wherever located, Congress also imposed a constraint: The EPA is authorized to regulate only sources that it finds cause or contribute significantly to air pollution that the EPA finds to be dangerous. Because CAA section 111(b)(1)(A) refers to air *pollution*, the EPA's determination that a source category should be listed for regulation can be based on all pollutants emitted by the category (*i.e.*, collective contribution), or for a specific pollutant.

After the EPA lists a source category, CAA section 111(b)(1)(B) then directs the EPA to propose regulations "establishing Federal standards of performance" for new sources within the source category, to allow public comment, and to "promulgate … such standards with such modifications as he deems appropriate." CAA section 111(a)(1) defines the term "standard of performance" as "a standard for emissions of air pollutants which [the Administrator is required to determine through a specified methodology]." These provisions read together make clear that the standards of performance that CAA section 111(b)(1)(A) directs the Administrator to promulgate must concern air pollutants emitted from the sources in the source category. However, industrial sources of the type subject to CAA section 111(b)(1)(A) invariably emit more than one air pollutant, and neither CAA section 111(b)(1)(B) nor CAA section 111(a)(1), by their terms, specifies for which of those air pollutants the EPA must promulgate standards of performance.

In the past, the EPA has interpreted CAA section 111(b)(1)(B) to authorize it to promulgate standards of performance for any air pollutant that the EPA identified in listing the source category and any additional air pollutant for which the EPA has identified a rational basis for regulation. 81 FR 35843 (2016 Oil & Gas Rule); 80 FR 64510 (2015 Rule). Inherent in this approach is the recognition that CAA section 111(b)(1)(A) does not, by its terms, necessarily

require the EPA to promulgate standards of performance for all air pollutants emitting from the source category. The EPA could list a source category on grounds that it emits numerous air pollutants that, taken together, significantly contribute to air pollution that may reasonably be anticipated to endanger public health or welfare, and proceed to regulate each of those pollutants, without ever finding that each (or any) of those air pollutants by itself causes or contributes significantly to—or, in terms of the text of other provisions, causes or contributes to—air pollution that may reasonably be anticipated to endanger public health or welfare.

As described in the 2020 Oil and Gas Policy Rule, CAA section 111(b)(1)(A) does not provide or suggest any criteria to define the rational basis approach, the EPA has not articulated any criteria in its previous applications in the EGU CO_2 NSPS and the 2016 40 CFR part 60, subpart OOOOa rules, and in instances before those rules in which the EPA has relied on the "rational basis" approach, the EPA has done so to justify not setting a standard for a given pollutant, rather than to justify setting such a standard. 85 FR 77037, December 1, 2020. Thus, the rational basis test allows the EPA virtually unfettered discretion in determining which air pollutants to regulate. As a result, the rational basis standard creates the possibility that the EPA could seek to promulgate NSPS for pollutants that may be emitted in relatively minor amounts.

In contrast, CAA section 111(b)(1)(A) is clear that the EPA may list a source category for regulation only if the EPA determines that the source category "causes or contributes *significantly*" (emphasis added) to dangerous air pollution. As described in the 2020 Oil and Gas Policy Rule, in light of the stringency of this statutory requirement for listing a source category, it would be unreasonable to interpret CAA section 111(b)(1)(B) to allow the Agency to regulate air pollutants from the source category merely by making an administrative determination under the open-ended and undefined rational basis test. The EPA, therefore, determined it is logical to

interpret CAA section 111(b)(1)(B) to require that the Agency apply the same degree of rigor in determining which air pollutants to regulate as it does in determining which source categories to list for regulation, and, therefore, must make a pollutant-specific SCF. *Id.*

Requiring a pollutant-specific SCF necessitates the establishment of a clearer framework for assessing which air pollutants merit regulatory attention that will require sources to bear control costs. The establishment of such a framework or criteria promotes regulatory certainty for stakeholders and consistency in the EPA's identification of which air pollutants to regulate and reduces the risk that air pollutants that do not merit regulation will nevertheless become subject to regulation due to an unduly vague standard.

As previously described, CAA section 111(b)(1)(B) requires the EPA to establish an NSPS for a source category listed under CAA section 111(b)(1)(A). For a source category previously listed under CAA section 111(b)(1)(A), in order to subsequently promulgate an NSPS for a pollutant that the EPA did not evaluate the source category for at the time of listing, the EPA must make a pollutant-specific SCF for the reasons described above. As part of making an SCF, the EPA concluded in the 2020 Oil and Gas Policy Rule that, "a standard or an established set of a criteria, or perhaps both, are necessary to identify what is significant and what is not." 85 FR 57039. The EPA did not finalize or take a position in the 2020 Oil and Gas Policy Rule on potential criteria, stating that it was deferring the identification of such criteria to a future rulemaking. *Id.* CAA section 111(b) itself does not specify what the criteria for a pollutant-specific SCF.

The "contributes significantly" provision in CAA section 111(b)(1)(A) is ambiguous as to what level of contribution is considered to be significant. *See* 84 FR 50267 and 50268, September 24, 2019 (citing *EPA* v. *EME Homer City Generation, L.P.*, 572 U.S. 489 (2014)

(holding that a similar provision in CAA section 110(a)(2)(D)(i), often termed the "good neighbor" provision, is ambiguous)). Accordingly, the EPA has authority to interpret that provision. *Id.* at 50268. As noted above, the EPA reads CAA section 111(b)(1)(B) in light of CAA sections 111(b)(1)(A) and 111(a)(1) to incorporate the "contributes significantly" standard in connection with promulgating NSPS for particular air pollutants. The EPA has concluded that to allow the EPA to distinguish between a *contribution* and a *significant contribution* to dangerous pollution, some type of (reasonably explained and intelligible) standard and/or established set of criteria that can be consistently applied is necessary.

A supporting basis for this conclusion can be found by looking at the EPA's interpretation of the similarly worded "contribute significantly" provisions of CAA section 189(e), concerning major stationary sources of particulate matter with a diameter of 10 micrometers or less (PM_{10}). This provision requires that the control requirements applicable to major stationary sources of PM_{10} also apply to major stationary sources of PM_{10} precursors "except where the Administrator determines that such sources [of precursors] do not contribute significantly to PM_{10} levels which exceed the standard in the area." As the EPA noted in the 2019 Oil and Gas Policy Rule proposal, in CAA section 189(e), Congress intended that, in order to be subject to regulation, the emissions must have a greater impact than a simple contribution not characterized as a significant contribution. However, Congress did not quantify how much greater. Therefore, the EPA developed criteria for identifying whether the impact of a particular precursor would "contribute significantly" to a NAAQS exceedance. 84 FR 50268. These criteria included numerical thresholds. *Id.* The EPA concluded similarly that, under CAA section 111(b), a standard or an established set of a criteria, or perhaps both, are necessary to identify what is significant and what is not.

These criteria help ensure that the EPA's decision-making is well-reasoned and consistent. The EPA considers it particularly important to develop a set of criteria and/or a standard in order to determine when a *significant* contribution occurs, in order, as noted above, to distinguish it from a simple contribution. A contribution can be greater or lesser and remain a contribution, but a significant contribution determination necessarily involves a judgment about the degree of the contribution that rises to the level of significance. For such a judgment to be meaningful (and, of critical importance, to be understood by regulated parties and by the public), the Agency must identify the criteria it will use to determine significance.

2. Other Comments Received on the EPA's Basis for Regulating GHG Emissions from EGUs

Comment: Commenters stated that the EPA must make the specific pollutant findings of endangerment and significant contribution that are required in listing a source category in order to establish a NSPS for that pollutant. Commenters stated they are not arguing that the EPA could not or should not make these findings. Rather, that the Clean Air Act (CAA) requires the EPA to make two specific findings: (i) the specific "air pollution" to be regulated is "reasonably … anticipated to endanger public health or welfare"; and (ii) the specific source category "causes or contributes significantly to" that endangering air pollution. CAA section 111(b)(1)(A). The commenters said section 111(b)(1)A) is not ambiguous at all in this respect, and therefore the Agency's interpretation in the 2015 Rule directly contradicts the plain language of this section. Additionally, they said that in the 2009 Endangerment Finding, the EPA specifically defined air pollution, as referred to in section 202(a) of the CAA, to be the mix of six long-lived and directly emitted GHGs: CO_2, CH_4, N_2O, HFCs, PFCs, and SF_6 (74 FR 66497, December 15, 2009). They commented that the EPA did not make a separate finding then, or now, that CO_2 alone is a danger to the public health or welfare and the EPA has argued that because CO_2 is the "dominant

anthropogenic GHG," it is not required to "make an endangerment finding with respect to a particular pollutant." (*Id*). They argued that this view does not satisfy the statutory standard and said the GHG endangerment determination in section 111(b)(1)(A) is fundamentally different than that in section 202(a) and other CAA sections, in part because it: (i) is source-category based; and (ii) requires a finding of significance.

These commenters stated that in the 2015 Rule, the EPA made three arguments as to why it believed it had met its statutory obligations. The commenters stated that none of these arguments are correct as a legal matter for the following primary reasons: (1) the EPA was wrong in claiming that new CO_2-specific findings were unnecessary, as the 2015 Rule was for a new category of electric utility generating unit (EGUs) emitting CO_2—a specific pollutant for which an endangerment finding had not been made. EPA's prior listings of "steam generators" and "stationary gas turbines" covered only emissions of NO_X, SO_2, and particulate matter. Because EPA's findings in earlier listings addressed different pollutants, those listings triggered and authorized only regulation of NO_X, SO_2, and particulate matter. *Cf. Nat'l Asphalt Pavement Ass'n v. Train*, 539 F.2d 775 (D.C. Cir. 1976). EPA has asserted the authority to regulate under section 111 any pollutant for which EPA believes it has a "rational basis" to regulate (see 83 FR 65432; 80 FR 64530). But this "rational basis" standard is not the one authorized by section 111; the endangerment and significant contribution standard governs section 111 regulation. EPA cannot rewrite the statute to circumvent the endangerment and significant contribution standard that Congress prescribed for section 111 regulation.; (2) the EPA cannot rely on its 2009 finding regarding GHG emissions from automobiles which determined that "six well-mixed GHGs" in the "aggregate" endanger public health or welfare, as this "combined mix" is different air pollutant than the single pollutant controlled here (CO_2 alone). EPA has never found that CO_2

alone endangers public health or welfare, much less that CO_2 from fossil fuel-fired steam generating units (as opposed to motor vehicles) has that effect; and (3) the EPA's attempt to rely on "information and conclusions" contained in the 2015 Rule does not satisfy the CAA. Simply identifying the evidence that might support a finding is not the same as completing the administrative process of distilling and analyzing that data in the context of the Agency's statutory obligations and its failure to make the requisite findings of endangerment and significant contribution in the 2015 Rule violated the CAA. They said the CAA grants the EPA narrowly bounded authority to regulate stationary sources that emit pollutants that may reasonably be anticipated to endanger public health or welfare *for those pollutants* which led to the endangerment finding and to which the source category significantly contributes. The CAA does not grant the Agency unlimited authority to regulate any pollutant emitted by that source. Accordingly, before the EPA finalizes the 2018 Proposal, it must make a specific and supportable finding that CO_2 emissions from fossil fuel-fired EGUs pose a danger to public health and welfare. They said the EPA should reject its ill-founded "rational basis test" for imposing performance standards without endangerment and contribution findings. The Agency's rational basis test is not in the CAA. They argued that section 111 never uses the term and the case law on which the EPA relied for this test addresses agency authority under a different statute, the Administrative Procedure Act (APA). The APA does not define the scope of the EPA's authority to undertake this rulemaking.

Commenters added that as a textual matter, the endangerment requirement modifies, and relates back to, "air pollution," not "sources": The provision requires the EPA to determine whether a source causes or contributes significantly to "air pollution which may reasonably be anticipated to endanger public health or welfare." 42 United States Code (U.S.C.) section

7411(b)(1)(A). Only after the EPA determines that a pollutant poses a threat to "public health or welfare" must it inquire whether the particular category of sources "contributes significantly" to that pollution. *Id.* The idea that an endangerment finding is "one and done" on a source level also cannot be squared with the surrounding statutory requirements. Section 111(b)(1)(B) provides that the EPA may issue performance standards after a source category is listed pursuant to section 111(b)(1)(A). *Id.* section 7411(b)(1)(B). Yet by definition, a "standard of performance" is tied to specific pollutants for which an endangerment finding has been made. *Id.* section 7411 (a)(1) (defining a "standard of performance" as "a standard for emissions of air pollutants). Commenters said that as such, the approach in the 2015 Rule would give the EPA unfettered authority to regulate any air pollutant emitted by a source regardless of whether it endangers health or welfare and the 2015 Rule's approach of mixing and matching elements of endangerment findings would allow the EPA to impose stringent regulations on sources that do not "contribute significantly" to emissions of a pollutant. In summary, the commenters argued that if the EPA "retain[s]" the "statutory interpretation" of section 111 as set out in the 2015 Rule, 83 FR 65432 n. 25, it will once again be setting standards beyond the scope of its authority and it may be that the EPA can make the findings section 111(b)(1)(A) requires for CO_2 emissions from fossil-fuel-fired electricity generating units, but unless and until the EPA makes those determinations under the proper legal standard, the Proposed Rule will rest on a flawed foundation.

Commenters stated that the previous endangerment findings the EPA listed in the 2015 Rule did not relate to "fossil fuel-fired electricity generating units." (80 FR 64527 nn.86 & 87). Rather, one related to "steam generators," (36 FR 5931, March 31, 1971, -cited at 80 FR 64527 n.86), and the other to "stationary gas turbines," (42 FR 53657. October 3, 1977, - cited at 80 FR

64527 n.87). The commenters stated that this failing should prevent the EPA's ability to move forward with proposed regulation because the Agency has not issued the required endangerment finding for the specific source category, it becomes irrelevant whether it may rely on that (nonexistent) finding to justify setting standards of performance for different emissions from sources in the category.

Commenters stated that in the 2016 subpart OOOOa rulemaking, the EPA established NSPS for CH_4 without making an endangerment finding for CH_4 emissions from oil and gas sources. Commenters and other industry groups filed comments pointing out the EPA's omission in failing to make a section 111(b) endangerment finding for the new pollutant subject to regulation under NSPS. By imposing NSPS requirements for a new pollutant without first establishing that that pollutant "may reasonably be anticipated to endanger public health or welfare" *(i.e.,* making an endangerment finding), commenters urged the EPA to reject and withdraw the interpretation that the EPA may skip the endangerment finding step in this context. The commenters further urged the EPA to clarify that a statutory prerequisite for regulation of a new pollutant under the NSPS program is an endangerment finding for that particular pollutant. Finally, and as a separate matter, the commenters urged the EPA to revisit the legal underpinnings for the subpart OOOOa standards as the commenters asserted the EPA did not follow the statutory prerequisites for the adoption of such standards. According to the commenters, those standards are illegal as being outside of the agency's authority, and as such should now be withdrawn.

Other commenters stated that the EPA's previous approach in the 2015 Rule to determining that it has a rational basis to regulate GHGs emitted by this source category is sound. The Agency has correctly not reopened this approach, nor has it proposed any alternatives

to it. They said in the context of section 111, the endangerment finding is made with respect to the source category, and not as to specific pollutants (80 FR 64530). It would be unlawful for the Agency to finalize any alternative approach. In 2015, the EPA concluded that it possesses authority to regulate GHG emissions from fossil fuel-fired EGUs under section 111 for two reasons: (1) there was no new evidence calling into question its determination that "GHG air pollution may reasonably be anticipated to endanger public health and welfare"; and (2) fossil fuel-fired EGUs have a "high level of GHG emissions." These considerations hew closely to the statutory factors that inform the decision whether to list a source category in the first place—namely, whether the category "causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare." In fact, in 2015 the Agency confirmed that, even if it were required to issue endangerment and significant contribution findings under this provision in order to regulate GHGs emitted by EGUs, the same information that underpinned its rational basis conclusion would support such findings (80 FR 64530). This approach, which closely parallels the listing analysis but does not require formal endangerment or cause-or-contribute findings, is legally sound. The statute is clear that a formal endangerment finding is required to initially list a sector to be regulated under section 111—and is also clear that such a finding is not required before regulating additional harmful pollutants from a previously-listed sector. Because Congress did not provide specific criteria for regulating additional pollutants from a source category that is already listed under section 111, it is reasonable to look to the statutory factors that trigger regulation initially when deciding whether to require reductions of other pollutants. They said the statutory factors for listing a source category—the endangerment and cause-or-contribute findings—provide a floor for when EPA *must* regulate an additional pollutant from a listed source category under the rational basis

inquiry. It would be irrational to fail to regulate an additional pollutant simply because a source category was already listed, if the same evidence regarding that pollutant would have triggered a formal listing of that source category had the source category not previously been listed. Thus, it would be arbitrary for the agency to decline to regulate a pollutant on the basis of considerations wholly unrelated to the harms that pollutant poses or the quantities in which it is emitted from a particular source category.

Other commenters also stated that any effort to reverse the EPA's decision to regulate CO_2 from power plants would require, among other things, that the EPA fully contend with each step of the statutory and legal analysis of section 111 it undertook in the 2015 Rule, and explain why each of them has become invalid. They said promulgating a final rule contrary to the 2015 Rule without the requisite record-based, factual analysis and reasoned explanation would yield "an unexplained inconsistency in agency policy" that is arbitrary, capricious, and unlawful. Commenters stated that that while the most comprehensive approach to sensible GHG regulation remains through congressional action, and while the CAA is far from the perfect tool for regulating GHGs, it is preferable to protracted legal battles and to the potential patchwork of judicial and regulatory outcomes. As a result, the Agency should retain the existing endangerment finding. They said that if the EPA fails to regulate GHG emissions from new coal-fired EGUs it would be wholly unreasonable and contrary to the endangerment finding.

Response: The EPA addressed the substance of these comments in a lengthy discussion in "Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review: Final Rule," 85 FR 57018, 57033-40, 57052-58 (September 14, 2020). That discussion is incorporated by reference here. That discussion further elaborates the rationale for EPA's determination that a pollutant-specific significant contribution determination is

appropriate, and EPA's related determinations. That discussion also responds in full to the comments on the present rule.

It should be noted that in the 2015 Rule, EPA combined the steam generating source category and combustion turbine source category into a single source category for purposes of GHG emission regulation, 80 FR 64510, 64521-32 (October 23, 2015), and determined, in the alternative, that GHG emissions from the combined source category contribute significantly to dangerous air pollution. *Id.* at 64531. In today's rulemaking, the EPA is not revising the source category determination in the 2015 Rule and, by the same token, the significant contribution finding that EPA is making in the present rulemaking for GHG emissions concerns emissions from the same, combined source category.

Comment: Commenters stated that if the Endangerment Finding is overturned, the electric power sector could be broadly exposed to tort and nuisance suits brought by citizens and states—as was the case prior to the EPA regulation of GHGs (*e.g.*, *American Electric Power Co. v. Connecticut*, 564 U.S. 610 (2011)). Accordingly, these efforts would create more uncertainty about the future of GHG regulations applicable to new EGUs—uncertainty that likely would not be resolved for years and could undermine any potential for generation owners and operators to consider new coal-based generation as a viable option. They said as a result, the Agency should retain the existing endangerment finding.

Response: The Agency has not proposed to overturn the existing Endangerment Finding and is not overturning it in this final rule.

Comment: Commenters stated that to the extent that emissions of CO_2 from new, modified, or reconstructed electric utility generating units are to be subjected by the EPA to regulation under the CAA, the proper path would be to regulate such emissions as part of a

broader effort to regulate CO_2 emissions from "numerous or diverse" sources under sections 108-110 of the CAA. Alternatively, if the EPA is adamant in engaging in regulating such emissions under section 111(b), at the very least the EPA must complete a specific endangerment finding for CO_2 emissions from such facilities under the applicable criteria set forth in section 111(b), which the EPA has failed to do to date. Either way, commenters stated that the proposed rule amendment is beyond the legal authority of the CAA.

Response: EPA is making a pollutant-specific significant contribution finding in this action.

Comment: Commenters quoted the NSPS proposal as stating that "the Agency will consider comments on the correctness of the EPA's interpretations and determinations, and whether there are alternative interpretations that may be permissible, either as a general matter or specifically as applied to GHG emissions" (83 FR 65242, 65432 n.25). Commenters then stated that they filed a petition in 2017 contending that the EPA should commence a new rulemaking on the subject of the Agency's 2009 endangerment finding. They provided the following arguments of the 2017 petition: 1) there had been no statistically significant atmospheric warming despite a continued increase in atmospheric CO_2 levels; 2) changes in global temperatures in recent decades were far from unusual; 3) new balloon and satellite data showed that the atmosphere was far less sensitive to CO_2 forcing than the climate models had predicted; and 4) there was mounting evidence that the EPA's GHG rules would have no discernible climate impact. For these reasons, they said there was a need to reexamine both the three lines of evidence for the EPA's endangerment finding as well as its underlying rationale. Regarding the proposal, the commenters stated that in addition to their still pending petition, they are providing new evidence for why the Agency should proceed with this petition and with similar petitions

pending before it. They submitted references (titles, weblinks, and synopses) to nine research papers published since filing their initial petition which they argue add additional support. They stated that given the points and data outlined in this newer research, in addition to those set forth in their 2017 petition, the EPA should commence a new proceeding to reexamine its 2009 endangerment finding.

Response: The Agency is retaining the existing endangerment finding. The submitted material is out of scope for this rulemaking. With regards to the claim that EPA was soliciting comments on this subject, the footnote quoted by the commenters goes on to specifically outline examples of the kind of comments referred to: this further elaboration made clear that EPA was not soliciting comments on the science of climate change but rather regarding interpretation of statutory language and legal opinion as to whether the Agency would need to make an endangerment finding for previously listed source categories ("For example, the Agency will consider comments on the issue of whether it is correct to interpret the "endangerment finding" as a finding that is only made once for each source category at the time that the EPA lists the source category or whether the EPA must make a new endangerment finding each time the Agency regulates an additional pollutant by an already-listed source category. Further, the EPA will consider comments on the issue of whether GHG emissions are different in salient respects from traditional emissions such that it would be appropriate to conduct a new "endangerment finding" with respect to GHG emissions from a previously listed source category. In addition, the EPA solicits comment on whether the Agency does have a rational basis for regulating CO_2 emissions from new coal-fired electric utility steam generating units and whether it would have a rational basis for declining to do so at this time" 83 FR 65242, 65432 n.25).

Comment: Commenters also said that the Agency suggestion in footnote 25 of the Proposal is unreasonable in that the Agency seems to presume that it might not be appropriate to regulate GHGs from new coal-fired power plants because the Agency projects that few such plants will be built in coming years. They said this approach asks the wrong question. The question should be whether there is a rational basis to regulate GHGs from power plants – not just new coal-fired plants. This is because, once new sources are regulated under section 111(b), the obligation to regulate existing sources under section 111(d) is triggered. If new sources in a source category could not be regulated under section 111(b), no sources in the category could be regulated. Commenters further stated that the EPA cannot reverse its position merely by asking for comments on whether it should adopt a new position diametrically opposed to both current law and the position it maintains in the Proposed Rule.

Commenters stated that using footnote 25 as a means of requesting public comment is misleading and violates administrative procedures. They said that it appears that the EPA is seeking rationale or justification to under the legal basis for this rule while claiming that is retaining its legal basis. The EPA cannot have it both ways: either EPA is using its legal basis, or it is looking for alternatives. If it is looking for alternatives, then EPA has not met its responsibilities under the Administrative Procedures Act for fair notice of the nature and scope of this rulemaking.

Commenters stated that in the endangerment finding footnote of the 2018 Proposal (83 FR 65432 n 25), the EPA suggests that it may consider whether it would have a rational basis to decline to regulate given that "no more than a few new coal-fired EGUs can be expected to be built." The commenters said this suggestion is not legally or factually sound and does not provides a valid reason not to regulate GHGs from fossil fuel-fired EGUs under section 111.

They said the statute is unambiguous: the EPA must consider pollution from both new and existing sources when deciding whether to regulate a pollutant within a source category. To the extent that the statute contains any ambiguity, a decision not to regulate based solely on projected levels of emissions from new sources would be disallowed as an impermissible construction. They argued that section 111(b) unambiguously expresses Congress's concern with pollution emitted from a source category as a whole, not just new sources and 111(b) directs the Administrator to base decisions about whether to list a source category on an analysis of the entire category, including existing sources. Section 111(b)(1)(A) does not distinguish between "new" and "existing" sources but rather conveys Congress's directive to address pollution across the source category.

The commenters also stated that Footnote 25 of the proposal raises the prospect that, on the question of regulating a pollutant from a listed source category, Congress inexplicably intended for the EPA to consider pollution from new sources only, irrespective of the harm caused by pollution from existing sources—and even though Congress directed the EPA to consider the air pollution from the sector as a whole, that plain language should be ignored. They said the Agency presents no support for this theory, which is contrary to both the clear terms and the evident objective of the statute. The commenters argued that Footnote 25's suggested interpretation disregards statutory language in other ways as well. For example, section 111(b)(1) provides that the Administrator "shall include a category of sources in such list if in his judgment it *causes, or contributes significantly to*, air pollution which may reasonably be anticipated to endanger public health or welfare." (42 U.S.C. section 7411(b)(1)(A)). Yet as of the date of when the EPA determines to list a source category, there are no "new" sources in existence. Section 111(a)(2) provides: "The term "new source" means any stationary source, the

construction or modification of which is commenced *after the publication of regulations (or, if earlier, proposed regulations) prescribing a standard of performance under this section* which will be applicable to such source." (*Id.* section 7411(a)(2)). They said under section 111, listing *precedes* promulgation of standards. So, when the EPA decides whether to list a category, by definition it has not yet *proposed* section 111 standards for that category and because it has not proposed such standards, no sources qualify as "new" sources under section 111(a)(2). Basing a decision not to list (and therefore not to regulate) a source category solely on the absence of emissions from as yet nonexistent "new" sources—while ignoring sources that already exist and are emitting pollutants that threaten harm to public health and welfare—is not a tenable reading of the statutory language.

Response: In this rule, EPA takes the position that GHG emissions from new and existing EGUs contribute significantly to dangerous air pollution. While EPA proposed to retain the position that it stated in the 2015 Rule that a pollutant-specific significant contribution finding is not required, it solicited comment on whether such a finding is required, and that comment solicitation provided adequate notice.

Comment: Commenters stated that though the EPA notes that it is not proposing to revisit its 2009 endangerment finding for greenhouse gases, the proposed NSPS revisions request comment on whether recent and projected power sector trends present a rational basis to decline to regulate CO_2 emissions from the power sector. The suggested comment area, presented in footnote 25, cites power sector trend projections from the Energy Information Administration's (EIA's) 2018 Annual Energy Outlook and findings from the EPA's proposed Affordable Clean Energy (ACE) rule as potential support for this position. Commenters also stated that the EIA's 2018 Annual Energy Outlook does not indicate that power sector CO_2 emissions will decline

significantly in the future. Instead, the estimates referenced by the EPA in the proposal project that CO_2 emissions from the power sector will remain the single largest sector-based source of CO_2 emissions over the long term, totaling 1.72 billion tons in 2020, 1.71 billion tons in 2030, and 1.78 billion tons in 2050. Commenters said though the EPA found that the transportation sector overtook the power sector as the largest sector-based source of GHG emissions in 2017, the 2018 Annual Energy Outlook projects that power sector emissions will regain the top ranking in 2026 and maintain a lead over the transportation sector by growing modestly through 2050. Commenters stated while newer EIA projections that were unavailable at the time of the EPA's proposal indicate slightly lower power sector CO_2 emissions, EIA still projects significant and sustained power sector GHG emissions through 2050, not a steady decline. Commenters said a report from the Rhodium Group based on preliminary EIA data for 2018 and released a few weeks after the EPA's proposal estimates that power sector-related GHG emissions increased 3.4 percent in 2018, breaking a three-year trend of decreases. Commenters added still more recent EPA data reveals the same pattern. Commenters stated preliminary 2018 emissions data compiled by EPA's Clean Air Markets Division (CAMD), also released after the proposed NSPS revisions were published in the *Federal Register*, show power sector CO_2 emissions rising from 1.92 billion tons in 2017 to 1.93 billion tons in 2018. Commenters said prior to the 2018 release, EPA's CAMD data had shown flat or declining CO_2 emissions for every year since 2013.

Commenters stated it would be unlawful and arbitrary for the EPA to use declining power sector emissions as reason for not regulating. They argued that even if power sector emissions are declining—which is not at all clear—they are far higher than levels necessary to keep CO_2 concentrations from rising further, let alone to achieve the necessary net-zero balance. CO_2 pollution accumulates in the atmosphere, where it lingers for centuries, such that a year-to-year

decline in emissions does not prevent atmospheric concentrations from continuing to rise, exacerbating the impacts of climate change. "[T]he urgency of reducing emissions now," (80 FR 64520) which the EPA acknowledged in the 2015 Rule, has only increased in recent years. Commenters said reliance on recent emission trends is even more unfounded because U.S. climate pollution significantly increased in 2018, including a 1.9 percent increase in power sector carbon pollution. Even before the 2018 data were available, U.S. Energy Information Administration (EIA) had recognized long-term market and economic uncertainty, which could potentially drive some shift back to coal generation. EIA projections now show that the general trend toward declining carbon pollution from the power sector is likely to flatten out in the early 2020s. Commenters stated standards that even if pollution levels were declining more steadily, that would not authorize the EPA to ignore its obligation to protect the public from what will continue to be a major threat to public health and the environment. The CAA is not concerned merely with whether pollution levels are currently below their historic peak. To the contrary, the Agency must ensure that pollution is controlled to the degree the statute requires—*i.e.*, in accordance with a standard of performance that reflects the best system of emission reduction (BSER) (42 U.S.C. section 7411(a)(1)).

The commenters also said that there may be other reasons why a developer would be willing to pay a premium to build a new coal-fired plant that the models do not consider (80 FR 64559-64562). Thus, it is unreasonable not to establish standards of performance on the assumption that coal-fired power plants will never again be built (or modified). They said that the Agency does not even consider the fact that the source category includes not only new sources but also existing sources that undergo certain "modifications," and that such modified sources have significant CO_2 emissions.

Commenters said that by asking whether the Agency has a rational basis for regulating CO_2 emissions from new coal-fired EGUs "in light of" the projections cited in footnote 25, the EPA is setting itself up to conduct continual market evaluations for all the EPA regulations for which regulation is premised on a similar type of prerequisite determination. An interpretation of section 111 that leads to that result is unreasonable and impractical. They said that there is no indication in the CAA that Congress intended the Agency to undertake a continual market assessment of this nature.

Commenters stated that the endangerment finding footnote of the 2018 Proposal (83 FR 65432 footnote 25) contains a fatal factual deficiency in that it suggests that the rational basis finding might be reversed because "no more than a few new coal-fired EGUs can be expected to be built, which raises questions about whether new coal-fired EGUs contribute significantly to atmospheric CO_2 levels." The commenters said that not only does this suggestion disregard the EPA's 2015 acknowledgment that "the CO_2 emissions from even a single new coal-fired power plant may amount to millions of tons each year," but it entirely ignores natural gas-fired power plants, which are also included in the source category. In making the 2015 determination, the EPA specifically observed that "the CO_2 emissions from even a single natural gas combined cycle (NGCC) unit may amount to one million or more tons per year." They said natural gas-fired power plants continue to be built at a steady clip as evidenced by the first ten months of 2018 in which 14.9 gigawatts (GW) of natural gas-fired EGU capacity was added to the grid. New gas plants must be accounted for and by failing to do so, the Agency would forfeit any "rational connection between the facts found and the choice made," and would fail to provide "a reasoned explanation . . . for disregarding facts and circumstances that underlay . . . the prior policy." Each of those flaws would render the decision arbitrary and capricious. Commenters

said that even if the EPA legally could regulate CO_2 emissions from new natural gas plants without regulating CO_2 emissions from new coal-fired power plants, the EPA should not do so because such partial regulation would provide an inadvertent subsidy to new coal-fired plants.

Response: In this rule, the EPA is determining that GHG emissions from EGUs contribute significantly to dangerous air pollution and is promulgating revised standards of performance for EGU GHG emissions. To the extent it is useful or necessary in this rulemaking for the EPA to further address whether long-term emission trends, or related considerations, are relevant for a significant contribution determination, the EPA does so elsewhere in this document.

C. Primary Criteria for Determining Significance

In this section, the EPA describes criteria for determining when GHG emissions from a source category contribute significantly to dangerous air pollution in response to comments submitted on this rule. The EPA indicated in the 2020 Oil and Gas Policy Rule that it would finalize these criteria in a separate rulemaking. 85 FR 57039.

1. GHG Emissions

The criteria discussed herein only apply to GHG in the context of the EPA's SCF under CAA section 111(b)(1)(B). This action does not discuss criteria for pollutants other than GHGs. Under this framework, the EPA is determining that the quantity of GHG emissions from a source category is the primary criterion in determining significance for purposes of regulation of GHGs from a source category under CAA section 111(b). Gross GHG emissions are important for this set of pollutants because GHGs are global long-lived pollutants and do not have the local, near-term ramifications found with other pollutants (*e.g.*, criteria pollutants). Unlike other pollutants where both the location and quantity of pollution emissions are factors in determining the impact

of the emissions, GHGs' impact (*i.e.*, climate change) is based on a cumulative global loading and the location of emissions is not nearly as important a factor as it is for assessing local, near-term impacts associated with criteria pollutants. It is for this reason that, when the EPA is assessing GHGs impact in contributing significantly to air pollution which may reasonably be anticipated to endanger public health and welfare, the quantity of emissions should be the primary criterion that the EPA should evaluate.

The GHG emissions are the best, but not necessarily only, indicator of significance because the quantity of emissions emitted from a source category correlates directly with impacts. Calculations using the Model for the Assessment of Greenhouse Gas Induced Climate Change (MAGICC model) to investigate the impact of including or eliminating a single sector's emissions from 2020 through 2100 have shown that the magnitude of emissions from that single sector is very close to being linearly related to the projected temperature change in 2100 resulting from eliminating that sector's emissions. This is consistent with the results of a number of peer reviewed publications in the past decade: *e.g.*, Matthews *et al.* found that the temperature change is roughly proportional to the total quantity of CO_2 emissions over a wide range of potential scenarios.[8]

A threshold of GHG emissions from the source category compared to the rest of the U.S. GHG emissions (*i.e.*, the percent of total U.S. GHG emissions) can be used to demonstrate significance. Emissions can be large enough from a source category that the evaluation of GHG emissions in isolation is sufficient for making a finding of significance for the source category. Conversely, the EPA believes that some source categories are sufficiently small in GHG

[8] H. Damon Matthews, Nathan P. Gillett, Peter A. Stott & Kirsten Zickfeld, The Proportionality of Global Warming to Cumulative Carbon Emissions. Nature 459, 829-832 (2009), available at *https://www.nature.com/articles/nature08047*.

emissions that a finding of insignificance can be made by only evaluating the GHG emissions from the source category. For many source categories, the evaluation of GHG emissions alone will be sufficient for determining whether there is significant contribution.

It should be noted that under section 111(b)(1)(A), the EPA is required to make a significance finding on a category-by-category basis. That provision requires the Administrator to list "*a* category of sources" for regulation if he determines that "*it* causes or contributes significantly to" dangerous air pollution. Section 111(b)(1)(A) (emphasis. added). As a result, the text of 111(b)(1)(A) compels or is at least best read to require the EPA to make the significance determination for a particular source category on the basis of the emissions (or other relevant attributes) of that particular source category. In contrast, the EPA may not combine source categories that individually would not meet the significance criteria and determine that, when combined, the source categories do meet the significance criteria.[9]

2. Using a Threshold in Significance Determination

Under this framework, the EPA is determining a threshold for the evaluation of significance of GHG emissions from source categories. The use of a clear threshold provides certainty regarding the EPA's process and allows the regulated entities to have insight into how the EPA will make determinations on significance for their respective source category. The threshold introduced in this rulemaking is a reflection of the EPA's best understanding of the landscape of the U.S. GHG emissions from stationary sources. The EPA is introducing a methodology to evaluate significance with respect to the U.S. GHG emissions that can be applied

[9] By the same token, as the EPA explained in the 2020 Oil & Gas Rule, there are limits to the EPA's ability to expand a source category to include other sources. As the EPA stated in that rule, "the authority to revise the scope of a source category must be exercised within reasonable boundaries and cannot be employed in a way that results in an unreasonable expansion of an existing source category.... [T]he EPA is not authorized to expand the scope of a listed source category to cover a new set of sources that are not sufficiently related to the sources in the pre-existing category...." 85 FR 57027.

for any source category, and that application of the methodology is only being directly applied to the EGU source category in this action as further introduction of this approach. It is important to note that a significance determination for the U.S. GHG emissions will be needed before the EPA may regulate any other source category under CAA section 111(b) for GHG emissions.

As Table 1, below, makes clear, there are at least two natural breakpoints between groups of emitting source categories. The first natural breakpoint is between EGUs and all other source categories. EGUs stand out as by far the largest stationary source of the U.S. GHG emissions, emitting over 25 percent of all the U.S. GHG emissions. Based on available data, the next largest source category, Oil and Natural Gas, emits just under 3 percent of U.S. GHG emissions. Two other source categories, Boilers and Petroleum Refineries, also fall between 2.5 percent and 3.0 percent of U.S. emissions. Between 1.5 percent and 2.5 percent of U.S. GHG emissions there is another natural breakpoint and all of the remaining source categories fall below 1.5 percent of the U.S. GHG emissions. Note that source category emissions in Table 1 are an estimate of what the Agency currently understands about the emissions from CAA section 111 source categories. If the EPA were to do a rulemaking and a significance determination for a specific source category, the EPA would do a thorough analysis of the available and attributable GHG emissions data to ensure appropriate determinations and assessments.

TABLE 1. EXAMINATION OF GHG EMISSIONS FROM LARGE STATIONARY SOURCES OF GHG EMISSIONS

% of Total US GHG Emissions	Emissions in that Range (MMT CO_2e)*	Source Categories Affected at Different Thresholds	Percent of US GHG Emissions from Stationary Sources Covered at Given Threshold
Above 25%	>1670 MMT	EGUs (1778 MMT/27% of total US GHG Emissions, 3.6% of Global emissions)	43%

3% to 25%	200 MMT-1670 MMT	No categories identified	43%
2.5% to 3.0%	167-200 MMT	Oil/Gas Production and Processing^; Refineries; Boilers	56%
2.0% to 2.5%	134-167 MMT	No categories identified	56%
1.5% to 2.0%	100-134 MMT	No categories identified	56%
1.0% to 1.5%	67-100 MMT	Landfills[1]; Iron and Steel	60%

** MMT CO_2e = Million metric tons of carbon dioxide equivalent*
^ Note that the oil and gas production and processing GHG emissions are very close to the 3% value and thus there is a possibility that this source category may be above the threshold in the near term.
[1] Note that the Landfills source category has already been regulated under CAA section 111 and the level of the emissions in Table 1. reflects reductions in GHG emissions as a result of that regulation as a co-benefit.

The EPA is introducing a threshold of 3 percent of U.S. GHG emissions to evaluate a source category's emissions to determine significance for purposes of CAA section 111(b). The EPA is also determining that source categories that are less than this value (*i.e.*, 3 percent or less) are necessarily insignificant without consideration of any other factors. The reasoning for choosing this threshold is presented later in this document.

The EPA acknowledges that, when interpreting other CAA provisions, the EPA has used different thresholds to define "significant contribution," but it is appropriate to select a threshold based on the nature of the problem being addressed. For example, to address the problem of interstate transport under CAA section 111(a)(2)(D)(i)(I) -- which concerns criteria pollutants, *i.e.,* pollutants that affect the NAAQS -- the EPA selected a threshold of 1 percent based on analysis of air quality modeling specific to the criteria pollutant at issue. 76 FR 48208, 48236 (August 8, 2011) (Cross-State Air Pollution Rule (CSAPR)). For criteria pollutants, both the location and quantity of emissions are factors in determining their impact. In contrast, the impact of GHGs (*e.g.*, climate change) is based on a cumulative global loading, and the location of emissions is not nearly as important a factor as it is for assessing local impacts associated with criteria pollutants. Because GHGs do not have the local near-term impacts that criteria pollutants

tend to have, a larger value is appropriate to use in determining significance as it still addresses the health and welfare impacts of GHG emissions without specifically evaluating local near-term impacts, which is analytically unreasonable to do given the global nature of GHGs. While the 3 percent threshold will be applied against domestic emissions, source categories exceeding that threshold represent a much smaller fraction of global GHG emissions.[10]

By determining a threshold, the EPA is setting a clear indication of how source categories will be evaluated for significance based on GHG emissions. For those source categories that are below the 3 percent threshold, the EPA would make a determination (through future rulemaking) of insignificance. This means that if a source category collectively emits 3 percent or less of the total U.S. GHG emissions, it will be considered to be insignificant. For those source categories that are above the threshold, a more detailed evaluation of other criteria can be used to make a determination of significance. This is described in section IV.D below. It is important for the EPA to make this clear indication as it allows source categories and the general public a level of transparency as to how the EPA will be evaluating source categories for significance. The threshold in this action will provide a degree of certainty regarding whether a source category will later be found significant or insignificant based on the threshold.[11]

After evaluating the two natural break points in GHG emissions, the EPA determined that 3 percent of the U.S. GHG emissions was the best threshold for determining significance. As

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[10] The EPA recognizes that in the 2016 Oil & Gas Rule, it determined that GHG emissions from the oil and natural gas source category contribute significantly to dangerous air pollution, in part, on the grounds that those emissions exceeded the total amount of emissions from various foreign countries. 81 FR 35824, 35840 (June 3, 2016). The EPA believes that its current approach of identifying a threshold for significance based on a percentage of U.S. emissions is better reasoned than the 2016 Oil & Gas Rule's approach of drawing comparisons to the absolute emissions of other countries.

[11] The EPA does not currently have a comprehensive inventory of the U.S. GHG emissions for all of the NSPS source categories. For the EPA to make determinations of significance for a source category, a more comprehensive emissions profile of a source category should be used. The EPA will make determinations of significance for other source categories in the future.

noted above, there is currently only one source category above this threshold, EGUs, and the evaluation of significance for the EGU source category has been a topic explored and discussed by the Agency in great detail over the course of the last decade.[12] Just below the 3 percent threshold are three source categories: Oil and Natural Gas, Petroleum Refineries, and Industrial-Commercial-Institutional Steam Generating Units (*i.e.*, "Boilers"). There are no other source categories with GHG emissions between 1.5 percent and the 3 percent. By using a threshold of 3 percent of the U.S. GHG emissions (*i.e.*, only including EGUs above the threshold), the EPA will effectively be covering 43 percent of the U.S. stationary source GHG emissions via regulation of a single source category. If the EPA were to instead set a threshold between the other identified breakpoint – between 1.5 percent and 2.5 percent of U.S. GHG emissions – the EPA observes that this threshold would lead to a relatively modest increase in the stationary source U.S. GHG emissions that would be regulated of an additional 13 percent (for a total of 56 percent of U.S. stationary source GHG emissions).[13] In addition, regulation of the additional source categories that comprise 13 percent of U.S. emissions would eliminate only a portion of those emissions. With an even lower threshold of significance set at 1.0 percent of U.S. GHG emissions, there would be significantly more source categories covered (about 10 based on the EPA estimates) above the threshold but likely would include an even more modest increase in stationary source GHGs that would cover 60 percent of U.S. stationary source GHGs. Under this framework, the EPA is basing a decision to apply a threshold of 3 percent on the relative contribution of regulating source categories that contribute significantly to the overall impact of climate change. To that end, the temperature impact associated with the hypothetical elimination

[12] *See* 79 FR 34960 and 80 FR 64510.

[13] Note that one of those "next three largest" source categories is oil and natural gas. In the recently finalized policy package, the EPA found that regulation of GHGs from this source category is unnecessary as it is currently being controlled by regulation of volatile organic compounds. See 85 FR 57018, 57030 (September 14, 2020).

of all source categories above a 3 percent threshold corresponds to a hypothetical global mean temperature reduction of 0.049 degrees Celsius (°C) (approximately 0.1 degree Fahrenheit, the calculated effect in 2100 of removing 1,780 million metric tons (MMT) of CO_2 emissions each year from 2020 through 2100) from source categories above that threshold (*i.e.,* just EGUs). Eliminating the next largest source category (*i.e.*, Oil and Gas Processing and Production) would only generate an additional hypothetical global mean temperature reduction of less than 0.01°C and even smaller source categories correspondingly contribute less to global temperature. The EPA is making the decision that the threshold for a significance determination for U.S. GHG emissions to be in the form of a percentage. A percentage is a metric that measures the relative contribution to the whole and, in this action, the EPA believes that it is appropriate to measure and evaluate significant contribution of U.S. GHG emissions as a relative contribution to the whole of GHG emissions in the U.S. The EPA is determining that a threshold in the form of a percentage is both reasonable and more appropriate for making the significance determination in this rule based on a percent's relative nature. This is important because the trajectory of U.S. GHG emissions is trending down. As overall emissions decrease over the course of time, a source category's relative contribution to GHGs may not have changed or may have even increased based on GHG reductions in other source categories and sectors. A relative percentage threshold recognizes that the EPA may later determine a source category is significant based on these circumstances, because a source category's emissions may eventually exceed the threshold even though it is currently below the threshold. Accordingly, a percentage threshold allows the EPA, over time, to always focus on the source categories with the potential to have the greatest impact. The framework on which EPA bases its decision today is, therefore, amenable to future use, which augurs in favor of the framework's use to make today's finding.

The EPA is introducing in this action that a threshold in the form of a percentage is both reasonable and more appropriate for making a significance determination for GHGs based on a percent's relative nature. A tonnage threshold is a static metric that would not change over time. As previously described, the trajectory of U.S. GHG emissions is trending down. As emissions decrease over the course of time, it is likely that source categories that were once above any static threshold will fall below such a threshold. Even though a source category may reduce overall U.S. GHG emissions, that source category's relative contribution to GHGs may not have changed or may have even increased based on GHG reductions in other source categories and sectors. Additionally, if emissions do decrease over time, the use of a tonnage threshold potentially results in no source category meeting the criteria for significance, even if collectively the U.S.GHG emissions continue to pose a danger to public health or welfare.

It should be noted that the U.S. GHG emissions of the EGU source category are more than an order of magnitude larger than the emissions threshold in the framework, representing 43 percent of U.S. stationary source GHG emissions. The EPA believes that it is possible for source categories with GHG emissions substantially larger than the threshold to be deemed significant on the basis of the primary criterion alone (*i.e.*, magnitude of emissions) and without consideration of the secondary criteria described elsewhere in this notice.

3. Tiers of Source Categories Based on GHG Emissions

As noted previously, the primary criterion in evaluating the significance of a source category is, again, the relative magnitude of the U.S. GHG emissions. The EPA believes that NSPS source categories may be grouped into three tiers on the basis of magnitude of the U.S. GHG emissions, as follows:

(1) *Source category with GHG emissions substantially above the threshold.* This source category has emissions of a large enough magnitude that a determination of significance can be made on the basis of the magnitude of emissions alone. As discussed later in this document, this tier is comprised solely of the EGUs source category; in other words, EGUs do not require consideration of the secondary criteria in order to determine significance.

(2) Source categories with an intermediate magnitude of the U.S. GHG emissions (i.e., those with emissions above the threshold but less than the quantity emitted by the EGU source category). For source categories with emissions above the threshold, evaluation of the magnitude of the U.S. GHG emissions is inconclusive. Rather, a significance determination requires an examination of the source category's magnitude of emissions combined with a more detailed look at the secondary criteria discussed elsewhere in this document.

(3) *Source categories with a small magnitude of GHG emissions (i.e., those with emissions below the threshold).* Source categories with a small magnitude of emissions will be deemed insignificant based on evaluation of the primary criterion alone, without detailed consideration of any secondary criteria.

D. Secondary Criteria for Determining Significance

As described above, the EPA is determining that the U.S. GHG emissions from a source category are the primary and most important criterion for making a determination of significance for a source category. However, there may be instances where the U.S. GHG emissions from a source category do not give a comprehensive enough picture to make a determination of significance. The threshold that the EPA has described above in Section IV.B would provide a

clear indication that the U.S. GHG emissions from source categories below that threshold are necessarily insignificant. However, under this framework, for any source category that is above that threshold, there are other source-category specific considerations that should be evaluated in addition to GHG emissions when making a determination of significance.[14] For that reason, the EPA will consider other, secondary, criteria in the evaluation of significance for certain source categories. These other criteria are described in the subsequent subsections. It is important for the EPA to consider secondary criteria in the evaluation of significance for certain source categories because the criteria provide unique context to the source category beyond the information provided by the magnitude of the source category's GHG emissions.

1. Evaluation and Context of GHG Emissions

Under the introduced framework, the evaluation of the magnitude of the U.S. GHG emissions from a source category is a substantial indicator of whether a source category is significant, but in the specific instance of source categories that have greater GHG emissions than the threshold, an evaluation based on the magnitude of the U.S. GHG emissions may be inconclusive. Within the introduced framework, there are other emissions-based metrics that must be evaluated to clarify and make a significance determination for these source categories.

a. *Source Category Trends*

An important criterion that can help illuminate and contextualize a significance determination is an evaluation of the trends in emissions and number of designated facilities within a source category. Primarily, the EPA is evaluating whether a source category is on a trajectory of the U.S. GHG emission decline. If the source category, as a whole, is decreasing its

[14] Although there is no source category other than EGUs above the 3% threshold, because the threshold is a percentage and as previously described, other source categories may move into this tier as overall GHG emissions decrease and other source category emissions increase.

GHG emissions, an explanation for why it is on the decline may aid in making a significance determination. In one scenario, if the source category is decreasing emissions because the source category is declining in production or other output (*e.g.*, due to decreasing demand for goods or other market conditions, due to relocation overseas, or due to the cumulative effect of regulations), it may lend towards an insignificance determination as the emissions are already declining and expected to continue to decline even without further regulation. In a separate scenario, if a source category's GHG emissions are declining due to increased efficiency and updated technology, it may lend towards a determination of significance. This would allow the EPA the ability to regulate the source category in order to ensure that efficiency and technology improvements become standard across the source category through both an NSPS (111(b) regulation) for new, modified and reconstructed sources and an emission guidelines (111(d) regulation) for existing sources.

In a scenario in which the EPA were to find a source category to be growing in either emissions or number of designated facilities (or both), it could lend towards that source category being found to be significant. This would allow EPA to regulate and mitigate emissions from new, modified and/or reconstructed designated facilities within that source category under CAA section 111(b) (*i.e.*, via a NSPS).

If the EPA were to evaluate the trend in the number of designated facilities and emissions of a source category, it might show a static number of existing facilities with a constant or slightly increasing quantity of the U.S. GHG emissions. In this scenario, there may be little utility in determining significance for that source category and consequentially developing a NSPS as there are little to no emissions that would be subject to such a standard. However, creating a NSPS for a source category and pollutant is a necessary predicate to regulating

existing sources under CAA section 111(d). Hence, in the scenario of a static number of existing facilities, a finding of significance for the source category may be warranted as it would allow eventual regulation of a group of existing source categories. Under this framework, the EPA expects the prospect of regulating a source category under CAA section 111(d) for existing sources to be a compelling reason for determining significance.

b. Source Category Emissions with Global Context

Another important criterion that the EPA considers, as a secondary factor, is the relative contribution of GHG emissions from the U.S. in a specific source category compared to worldwide emissions of similar sources. As previously described, Section 111(b)(1)(A) of the CAA states that the Administrator shall include source categories that contribute significantly to endangerment of health and welfare. When evaluating a global pollutant such as GHGs, the EPA views the impact of domestic emissions from domestic sources as a more germane consideration when determining whether a pollutant contributes significantly to endangerment of health or welfare. Because every ton of GHG contributes to the global problem, a domestic ton will still have some impact in the U.S. Accordingly, it is reasonable for the EPA to evaluate whether a source category is well-regulated internationally and whether the U.S. emissions from that sector make up a relatively large share of GHG emissions on a worldwide scale, as such evaluation in turn would inform whether U.S. emissions are significantly contributing to domestic impacts. If the emissions from the U.S. are comparatively a large contribution to source category/sector emissions worldwide, it may lend towards a finding of significance for the source category based on the U.S.'s substantial global contribution to the source category. If, however they are relatively small, it would suggest less benefit from the EPA regulation of that source category.

The EPA also considers, as one of the secondary criteria, an evaluation of whether a source category is vulnerable to being trade exposed (*i.e.* whether the source category is constrained in the sources' ability to pass through carbon costs due to actual or potential international competition). The EPA evaluates whether regulation of the source category would create a financial incentive for that source category/industry to move into, or increase production in, another country. This could be manifested as either a shift in production to facilities internationally or a complete closure of existing designated facilities in the U.S. It is not the EPA's intention in regulating source categories to drive production from the U.S. to other countries, and there is an environmental concern in pushing industries to other international locations. This concern is based on the potential for these new international emissions to increase compared to the corresponding displaced U.S. emissions.[15] While this is always a concern for the EPA in the regulation of industry within the U.S., it even more pronounced with the consideration of GHG emissions. As discussed, previously, the U.S. GHG emissions are a global pollutant that also have domestic impacts. As such, if a smaller quantity of domestic GHG emissions would be displaced, due to a regulation, by a greater quantity of international GHG emissions it may support a finding of insignificance for a given source category. This would occur if the U.S. sources are already significantly lower emitting in GHG emissions than sources in other countries. It should also be noted that source categories whose sources in the U.S. make up a relatively smaller proportion of the world's emissions from corresponding international

[15] If U.S. production shifted overseas to a jurisdiction that has laxer environmental regulations, for a global pollutant such as mercury or GHGs, there could be both increased local environmental and health impacts at the new overseas location and domestic impacts to the U.S. resulting from the increased U.S. GHG emissions.

sectors may be particularly vulnerable to being trade exposed as there is likely a greater international capacity to absorb the displaced U.S. production.

Given the global nature of GHG emissions, assessing and understanding the estimated potential net emissions impact of GHG control technologies provides useful context in which to consider the significance of a given set of GHG emissions In addition, there may also be value in evaluating and considering the technology with the associated source category (*i.e.,* intrinsic to the process of the source category) - a prime example of reductions associated with this evaluation might be assessing the likely impacts of efficiency improvements. From a public welfare and human health perspective, targeting source categories that provide the largest overall possible scope for emissions reductions could be an intrinsic part of determining the significance of a given magnitude of emissions. Thus, the EPA is determining that it is appropriate in a given instance to consider feasible technologies (including efficiency improvements) for further context in the Agency's determination of significance of a source category's overall emissions. Here, the magnitude of GHG emissions from EGUs coupled with the reductions available through efficiency improvements supports the EPA's determination of significance.

d. Temporal Evaluation of Criteria

As introduced in this framework, the evaluation of the secondary criteria is not intended to be performed in isolation. Rather, the EPA considers the weight of evidence of all the factors (both primary and secondary) to make an informed and comprehensive decision as to whether a source category that exceeds the 3-percent threshold contributes significantly to the U.S. GHG emissions. The consideration of criteria also has a temporal consideration to a significance determination. A source category's determination can be reevaluated in the future as the status and criteria described here may have changed for that source category. For example, the

technology to adequately regulate GHGs from a source category may not be readily available at this time, but in the future that technology may become more broadly available causing the EPA to then make a SCF.

E. Significant Contribution Finding for EGUs

As noted above, the Agency is finalizing a determination that GHG emissions from EGUs[16] contribute significantly to dangerous air pollution. The primary criterion in determining whether to make a SCF is the magnitude of GHG emissions from a given source category. It is readily apparent that EGUs emit a uniquely large amount of GHGs compared to all other categories of stationary sources. The EPA made this clear in the 2015 Rule, quoted above, and reiterated it in the 2020 Oil & Gas Rule: "the unique CO_2 emissions profile of fossil fuel-fired EGUs should be noted: the volume of emissions from EGUs dwarfs the amount of GHG emissions from every other source category." 85 FR 57039, n.49.

Although GHG emissions from EGUs have fallen since the EPA promulgated the 2015 Rule, they still remain uniquely large among stationary source categories. The EPA's Inventory of U.S. Greenhouse Gas Emissions[17] indicates that, as of 2018, the Electric Power sector directly emitted 1,778.5 MMT of GHGs.[18] This amount was more than twice the amount of GHGs emitted by all other industrial sources combined and more than all other industrial, commercial,

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[16] For this purpose, EGUs include the affected sources in the combined source category for boilers and turbines. In the 2015 Rule, the EPA "combine[d] the two categories of EGUs—steam generators and combustion turbines—into a single category of fossil fuel-fired EGUs for purposes of promulgating standards of performance for CO_2 emissions." 80 FR 64529 (2015 Rule).

[17] *See* Table 3-9, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2018, Report 430-R-20-002, April 13, 2020, *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2018*.

[18] The global warming potential (GWP) of a greenhouse gas is defined as the ratio of the accumulated radiative forcing within a specific time horizon relative to that of the reference gas CO_2. Total GHG emissions are the GWP-weighted emissions of all GHG emissions and reported in million metric tons of CO_2 equivalent (MMT CO_2e.).

and residential stationary combustion sources combined.[19] In addition, direct GHG emissions from EGUs account for approximately 27 percent of total U.S. GHG emissions and 43 percent of U.S. stationary source emissions. The direct GHG emissions from EGUs account for approximately 4 percent of total worldwide GHG emissions and are greater than the emissions of all but four countries.[20] These facts confirm that at current emission levels, EGUs have measurable impacts on both the U.S. contribution to GHG emissions and the worldwide total GHG emissions and continue to be uniquely large stationary source emitters of GHGs. It should be noted that if domestic EGUs no longer emitted any GHG emissions, there would be a measurable impact on worldwide GHG emissions and between 2020 and 2100, there would be a reduction in the projected increase in global temperatures by 0.049 degrees Celsius (^{o} C).

Because EGUs represent by far the largest stationary source of GHGs from combustion of fossil fuels, the EPA believes that this is the most appropriate place for the EPA, states, and sources to devote resources to reducing GHGs from stationary sources. Indeed, this uniquely large magnitude of emissions is the reason over the last 8 years, the Agency has devoted significant effort to determine how to best reduce GHGs from EGUs. Because EGUs are a relatively large U.S. source of emissions in an overall large pool of international EGU sources, regulation over time could help produce practices and technologies that have application to EGUs worldwide.

It is noteworthy that GHG emissions from EGUs are approximately an order of magnitude greater than the estimated emissions of the second largest stationary source category

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[19] See Table 3-9, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2018, Report 430-R-20-002, April 13, 2020, *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2018*.

[20] In 2016, worldwide GHG emissions were estimated to have been 49.4 gigaton (Gt) CO_2e. The GHG emissions of China, India, Russia, and Indonesia are 11,577, 3,235, 2,391, and 2,229 MMT CO_2e respectively. *https://www.wri.org/blog/2020/02/greenhouse-gas-emissions-by-country-sector*.

of GHGs attributed to combustion, industrial boilers. Because the magnitude of GHG emissions from EGUs is large compared to other stationary sources, this makes them clearly significant even without detailed consideration of other factors. As mentioned earlier, the EPA is also introducing a framework under which a source category that emits above a threshold of 3 percent of U.S. stationary source GHG emissions may contribute significantly to dangerous GHG air pollution. For those source categories above that threshold, the EPA is also determining that consideration of certain secondary criteria may, collectively, also inform the evaluation of whether a source category should be considered to significantly contribute. However, within this framework, that analysis of secondary criteria is not necessary in the case of EGUs, due to the overwhelmingly large emissions of the source category; it is clear that controlling GHG emissions from the EGU source category will be necessary to appropriately address dangerous air pollution. This conclusion is consistent with the EPA's 2018 Proposal where the Agency explained that if the EPA was required to evaluate significance, EGUs would be considered significant.

1. Secondary Criteria

The EPA is determining that the uniquely large GHG emissions from EGUs makes a finding of significant contribution and regulation appropriate by itself. Under the introduced framework, while the EPA does not think it is necessary to consider secondary criteria because of the uniquely large emissions from the EGU source category, as explained below, the EPA would make the same determination even if it did consider those criteria.

a. Source Category Trends

As mentioned earlier, an important criterion is the evaluation of the trends in emissions and number of designated facilities within a source category, such that the EPA can evaluate whether a source category is on a trajectory of U.S. GHG emission decline.

While electricity demand is projected to increase the U.S., due to the increased use of less carbon intensive generation technologies and more efficient generation, GHG emissions from the power sector are projected to remain relatively steady for the foreseeable future. However, EGUs are projected to remain the single largest stationary source of GHG emissions, and while the Agency expects few, if any, new coal-fired EGUs will be built to meet the demand for electricity, coal-fired EGUs are expected to continue to supply electricity and emit significant GHG emissions for the foreseeable future.[21] The EGU source category also includes stationary combustion turbines. The EPA expects new simple cycle and combined cycle combustion turbine EGUs will be built in the future and that the existing fleet of combustion turbines will continue to operate.[22] Therefore, efficient generation technology could eventually become standard for all new and existing EGUs. Consequently, the EPA would consider the source category trends as supporting the regulation of GHG emissions from EGUs.

b. Source Category Emissions with Global Context

The EPA is also determining that it can consider, as a secondary criterion, the relative contribution of GHG emissions from the U.S. in the specific source category compared to worldwide emissions of similar sources. Accordingly, the EPA evaluates whether a source category is well-regulated internationally and whether the U.S. emissions from that sector make

[21] According to Table 8 of the Annual Energy Outlook (AEO) 2020, while coal fired generation will decline between 2019 and 2025 from 959 billion kWh to 709 billion kWh, generation from coal-fired EGUs is projected to subsequently remain relatively steady through 2050.

[22] According to Table 8 of the AEO 2020, natural gas fired generation is projected to increase from 1,322 billion kWh to 1,629 billion kWh.

up a relatively large share of global GHG emissions, as such evaluation in turn would inform whether U.S. emissions are significantly contributing to domestic impacts. In this instance, this criteria points towards a finding of significance given that U.S. EGUs make up a sizeable portion (13 percent of the emissions) from EGUs worldwide.[23]

As mentioned earlier in this notice, the EPA is also introducing that one of the secondary criteria is an evaluation of whether a source category is vulnerable to being trade exposed (*i.e.*, whether the source category is constrained in its ability to absorb regulatory costs due to actual or potential international competition). Concerns about international competition would not impact the Agency's decision to regulate EGUs because electricity must be transported over power lines and it is not as easy to relocate or shift production locations as it is for other source categories. The ability to locate generation in Mexico and Canada and transmit the power to the U.S. is limited because of constraints on existing transmission lines and the expense to build additional transmission capacity. The only additional transmission capacity currently being considered is for electricity generated from hydroelectric power in Canada to supply power to New England. Since this electricity has a low carbon intensity, it would not contribute to an overall increase in GHG emissions. Furthermore, the emission standards in this rule will not increase the costs of electricity from a new coal-fired EGU such that it might be financially advantageous to locate new production internationally to countries with less stringent regulations. If international competition were a concern, the Agency would compare the forecast GHG emissions from international sources (in this case, EGUs in Canada and Mexico) against the forecast GHG emissions from domestic sources (in this case domestic EGUs) in both the

[23] U.S. EGU emissions from the Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2018, Report 430-R-20-002, April 13, 2020, *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2018*. Worldwide EGU emissions from the International Energy Agency estimates IEA (2020), CO_2 Emissions from Fuel Combustion, *https://www.iea.org/subscribe-to-data-services/co2-emissions-statistics*.

absence of and implementation of the NSPS. In addition, since few, if any, new coal-fired EGUs are forecast to be built in the U.S., the standards in this final rule will not impact electricity prices to end users to an extent that other industries would be incentivized to relocate internationally due to increased electricity costs. Therefore, domestic reductions in GHG emissions from regulating EGUs will not be offset by increased international GHG emissions. In contrast, for source categories that supply raw materials to other domestic source categories, the impact of international competition on those source categories and the resultant GHG impacts could be considered when determining an appropriate NSPS. It is conceivable that an overly stringent NSPS could result in an increase in global GHG emissions, if the increase in international emissions is greater than the reduction in domestic emissions.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected facilities?

This rule takes final action affecting fossil fuel-fired EGUs. These EGUs take two forms that are relevant for present purposes: steam generating units (utility boilers and gasification units) and stationary combustion turbines. Fossil fuel-fired steam generating units can burn natural gas, oil, or coal. However, coal is the dominant fuel for electric utility steam generating units. Coal-fired steam generating units are primarily either PC or fluidized bed (FB) steam generating units.[24] At a PC steam generating unit, the coal is crushed (pulverized) into a powder to increase its surface area. The coal powder is then blown into a steam generating unit and burned. In a fossil fuel-fired steam generating unit using FB combustion, the solid fuel is burned in a layer of heated particles suspended in flowing air. Power can also be generated from coal or

[24] Fossil fuel-fired utility steam generating units (*i.e.*, boilers) are most often operated using coal as the primary fuel. However, some utility boilers use natural gas and/or fuel oil as the primary fuel.

other fuels using gasification technology. An Integrated Gasification Combined Cycle (IGCC) unit gasifies coal or petroleum coke to form a synthetic gas (or syngas) composed of carbon monoxide (CO) and hydrogen (H_2), which can be combusted in a combined cycle system to generate power. Stationary combustion turbines include both fossil fuel-fired simple cycle and combined cycle combustion turbine EGUs.

B. What are the air quality impacts?

The EPA does not anticipate that this final rule for fossil-fuel-fired EGUs will result in significant CO_2 emission changes.

C. What are the energy impacts?

This final rule for fossil-fuel-fired EGUs is not anticipated to have an effect on the supply, distribution, or use of energy.

D. What are the cost impacts?

The EPA does not believe that this final rule for fossil-fuel-fired EGUs will have compliance costs associated with it.

E. What are the economic impacts?

The EPA does not anticipate that this final rule for fossil-fuel-fired EGUs will result in economic or employment impacts. Likewise, the EPA believes this rule will not have any impacts on the price of electricity, employment or labor markets, or the U.S. economy.

F. What are the benefits?

The EPA does not anticipate emission changes resulting from the final rule for fossil-fuel-fired EGUs.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action. There are no quantified cost estimates for this final rule because the EPA does not anticipate this action to result in costs or cost savings.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing parts 75 and 98 regulations and has assigned OMB control numbers 2060-0626 and 2060-0629, respectively.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. The EPA expects there to be few, if any, new, modified, or

reconstructed coal-fired EGUs. As such, this final rule would not impose significant requirements on those sources, including any that are owned by small entities. The EPA has, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. It would neither impose substantial direct compliance costs on tribal governments, nor preempt Tribal law. The EPA is aware of three coal-fired EGUs located in Indian Country but is not aware of any EGUs owned or operated by tribal entities. The EPA notes that this action would affect only existing sources such as the three coal-fired EGUs located in Indian Country if those EGUs were to take actions constituting modifications or reconstructions as defined under the EPA's NSPS regulations. However, as previously stated, the EPA expects there to be few, if any, new, reconstructed, or modified EGUs. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA offered consultation with tribal officials during the development of this action; however, the Agency did not receive a request for consultation. The EPA held meetings with tribal environmental staff during the public comment period to inform them of the content of the proposed rule and to encourage them to submit comments on the proposed rule.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs (OIRA). This final action is not anticipated to have impacts on emissions, costs, or energy supply decisions for the affected electric utility industry.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specific in Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not affect the level of protection provided to human health or the environment. As previously stated, the EPA expects that few, if any, coal-fired EGUs would be affected by this action.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Andrew Wheeler,
Administrator

Message

From: Teresa, Tyler [Teresa.Tyler@epa.gov]
Sent: 1/6/2021 11:14:16 PM
To: Burgess, Michael [Burgess.Michael@epa.gov]; Block, Molly [block.molly@epa.gov]; Allen, Jacob [Allen.Jacob@epa.gov]; Coxen, Carrie [coxen.carrie@epa.gov]; Dickerson, Aaron [dickerson.aaron@epa.gov]; Etheridge, George [Etheridge.George@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Hewitt, James [hewitt.james@epa.gov]; Hoverman, Taylor [hoverman.taylor@epa.gov]; Hyman, Alana [Hyman.Alana@epa.gov]; Johnson, Taylor [Johnson.Taylor.C@epa.gov]; Keith, Jennie [Keith.Jennie@epa.gov]; Meadows, Carrie Vicenta [Meadows.CarrieVicenta@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Murray, William [Murray.William@epa.gov]; Ex. 7(C), 7(F); Scott, Corey [scott.corey@epa.gov]; Vella, Sophia [Vella.Sophia@epa.gov]; Tran, Victoria [tran.victoria@epa.gov]; Zimmer, Nathaniel [zimmer.nathaniel@epa.gov]; Barker, Kendal [Barker.Kendal@epa.gov]; Rodriguez, Alejandra (Allie) [rodriguez.alejandra@epa.gov]; Hill-Macon, Cam [Hill-Macon.Cam@epa.gov]; Kasman, Mark [Kasman.Mark@epa.gov]; Gonzalez, Orlando [Gonzalez.Orlando@epa.gov]; McIntosh, Chad [mcintosh.chad@epa.gov]
CC: Ryder-Rude, Meredith V [RyderrudeMV@state.gov]; Bannister, Sarah J [BannisterSJ@state.gov]; Hall, Sheena [HallS@state.gov]
Subject: V4. LxL Costa Rica
Attachments: v4. LxL Costa Rica.docx; v4. LxL Costa Rica.pdf

All,

Please see v4 of the LxL.

Major Updates:
1/7 – Complete meeting participation list for all events
1/7 – Updated ROS for Mundorep

Best,

Tyler T.

From: Teresa, Tyler
Sent: Wednesday, January 6, 2021 12:23 AM
To: Burgess, Michael <Burgess.Michael@epa.gov>; Block, Molly <block.molly@epa.gov>; Allen, Jacob <Allen.Jacob@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dickerson, Aaron <dickerson.aaron@epa.gov>; Etheridge, George <Etheridge.George@epa.gov>; Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Hewitt, James <Hewitt.James@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Hyman, Alana <Hyman.Alana@epa.gov>; Johnson, Taylor <Johnson.Taylor.C@epa.gov>; Keith, Jennie <Keith.Jennie@epa.gov>; Meadows, Carrie Vicenta <Meadows.CarrieVicenta@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Murray, William <Murray.William@epa.gov>; Ex. 7(C), 7(F); Scott, Corey <scott.corey@epa.gov>; Vella, Sophia <Vella.Sophia@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Barker, Kendal <Barker.Kendal@epa.gov>; Rodriguez, Alejandra (Allie) <Rodriguez.Alejandra@epa.gov>; Hill-Macon, Cam <Hill-Macon.Cam@epa.gov>; Kasman, Mark <Kasman.Mark@epa.gov>; Gonzalez, Orlando <Gonzalez.Orlando@epa.gov>
Cc: Ryder-Rude, Meredith V <RyderrudeMV@state.gov>; Bannister, Sarah J <BannisterSJ@state.gov>; Hall, Sheena <HallS@state.gov>
Subject: V3. LxL Costa Rica

All,

Please see the attached v3. LxL for Costa Rica.

Major Updates (per day):
01/06 – Ambassador Day will be in Country Briefing at 3:00 PM
01/07 – Change in MFA personnel attending the Bilateral Meeting with the Vice Minister of Environment
01/07 – Updated run of show for IICA programs
01/07 – Earlier start time for Dinner with Ambassador Day at CMR
01/08 – Ambassador Day will unfortunately not be able to make any of the day events
01/09 – Earlier departure time for Airport

I will have copies ready tomorrow at the Hotel for traveling delegation.

Please let me know if you have any questions!

Best,

Tyler T.

From: Teresa, Tyler
Sent: Monday, January 4, 2021 7:34 AM
To: Burgess, Michael <Burgess.Michael@epa.gov>; Block, Molly <block.molly@epa.gov>; Allen, Jacob <Allen.Jacob@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dickerson, Aaron <dickerson.aaron@epa.gov>; Etheridge, George <Etheridge.George@epa.gov>; Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Hewitt, James <Hewitt.James@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Hyman, Alana <Hyman.Alana@epa.gov>; Johnson, Taylor <Johnson.Taylor.C@epa.gov>; Keith, Jennie <Keith.Jennie@epa.gov>; Meadows, Carrie Vicenta <Meadows.CarrieVicenta@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Murray, William <Murray.William@epa.gov>; Ex. 7(C), 7(F); Scott, Corey <scott.corey@epa.gov>; Vella, Sophia <Vella.Sophia@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Barker, Kendal <Barker.Kendal@epa.gov>; Rodriguez, Alejandra (Allie) <Rodriguez.Alejandra@epa.gov>; Hill-Macon, Cam <Hill-Macon.Cam@epa.gov>; Kasman, Mark <Kasman.Mark@epa.gov>; Gonzalez, Orlando <Gonzalez.Orlando@epa.gov>
Cc: Ryder-Rude, Meredith V <RyderrudeMV@state.gov>; Bannister, Sarah J <BannisterSJ@state.gov>; Hall, Sheena <HallS@state.gov>
Subject: V2. LxL Costa Rica

All,

Attached is the v2. LxL for Costa Rica.

Please let me know if you have any edits or updates!

Best,

Tyler T.

From: Teresa, Tyler
Sent: Thursday, December 31, 2020 11:16 AM
To: Burgess, Michael <Burgess.Michael@epa.gov>; Block, Molly <block.molly@epa.gov>; Allen, Jacob <Allen.Jacob@epa.gov>; Coxen, Carrie <coxen.carrie@epa.gov>; Dickerson, Aaron <dickerson.aaron@epa.gov>; Etheridge, George <Etheridge.George@epa.gov>; Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Hewitt, James <Hewitt.James@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Hyman, Alana <Hyman.Alana@epa.gov>; Johnson, Taylor <Johnson.Taylor.C@epa.gov>; Keith, Jennie <Keith.Jennie@epa.gov>; Meadows, Carrie Vicenta <Meadows.CarrieVicenta@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Murray, William <Murray.William@epa.gov>; Ex. 7(C), 7(F); Scott, Corey <scott.corey@epa.gov>; Vella, Sophia

<Vella.Sophia@epa.gov>; Tran, Victoria <tran.victoria@epa.gov>; Zimmer, Nathaniel <zimmer.nathaniel@epa.gov>; Barker, Kendal <Barker.Kendal@epa.gov>; Rodriguez, Alejandra (Allie) <Rodriguez.Alejandra@epa.gov>; Hill-Macon, Cam <Hill-Macon.Cam@epa.gov>; Kasman, Mark <Kasman.Mark@epa.gov>; Gonzalez, Orlando <Gonzalez.Orlando@epa.gov>
Cc: Ryder-Rude, Meredith V <RyderrudeMV@state.gov>; Bannister, Sarah J <BannisterSJ@state.gov>; Hall, Sheena <HallS@state.gov>
Subject: V1. LxL Costa Rica

All,

Attached is the V1. LxL for Costa Rica.

Please send me any edits or updates you might have and have a Happy New Year!

Best,

Tyler T.

Tyler C. Teresa
Deputy Director of Advance
Office of the Administrator
Environmental Protection Agency
202-306-7337 (Cell)

SAN JOSE, COSTA RICA
THURSDAY, JANUARY 7 – SATURDAY, JANUARY 9, 2021

THURSDAY, JANUARY 7

***Breakfast:** The Market from 6:00am – 10:00am in the lobby

8:40am ADMINISTRATOR WHEELER departs the Hotel en route to the Chief of Missions Residence (CMR) for Bilateral Meeting with Vice Minister Franklin Paniagua, Vice Minister of the Environment, Republic of Costa Rica Ministry of Environment and Energy

Vehicle Assignments:

EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER ADRIAN CASTRO
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) – PSD TYLER TERESA

Drive Time: 10 Minutes

Event Location
The Chief of Mission Residence

8:50am ADMINISTRATOR WHEELER arrives at the CMR

EVENT **BILATERAL MEETING – MINISTRY OF ENVIRONMENT AND ENERGY**

LOCATION: Courtyard - Chief of Missions Residence
TYPE: Bilateral Meeting
SPEAKING: Talking Points
ATTIRE: Business Professional
PRESS: Closed
GIFTS: No
INTERPRETATION: N/A – On Standby
PARTICIPANTS: **EPA**
P. ADMINISTRATOR WHEELER
1. T.H. Sharon Day, U.S. Ambassador to Costa Rica
2. T.H. Chad McIntosh, AA OITA
3. Michael Molina, Deputy Chief of Staff
4. Corey Scott, Executive Advisor to the Administrator
5. Michael Stewart, Economic Section Chief

MINISTRY OF ENVIRONMENT AND ENERGY (MINAE)
P. Franklin Paniagua, Vice Minister of the Environment
1. Haydeé Rodriguez, Vice Minister of Water and Oceans
2. Director Patricia Campos, Climate Change
3. Adolfo Constenla International Cooperation Official for North and Central America, MFA
4. Daniela Villalta, Advisor, MINAE
5. Alejandra Aguilar, Trade & Environment Advisor, Ministry of Foreign Trade (COMEX)

SCENARIO:

8:50am *- ADMINISTRATOR WHEELER and U.S. Delegation arrives to CMR and proceeds to the Courtyard*

8:55am *- Introductions take place in Courtyard between EPA and MINAE*

9:00am *- Delegations take their seats and Bilateral Meeting Begins*

10:00am Event concludes; ADMINISTRATOR WHEELER departs CMR en route to Inter-American Institute for Cooperation on Agriculture (IICA)

Vehicle Assignments:

AMB LIMO:	AMBASSADOR DAY ADMINISTRATOR WHEELER EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F)
FOLLOW (EPA LIMO):	EMBASSY DRIVER – Follow Driver VANESSA FREEMAN - RF Ex. 7(C); Ex. 7(F)
SPARE LIMO (EPA FOLLOW):	EMPTY
EPA STAFF VEHICLE:	CHAD MCINTOSH MICHAEL MOLINA COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER TONANTZIN JUAREZ ADRIAN CASTRO
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) TYLER TERESA

Drive Time: 40 Minutes

Event Location

Inter-American Institute for Cooperation on Agriculture (IICA)
600 metros norte del Cruce Ipís Coronado San Isidro
San Jose CR 2200,
San José, Ipis, Costa Rica

10:40am ADMINISTRATOR WHEELR arrives at IICA and begins meetings: Bilateral Meeting with Minister Luis Renato Alvarado, Minister of Agriculture and Livestock, Republic of Costa Rica Ministry of Agriculture and Livestock and IICA Brief Presentation

EVENT BILATERAL MEETING WITH MINISTRY OF AGRICULTURE AND LIVESTOCK AND IICA PRESENTATION

LOCATION:	Director General's Office - IICA
TYPE:	Roundtable
SPEAKING:	Talking Points
ATTIRE:	Business Professional
PRESS:	Closed
GIFTS:	No
INTERPRETATION:	N/A – On Standby
PARTICIPANTS:	**EPA**

P. ADMINISTRATOR WHEELER
1. T.H. Sharon Day, U.S. Ambassador to Costa Rica
2. T.H. Chad McIntosh, AA OITA
3. Michael Molina, Deputy Chief of Staff
4. Carrie Meadows, Agricultural Advisor

MINISTRY OF AGRICULTURE AND LIVESTOCK
P. Luis Renato Alvarado, Minister of Agriculture & Livestock
1. Edgar Mata, Director of the Executive Secretariat of Agricultural Sector Planning

IICA – BILATERAL MEETING PARTICIPANTS
P. Lloyd Day, Deputy Director General

IICA – PRESENTATION PARTICIPANTS
P. Lloyd Day, Deputy Director General
1. Miguel Angel Arvelo, Chief of Staff
2. Kelly Witkowski, Manager of the Climate Change and Natural Resources Program
3. Ana Marisa Cordero, Interim Manager of Sanitation and Food Quality
4. Pedro Rocha, International Biotechnology and Biosecurity Specialist

SCENARIO:

10:40am	*-ADMINISTRATOR WHEELER arrives and is greeted by Deputy Director General Lloyd Day and is escorted to the Founder Lobby for Delegation Introductions*
10:43am	*- ADMINISTRATOR WHEELER is introduced to Minister Alvarado and Director Mata and takes a Principal photo in the Founder Lobby*
10:45am	*-Delegations are escorted to the Director Generals Office; ADMINISTRATOR WHEELER participates in Bilateral Meeting with Minister Luis Renato Alvarado*
Note:	*Minister Luis Renato Alvarado will be departing after Bilateral Meeting but will have a quick pull aside with Ambassador Day*
11:15am	*- Bilateral Meeting concludes; ADMINISTRATOR WHEELER participates in brief presentation about IICA's work; led by Deputy Director General Lloyd Day*

11:30am Presentation concludes; ADMINISTRATOR WHEELER proceeds to USA Ministerial for IICA Shareholder Roundtable

EVENT **SHAREHOLDER ROUNDTABLE LUNCHEON - IICA**

LOCATION:	USA Ministerial Room - IICA
TYPE:	Roundtable Luncheon
SPEAKING:	Talking Points
ATTIRE:	Business Professional
PRESS:	Closed
GIFTS:	No
INTERPRETATION:	N/A – On Standby
PARTICIPANTS:	**EPA** ADMINISTRATOR WHEELER T.H. Sharon Day, U.S. Ambassador to Costa Rica T.H. Chad McIntosh, AA OITA Michael Molina, Deputy Chief of Staff Carrie Meadows, Agricultural Advisor Molly Block, Deputy Associate Administrator for OPA Corey Scott, Executive Advisor to the Administrator **IICA** Mr. Lloyd Day, Deputy Director General Miguel Angel Arvelo, Chief of Staff Ana Marisa Cordero, Interim Manager of Sanitation and Food Quality Kelly Witkowski, Manager of the Climate Change and Natural Resources Program

Pedro Rocha, International Biotechnology and Biosecurity Specialist

CROPLIFE
Javier Fernández, Legal Counsel and Director of Regulatory Affairs
Alejandro Hernández, Manager of Central America and Caribbean Biotechnology
Martín Zúñiga, Director Centro América and Caribbean

BAYER
Adrián Vargas, Costa Rica T&PD Lead

INDUSTRY LEADERS
Xinia Chaves, Executive Director, Café Institute of Costa Rica (ICAFE)
Sergio Herrera, Manager of Product Stewardship & Regulatory Affairs, BASF Costa Rica
Carlos Hidalgo, Latin America EH&S Leader, CORTEVA
Juan Rafael Lizano, Executive President, National Chamber of Agriculture and Agro-industry
Geovanny Sandi, Regional Manager, Syngenta
Sergio Laprade, Social and Environmental Responsibility Coordinator, National Banana Corporation (CORBANA)
Edgar Villalobos, Commercial Manager for Central America, Corporación FMC

SCENARIO:

11:30pm *-ADMINISTRATOR WHEELER participates in the Roundtable led by Deputy Director General Lloyd Day*
- *Lloyd Day, Welcome Remarks*
- *Ambassador Day, Remarks*
- *ADMINISTRATOR WHEELER, Remarks*
- *Lloyd Day turns it over to Shareholder; Lunch will be brought out during this time*

12:50pm *- Roundtable concludes; ADMINISTRATOR WHEELER is escorted to the Garden for group photo with IICA Shareholders*

1:00pm Event concludes; ADMINISTRATOR WHEELER departs IICA en route to Mundorep Recycling for meeting with FundaTec

Vehicle Assignments:

EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER ADRIAN CASRO
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) – PSD TYLER TERESA

Drive Time: 45 Minutes; 6.8 Miles

Event Location
Mundorep Recycling
100 metros Sur de Pequeño Mundo,
Los Lagos, San Francisco, Heredia

2:00pm ADMINISTRATOR WHEELER arrives at Mundorep Recycling for Meeting with FundaTec.

EVENT FUNDATEC. – COSTA RICA MARINE LITTER ACTION PLAN

LOCATION: Mundorep Recycling
TYPE: Meeting & Tour
SPEAKING: Talking Points
ATTIRE: Business Professional
PRESS: Closed
GIFTS: No
INTERPRETATION: N/A – On Standby
PARTICIPANTS: **EPA**
ADMINISTRATOR WHEELER
T.H. Chad McIntosh, AA OITA
Michael Molina, Deputy Chief of Staff
Carrie Meadows, Agricultural Advisor
Molly Block, Deputy Associate Administrator for PA
Corey Scott, Executive Advisor to the Administrator

FUNDATEC
Floria Roa Gutierrez, Director for International Affairs, Technology Institute of Costa Rica
Victoria Rudin, Project Manager, ACEPESA-Fundatec
Jaime Cerdas, Mundorep General Manager
José Antonio Salas, Mundorep Co-Owner
Lilliana Carranza, Mundorep Communications and Public Relations Advisor

SCENARIO:

2:00pm *- ADMINISTRATOR WHEELER arrives at Mundorep Recyling and is greeted by Jaime Cerdas and begins COVID-19 protocol (temperature checks and hand washing)*

2:02pm *- ADMINISTRATOR WHEELER and small group participates in Meeting with FundaTec. About Marine Action Plan*

SMALL GROUP
ADMINISTRATOR WHEELER
CHAD MCINTOSH
MICHAEL MOLINA
Ex. 7(C); Ex. 7(F) – RF

2:30pm *- Meeting concludes; ADMINISTRATOR WHEELER tours Mundorep Recycling with small group*

2:50pm *- Tour concludes; ADMINISTRATOR WHEELER participates Mundorep two question Q&A with Lilliana Carranza*

3:00pm *- Q&A concludes; ADMINISTRATOR WHEELER participates in Press Interview over the phone with Juan Fernando Lara (La Nación) in Mundorep Recyling Conference Room*

Note: *Molly Block will have the call ready for ADMINISTRATOR WHEELER in Mundorep Recyling Conference Room*

3:30pm Interview concludes; ADMINISTRATOR WHEELER departs Mundorep Recyling en route to InterContinental Costa Rica (RON)

Vehicle Assignments:

EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA COREY SCOTT EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER ADRIAN CASTRO
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) – PSD TYLER TERESA

Drive Time: 20 Minutes; 9 Miles

RON Location
InterContinental Costa Rica at Multiplaza Mall
Multiplaza Shopping Center,
San José Province, Escazu, 10202, Costa Rica

3:50pm ADMINISTRATOR WHEELER arrives at InterContinental Costa Rica (RON) and begins Executive Time

5:00pm Executive Time concludes; ADMINISTRATOR WHEELER departs InterContinental Costa Rica (RON) en route to CMR for Dinner with the Ambassador Day

Vehicle Assignments:	
LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA COREY SCOTT CHAD MCINTOSH EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) – PSD
CONTROLL VEHICLE:	SARAH BANNISTER

Drive Time: 10 – 15 Minutes

Dinner Location
The Chief of Mission Residence

5:15pm ADMINISTRATOR WHEELER arrives at the CMR and begins dinner program

8:00pm Dinner concludes; ADMINISTRATOR WHEELER departs the CMR en route to the InterContinental Costa Rica (RON)

8:30pm ADMINISTRATOR WHEELER arrives back at the InterContinental Costa Rica (RON) and begins Executive Time

RON **INTERCONTINENTAL COSTA RICA**

FRIDAY, JANUARY 8

***Breakfast:** The Market from 6:00am – 10:00am in the lobby

8:30am ADMINISTRATOR WHEELER departs InterContinental Costa Rica (RON) en route to La Hacienda Alsacia

Vehicle Assignments:	
EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) – PSD TYLER TERESA

Drive Time: 1 Hours; 18 Miles

Event Location
Hacienda Alsacia - Starbucks Coffee Farm
15 KM North from the Alajuela Justice Courts,
Alajuela Dulce Nombre de San Isidro, 20106, Costa Rica

9:30am ADMINISTRATOR WHEELER arrives at Hacienda Alsacia

EVENT **LA HACIENDA ALSACIA**

LOCATION:	Hacienda Alsacia – Starbucks Coffee Farm
TYPE:	Tour
SPEAKING:	N/A
ATTIRE:	Business Rugged (Boots/Tennis Shoes, Khakis, Polo Shirt, and Rain Jacket)
PRESS:	Closed
GIFTS:	No
INTERPRETATION:	N/A
PARTICIPANTS:	**EPA** ADMINISTRATOR WHEELER T.H. Chad McIntosh, AA OITA Michael Molina, Deputy Chief of Staff Carrie Meadows, Agricultural Advisor Molly Block, Deputy Associate Administrator for PA Corey Scott, Executive Advisor to the Administrator **HACIENDA ALSACIA - STARBUCKS COFFEE FARM** Fernando Perez, Country Manager Marlon Prendas, Manager

SCENARIO:

9:30am *- ADMINISTRATOR WHEELER arrives at Hacienda Alsacia and is greeted by Fernando Perez and is offered coffee/tea and then split into two groups for the Tour*

GROUP 1
ADMINISTRATOR WHEELER
CHAD MCINTOSH
MICHAEL MOLINA
COREY SCOTT
JAKE ALLEN – Photographer
Ex. 7(C); Ex. 7(F) RF

GROUP 2
MOLLY BLOCK
CARRIE MEADOWS
TYLER TERESA
SARAH BANNISTER

9:32am - *ADMINISTRATOR WHEELER begins tour*
- *Welcome Overview*
- *Nursery*
- *Coffee Plant Viewing & Picking*
- *Gazebo - Solar Panels and Coffee Fields*
- *Watermill and Sun Drying*
- *Micro Green House - Research and Development*
- *Visitor Center/Tasting Room/Café*

11:30am Tour concludes; ADMINISTRATOR WHEELER departs Hacienda Alsacia en route to La Paz Waterfall Gardens

Vehicle Assignments:

EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) PSD TYLER TERESA

Drive Time: 30 Minutes; 13 Miles

Event Location
La Paz Waterfall Gardens
6KM al norte de la Gasolinera
Vara Blanca de Heredia, Costa Rica 20101

12:00pm ADMINISTRATOR WHEELER arrives at La Paz Waterfall Gardens and proceeds to La Paz Waterfall Gardens Restaurant for lunch

1:30pm Lunch concludes; ADMINISTRATOR WHEELER proceeds to the start of the trail

EVENT **LA PAZ WATERFALL GARDENS**

LOCATION:	La Paz Waterfall Gardens
TYPE:	Hike
SPEAKING:	N/A
ATTIRE:	Business Rugged (Boots/Tennis Shoes, Khakis, Polo Shirt, and Rain Jacket)
PRESS:	Closed
GIFTS:	No
INTERPRETATION:	N/A
PARTICIPANTS:	**EPA** ADMINISTRATOR WHEELER T.H. Chad McIntosh, AA OITA Michael Molina, Deputy Chief of Staff Carrie Meadows, Agricultural Advisor Molly Block, Deputy Associate Administrator for PA Corey Scott, Executive Advisor to the Administrator

SCENARIO:

1:30pm *- ADMINISTRATOR WHEELER begins the 2.2-mile trail en route to La Paz Waterfall Gardens to view the biodiversity in the area*

4:30pm Hike concludes; ADMINISTRATOR WHEELER departs La Paz Waterfall Gardens en route to CMR and then InterContinental Costa Rica (RON)

Vehicle Assignments:	
EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) – PSD
EPA STAFF VEHICLE:	CHAD MCINTOSH COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) – PSD TYLER TERESA

Drive Time: 1 Hour, 30 Minutes; 35 Miles

RON Location
InterContinental Costa Rica at Multiplaza Mall
Multiplaza Shopping Center,
San José Province, Escazu, 10202, Costa Rica

6:00pm ADMINISTRATOR WHEELER arrives to the InterContinental Costa Rica (RON) and begins Executive Time

6:45pm Executive Time concludes; ADMINISTRATOR WHEELER proceeds to Zambra Lobby Restaurant in the InterContinental Costa Rica for dinner

8:45pm Dinner concludes; ADMINISTRATOR WHEELER begins Executive Time

RON **INTERCONTINENTAL COSTA RICA**

SATURDAY, JANUARY 9

***Breakfast:** The Market from 6:00am – 10:00am in the lobby

***Note:** Hotel provides transportation to the airport for staff departing on earlier flight*

11:30am Executive Time concludes; ADMINISTRATOR WHEELER departs the InterContinental Costa Rica (RON) en route to Juan Santamaría International Airport (SJO)

Vehicle Assignments:

EPA LIMO:	ADMINISTRATOR WHEELER MICHAEL MOLINA EMBASSY DRIVER – Limo Driver Ex. 7(C); Ex. 7(F) – RF
EPA FOLLOW:	EMBASSY DRIVER – Follow Driver Ex. 7(C); Ex. 7(F) - PSD
EPA STAFF VEHICLE:	COREY SCOTT CARRIE MEADOWS MOLLY BLOCK JAKE ALLEN
CONTROLL VEHICLE:	SARAH BANNISTER
STAFF/PSD ADVANCE:	Ex. 7(C); Ex. 7(F) - PSD TYLER TERESA

Drive Time: 25 Minutes; 12 Miles

Departure Airport
Juan Santamaría International Airport
Alajuela Province
Alajuela, Costa Rica

12:00pm ADMINISTRATOR WHEELER arrives at Juan Santamaría International Airport (SJO) and begins boarding process for United Airlines Flight 1099

Note: *Only those flying on ADMINISTRATOR WHEELER flight will be escorted to Diplomatic Waiting Room all other staff will proceed to their gate for departure*

EVENT AIRPORT DEPARTURE

2:20pm ADMINISTRATOR WHEELER departs Juan Santamaría International Airport (SJO) en route to George Bush Intercontinental Airport (IAH)

AIRLINE LOCATOR NUMBER: Ex. 6
ADMINISTRATOR SEAT: 11C

UNITED AIRLINES FLIGHT(UA1099)
ADMINISTRATOR WHEELER
MICHAEL MOLINA
Ex. 7(C); Ex. 7(F) – RF

Flight Time: 3 Hour, 45 Minutes
Time Change: N/A

EVENT AIRPORT CONNECTION

Connection Airport
George Bush Intercontinental Airport
2800 N Terminal Rd,
Houston, TX

6:05pm ADMINISTRATOR WHEELER arrives at George Bush Intercontinental Airport (IAH) and proceeds to United Airlines Flight 4320

Layover: 2 Hours, 19 Minutes

8:25pm ADMINISTRATOR WHEELER departs George Bush Intercontinental Airport (IAH) en route Jackson-Medgar Wiley Evers International Airport (JAN)

AIRLINE LOCATOR NUMBER: Ex. 6
ADMINISTRATOR SEAT: 22A

UNITED AIRLINES FLIGHT(UA4320)
ADMINISTRATOR WHEELER
MICHAEL MOLINA
Ex. 7(C); Ex. 7(F) RF

Flight Time: 1 Hour, 27 Minutes
Time Change: N/A

EVENT AIRPORT ARRIVAL

Arrival Airport
Jackson-Medgar Wiley Evers International Airport
100 International Dr,
Jackson, MS

9:52pm ADMINISTRATOR WHEELER arrives in Jackson Mississippi and begins separate program

Message

From: Barker, Kendal [Barker.Kendal@epa.gov]
Sent: 1/7/2021 2:14:33 AM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Benevento, Douglas [benevento.douglas@epa.gov]; Molina, Michael [molina.michael@epa.gov]
CC: Vella, Sophia [Vella.Sophia@epa.gov]; Scott, Corey [scott.corey@epa.gov]
Subject: Thursday (1/7) AA Meeting Agenda
Attachments: January 5, 2021 SABSO update.docx; Weekly AA Meeting 01.07.21.docx

Good evening all,

Attached is tomorrow's **AA meeting agenda** and one supplemental item from David Dunlap. It is my understanding that Administrator Wheeler will not be joining as he is traveling, so Doug will lead the meeting.

In the morning, I will email David's attachment to all AAs for those continuing to telework. Please let me know if you have any questions. Thank you and safe travels.

Best,

Kendal Barker
Special Advisor to the Chief of Staff
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, D.C. 20004
O: (202) 564-6624
C: Ex. 6
barker.kendal@epa.gov

SAB and CASAC Projects
1/5/2021 Update

SAB & WORK GROUP PROJECTS:

1. Economic Guidelines
   - (T) Final report sent to the Administrator 1/7/21.

2. Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), Revision 2 – OAR timing summer 2020.
   - Public panel meeting 1/11/21 to 1/14/21.

3. STAA Awards Panel
   - Non-public (closed) Panel meeting 1/11/21 and 1/12/21.

4. BENMap
   - Panel formation is in process.
   - Meeting date TBD

New projects for CASAC/SAB to be scheduled soon:

1. Consultation: Biosolids Risk Assessment Model – OW expected in FY21.
2. Fifth Contaminant Candidate List (Draft) – OW expected in March 2021.
3. Vessel Incident Discharge Act: Viability Testing for Ballast Water – OW expected in FY21.
4. Four IRIS Assessments: The first review will likely be Chloroform (Inhalation). Other reviews will be Mercury Salts; Vanadium (oral); and, Chromium VI – ORD expected in FY21.
5. Evaluation of Exposure Potential for Trespassers – OLEM expected in FY21.
6. CASAC lead NAAQS reviews – TBD.

01/07/21

Weekly AA Meeting

New Discussion

- SAB Projects (see attachment) – David Dunlap
- Vaccine Distribution Prioritization – Susan Bodine
- Update on PFAS-Leaching Containers – Alex Dunn
    - OECA Involvement – Susan Bodine
- Succession Announcements – Alex Dunn
- Grignard Air Disinfectant FIFRA – Alex Dunn
- Treatment of AD Employees – Anne Idsal
- Ethylene Oxide – Anne Idsal

Message

From: Bolen, Brittany [bolen.brittany@epa.gov]
Sent: 1/7/2021 3:03:59 AM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
CC: Molina, Michael [molina.michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: Re: 111B

That is the question

Sent from my iPhone

On Jan 6, 2021, at 9:37 PM, adm15.arwheeler.email <adm15.arwheeler.email@epa.gov> wrote:

2B or not 2B
<111(b) EGU Preamble and Rule 01_06_2021_Admin.docx>

Message

From: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
Sent: 1/6/2021 10:46:26 PM
To: Bolen, Brittany [bolen.brittany@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: Pests
Attachments: 10011-06_FR_Doc_Product Performance Data_eSignature_EPA_ADMIN.docx

Spineless pests

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[EPA-HQ-OPP-2020-0124; FRL-10011-06]

RIN 2070-AJ49

Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to codify product performance data requirements to support registration of pesticidal products claiming efficacy against three categories of invertebrate pests: those identified to be of significant public health importance (e.g., ticks, mosquitoes, cockroaches, etc.), wood-destroying insects (e.g., termites), and certain invasive invertebrate species (e.g., Asian longhorned beetle). The latter two categories are pests considered to be of significant economic or ecological importance. Product performance data (efficacy studies) document how well the pesticide performs the intended function, such as killing or repelling, against an invertebrate pest.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE ***FEDERAL REGISTER***].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2020-0124, through the Federal eRulemaking Portal at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Sara Kemme, Mission Support Division (7101M), Office of Program Support, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347-8533; e-mail address: *kemme.sara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You potentially may be affected by this action if you are a producer or registrant of pesticide products making claims against the specified categories of invertebrate pests. The North American Industrial Classification System (NAICS) codes are provided to assist you and others in determining if this action might apply to certain entities. This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. Other types of entities not listed could also be affected. Potentially affected entities may include, but are not limited to,

• Chemical Producers (NAICS 32532), e.g., pesticide manufacturers or formulators of

pesticide products, pesticide importers or any person or company who seeks to register a pesticide.

• Research and Development in the Physical, Engineering, and Life Sciences (NAICS code 541712), e.g., research and development laboratories or services that perform efficacy testing for invertebrate pests.

• Colleges, universities, and professional schools (NAICS code 611310), e.g., establishments of higher learning which are engaged in development and marketing of products for invertebrate pest control.

B. What action is the Agency taking?

EPA is proposing to codify product performance data requirements for pesticide products claiming efficacy against three categories of invertebrate pests: those identified to be of significant public health importance (e.g., ticks, mosquitoes, cockroaches, etc.), wood-destroying insects (e.g., termites), and certain invasive invertebrate species (e.g., Asian longhorned beetle). The latter two categories are considered to be of significant economic and/or ecological importance.

Product performance data (efficacy studies) document how well the product performs the intended function, such as killing or repelling, against an invertebrate pest. The product performance data requirements being proposed would inform the data needed to substantiate pesticidal claim(s) made on the label of the pesticide products. The proposed numerical performance standards specify the level of efficacy that would need to be achieved for EPA to deem the submitted data as acceptable for a product bearing the specified claim(s) against the invertebrate pest. For the most part, the data requirements that EPA is proposing for codification are consistent with EPA's current practices in data supporting applications for registration of a

pesticide product that bears a pesticidal claim against one or more of these pests.

This proposed rule presents the data requirements in tabular format. These tables link the efficacy claim on the label of a pesticide product with the data needed to substantiate that claim. EPA is proposing that the studies submitted by an applicant demonstrate the product's efficacy in studies using specified test species and with results demonstrating that the product achieved a specified level of performance, called a performance standard. Numerical performance standards, such as the percent mortality, percent repellency, percent knockdown, or complete protection time would need to be achieved to deem the data acceptable for the purpose of supporting a product making a claim against an invertebrate pest. The Agency believes that codifying essential elements relating to test species and performance standards will provide the regulated community a better understanding of the data EPA believes to be necessary to support registration of a product that claims efficacy against invertebrate pests.

EPA is proposing to:

• Codify a new subpart R in 40 CFR part 158 entitled, "Product Performance for Products Claiming Effectiveness Against Invertebrate Pests;"

• Rename 40 CFR part 158, subpart E to "Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion-related Claims, and Products for Control of Organisms Producing Mycotoxins" in order to add specificity to the title and reduce the potential for confusion with the proposed subpart R; and

• Revise the data requirements for biochemicals in 40 CFR 158.2070 and microbials in 40 CFR 158.2160 to clarify the requirements for claims that would be subject to both subpart R and either subpart U or V.

Additionally, EPA proposes to update 40 CFR 158.1(c) to insert references to the

subparts to categorize them under the "scope of the subparts" section. EPA is also proposing to update subpart W at 40 CFR 158.2200(b) to insert a cross reference to the proposed subpart R to clarify the status of a product that bears both an antimicrobial claim and a non-antimicrobial claim against one of the pests specified in proposed subpart R.

C. What is EPA's authority for taking this action?

This action is issued under the authority of sections 3, 5, 10, 12, and 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136-136y), as amended. Under FIFRA section 3(c)(2)(A), EPA is required to specify "the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time." EPA's codification of these data requirements is in 40 CFR part 158.

Additionally, the Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) (7 U.S.C. 136 note, 133 Stat. 484) was enacted into law on March 8, 2019. PRIA was developed by a coalition of pesticide stakeholders representing seven different trade groups within the pesticide industry and public interest groups reflecting the environmental and farmworker safety communities. The result of this collaboration is that there are elements of PRIA 4 important to all the represented stakeholder entities in the coalition. PRIA 4 specifically establishes a new maintenance fee set-aside of up to $500,000/year to develop and finalize rulemaking and guidance for product performance data requirements for certain invertebrate pests of significant public health or economic importance. Specific to this rule, PRIA 4 requires EPA to finalize product performance data requirements by September 30, 2021. Specifically, the Act states that, "The Administrator shall, not later than September 30, 2021, issue regulations prescribing product performance data requirements for any pesticide intended for preventing, destroying, repelling, or mitigating any invertebrate pest of significant public health or economic importance

specified in clauses (i) through (iv) of subparagraph (B) [bed bugs; premise (including crawling insects, flying insects, and baits), pests of pets (including pet pests controlled by spot-ons, collars, shampoos, powders, or dips), and fire ants]."

This proposed rule includes product performance data requirements for the categories of invertebrate pests specified in PRIA 4 and, thus, is intended to satisfy the aforementioned rulemaking requirement. EPA notes that this proposed rule covers some invertebrate pests in addition to those specified in PRIA 4 due to their public health, economic, or ecological significance.

D. Why is EPA taking this action?

The following objectives were considered by EPA in developing this proposed rule:

1. *Obtaining reliable data to make the statutory finding*. The data submitted to EPA for review and evaluation as a result of this rule, once final, are expected to improve the Agency's understanding of the effectiveness of pesticides that make claims against pests of public health or significant economic importance.

2. *Provide clear and transparent data requirements*. Once final, the regulatory text proposed in this rule is intended to identify the specific data requirements that apply to pesticides making claims against certain categories of invertebrate pests. As with the original design of part 158 in 1984, and continued in 2007, given the variations in pesticide chemistry, exposure, and hazard, this proposal for product performance data requirements is intended to be clear and transparent while retaining sufficient flexibility to account for special circumstances.

E. What are the estimated incremental impacts?

In conjunction with this proposed rulemaking, EPA prepared an economic analysis entitled, "Cost Analysis of the Proposed Product Performance Rule" (Ref. 1) which presents an

analysis of the effects of codifying data requirements for product performance, as well as the effects of changes to label claim data requirements published simultaneously.

As noted previously, FIFRA mandates the Agency to register pesticides, including those used against invertebrate pests of public health importance, invertebrate wood destroying pests, and invasive invertebrate pests, under conditions of use such that the pesticide is of a composition to warrant the proposed claims. To make this finding, the Agency requires that registrants submit data demonstrating product efficacy against invertebrate pests of public health importance, invertebrate wood destroying pests, and invasive invertebrate pests. The product performance data requirements historically sought by the EPA and those being proposed in the rule are for claims against pests that either pose a threat to human health (e.g., mosquitoes and cockroaches) or have significant economic impacts, against which the efficacy of a pesticide cannot be readily determined by the user (e.g., termites and emerald ash borers). In those situations, market forces may operate too slowly to remove ineffective products. The proposal, once final, would codify data requirements for support of label claims that have, to date, been necessary, as determined on a case-by-case basis, to conduct assessments of product performance. This will provide needed clarity to firms seeking to develop and market products to control invertebrate pests of public health importance, invertebrate wood destroying pests, and invertebrate invasive pests.

This rule, when finalized, will clarify data requirements and therefore improve efficiency and effective use of resources by both the Agency and industry. Moreover, this rule-making measure will serve the public by ensuring that appropriate efficacy data are available to substantiate public health pest claims. While experience over time has led to a fairly standardized set of data requirements for invertebrate pests of significant public health importance, wood-

destroying insects, and invasive pests, codifying these data needs will ensure that new entrants to the field are clear about the information necessary to support registration. As a result, this rule, when finalized, would help alleviate uncertainties in the regulatory process and enhance transparency for stakeholders. The Agency is specifying data requirements for invertebrate pests of significant public health importance, wood-destroying insects, and invasive invertebrate pests to better indicate when certain data are needed or not. Consistent with 40 CFR 158.45 and proposed 40 CFR 158.1707, on a case-by-case basis the Agency may consider alternative data that are more appropriate than the proposed requirements considering the intended purpose and pesticidal claims of a pesticidal product.

EPA estimates that the proposed rule would result in cost savings of one million dollars annually across all registrants seeking label claims against invertebrate pests of significant public health importance, wood-destroying insects, and invasive invertebrate pests, equivalent to about $17,000 in savings per data package submitted to the Agency (Table 1). The average savings per registrant is $5,500 annually, considering that registrants do not submit products for review every year. This impact is expected to remain consistent over the next ten years, with total cost savings to industry of $1 million annually using either a 3% or a 7% discount rate. Over ten years, this amounts to about $8.5 million in savings at a 3% discount rate or about $7 million in savings at a 7% discount rate. The most expansive estimate of registrant cost savings of the proposed rule, including all likely impacts of the publication of the rule and the impact of changes in data requirements published concurrently with the rule, is $1.7 million annually. The estimated worst case is a cost increase to registrants of $600,000 annually.

EPA's registration program and efficacy review has substantial benefits for consumers. It ensures product efficacy and label consistency across products, increases consumer confidence in

product efficacy, and reduces consumer search costs for effective products. This may help reduce the incidence of vector-borne diseases and damage from wood-destroying and invasive pests. Clarity in data requirements would enhance the efficiency of the registration process and aid new products to market, providing consumers with more product choices.

Table 1—Benefits and Costs of the Proposed Rule

Expected Benefits of the Proposed Rule	
Cost savings per data package submitted	• Average impact per submitted data package of $17,000
Cost savings per registrant submitting data packages	• Average annual impact per registrant of $5,500
Annualized Cost Savings	• $1 million at both 3% and 7% discount rates • This projection assumes 60 data packages submitted annually to the Agency.
Qualitative Effects	• For registrants: Quicker label changes, lower discovery costs, lower barriers to innovation. • For consumers: Ensuring product efficacy and label consistency; increased consumer confidence in product efficacy; reduced search costs for effective products; and reduction in damage from covered pests.
Expected Costs of the Proposed Rule	
No increased risk to human health or the environment is expected from publication of the proposed rule. No increased costs to registrants or consumers are expected from publication of the proposed rule. Expected direction of costs for the Agency from the proposed rule are unknown.	
Other Impacts	
Small Business Impacts	• No significant impact on a substantial number of small entities • Affected NAICS codes contain up to 5,438 small entities. No increased costs to small entities expected, and cost savings may be relatively larger for small firms who do not have experience with the registration process for invertebrate pests of public health importance, invertebrate wood destroying pests, and invertebrate invasive pests.

F. What should I consider as I prepare my comments for EPA?

1. *Submitting Confidential Business Information (CBI)*. Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the

outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Statutory Framework

As a general matter, no person may distribute or sell an unregistered pesticide in the U.S. (FIFRA section 3(a)). The process for obtaining a registration for a pesticide so that it may be distributed or sold begins with submission to EPA of an application with the necessary data to review the application request. Taking into account the information submitted, EPA must grant the requested registration, if it concludes, when considered with any restrictions imposed, that:

• Composition of the proposed pesticide is such as to warrant the proposed claims for it;

• Labeling for the proposed pesticide and other material required to be submitted comply with the requirements of FIFRA;

• The proposed pesticide will perform its intended function without unreasonable adverse effects on the environment; and

• When used in accordance with widespread and commonly recognized practice, the proposed pesticide will not generally cause unreasonable adverse effects on the environment.

FIFRA section 3(c)(5) further provides that EPA "may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy."

The proposed regulations identify the data requirements EPA believes are necessary to determine whether the proposed claims of efficacy are warranted, the opportunity for waiver is covered by 40 CFR 158.45 and proposed 40 CFR 158.1707.

EPA notes that "unreasonable adverse effects on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs, and benefits of the use of any pesticide …" as described in FIFRA section 2(bb). That definition was amended in 1998 as part of the Food Quality Protection Act, requiring EPA to consider "the risks and benefits of public health pesticide separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this Act, the administrator shall weigh any risks of the pesticide against the health risks such as the disease transmitted by the vector to be controlled by the pesticide." While this rule proposes to codify product performance data requirements for invertebrate pests of significant public health importance, (Ref. 2) this rule does not address classification of pesticides as "public health pesticides" as that term is defined in FIFRA section 3(nn). The data requirements proposed in this rule will be used to make appropriate determinations under the FIFRA "unreasonable adverse effects" standard.

To determine whether the proposed use of the pesticide will not cause unreasonable adverse effects, EPA generally considers the maximum proposed use of a new pesticide to estimate the maximum exposure potential, evaluates the hazard data on the pesticide, and compares the rates at which effects are found based on well conducted studies with the maximum exposure estimate. However, for pesticides intended for use against pests of public health or economic importance, EPA has for some time considered whether the pesticide may cause human health, environmental or economic harm if its use as proposed will not work as

intended or claimed. Data on the pesticide's performance under the conditions of use proposed are essential to make this determination.

A. Registration

Section 3 of FIFRA contains the requirements for granting and maintaining registration. FIFRA section 3(c)(2) provides EPA broad authority, before and after registration, to require scientific testing and submission of the resulting data to the Agency. Under this authority, EPA requires such testing and submission of data through rulemaking, see, 40 CFR part 158 or, for existing registrations, through issuance of a "data call-in." (See, FIFRA section 3(c)(2)(B)). EPA may also request further data if the data submitted fail to adequately address an issue necessary for making the requisite statutory findings. (See, 40 CFR 158.75). Consistent with the requirements EPA has imposed and the data that have been identified as needed to review applications for registration of pesticides of significant health or economic importance, an applicant for registration must furnish EPA with data on the pesticide, its composition, toxicity, potential human exposure, environmental properties and ecological effects, as well as its product performance (efficacy).

B. Registration Review

FIFRA section 3(g) mandates that the registrations of all pesticides are to be periodically reviewed. Periodic review is needed as changes in science, public policy, and pesticide use practices occur over time. The registration review program was implemented via a regulation promulgated on August 9, 2006 (71 FR 45719) (FRL-8080-4). Therefore, starting in 2006, registration review began to replace EPA's reregistration program as the mechanism for systematic review of existing pesticides. The registration review process begins by reviewing the available information in the possession of the Agency and then determining if and what data are

needed to assess the current risks of a particular pesticide. Thus, as with registration, the data needed and the scope and depth of the Agency's review for registration review continue to be tailored to the specific circumstances and use of the registered pesticide. Section 3(g)(2)(A) of FIFRA authorizes EPA to require generation and submission of additional data necessary for registration review pursuant to its authority under FIFRA section 3(c)(2)(B).

III. Regulatory Framework

The existing regulatory data requirements for product performance for pesticides are contained in 40 CFR part 158, subpart E, and for the most part the table in 40 CFR 158.400(d) is specific to vertebrates (e.g., birds, rodents, etc.); 40 CFR part 158 subpart W also contains pesticide data requirements for antimicrobials. However, subpart E does not specifically require submission of product performance data for those pesticide products claiming effectiveness against invertebrate pests (e.g., insects, spiders, etc.). Instead, the test note in 40 CFR 158.400(e)(1) contemplates requiring the submission of product performance data on a case-by-case basis, consistent with the general authority in 40 CFR 158.75 to require additional data as part of the registration process, if the information that is required and submitted for registration is not sufficient to make the requisite statutory findings. EPA has relied on these authorities for some years to obtain needed product performance data for conventional pesticides intended for use against certain invertebrate pests of public health or economic significance.

Although the updating of 40 CFR part 158 regulations began years ago, EPA made no changes to the product performance data requirements at 40 CFR part 158, subpart E, as they relate to the invertebrate pests covered in this action. (72 FR 60934, October 26, 2007) (FRL-8106-5). However, EPA did make some changes to the data requirements for biochemical and microbial pesticides by codifying product performance data requirements for biochemical and

microbial pesticides in 40 CFR 158.2070 and 158.2160, subparts U and V, respectively (72 FR 60934, October 26, 2007) (FRL-8106-5). That final rule adopted the requirement for applicants to submit product performance data to support registration of biochemical and microbial products claiming effectiveness against invertebrate species.

This rulemaking proposes to create a new subpart R for invertebrate product performance requirements to capture the updates to the product performance data requirements for pesticides, and to make conforming edits to subparts E, U, V, and W.

IV. Background

Since the early years of the registration program, EPA has waived the need for product performance data for many pesticides, consistent with the congressional authority in FIFRA section 3(c)(5), to waive such data and to not make the finding that a proposed pesticide's "composition is such as to warrant the proposed claims for it." (44 FR 27932, May 11, 1979) (FRL-2767-8). However, EPA did not codify its early intent not to waive product performance data for pesticides intended for use against certain invertebrate pests. Specifically, in May of 1979, EPA initially announced the need for product performance data for "[i]nvertebrate control products intended for use in or on humans (or in or on pets for control of pests which attack humans) to control pests such as fleas, mites, lice, ticks, biting flies, and mosquitoes" and for"[i]nvertebrate control products intended for use either in premises or in the environment to control pests of sanitary or public health significance such as mosquitoes, biting flies, ticks, fleas, houseflies, cockroaches, fire ants, hornets, wasps, poisonous spiders, scorpions, centipedes, and bedbugs." (44 FR 27932, May 11, 1979) (FRL-2767-8). In contrast, in other subsequent rulemaking actions, EPA announced its intent to require product performance data only for products "where lack of control would clearly result in adverse health effects" (47 FR 40659,

September 15, 1982) (FRL-2138-1) or where "control cannot reasonably be observed by the user…" (47 FR 40659, 40661) because other pests were more of an aesthetic and nuisance problem rather than one of public health.

Ultimately, EPA's final part 158 rule announced that EPA had "decided to rescind the proposed efficacy data waiver with respect to vertebrate control agents intended for control of pests that directly or indirectly transmit disease to humans" and included a test note indicating that EPA waived product performance data "unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his/her product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration." (49 FR 42856, 42875, October 24, 1984) (FRL-2591-5); 40 CFR 158.400(e)(1). That provision remains largely unchanged today, although in the subsequent updates to the data requirements for microbial and biochemical pesticides, EPA made clear that the submission of efficacy data would be required if "the pesticide product bears a claim to control … invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans." (40 CFR 158.2160). Thus, existing EPA regulations for conventional pesticides continue to presume the waiver of product performance data for invertebrate pests unless EPA exercises its discretion to require on a case-by-case basis submission of the data to support claims against pests, including

pests of significant public health importance.

In 2002, EPA issued Pesticide Registration Notice (PRN) 2002-1 in compliance with the requirement in FIFRA section 28(d) to coordinate with United States Department of Health and Human Services (HHS) and United States Department of Agriculture (USDA) in identifying pests of significant public health importance. The list of pests identified in that PRN was "derived in large part from review of the pesticide/pest combinations for which efficacy (product performance) data are generally required to be submitted and reviewed prior to registration." (Ref. 2). EPA is the process of updating this document and has recently made an updated draft available for public comment (Ref. 2).

A. Why does product performance matter?

The primary goal of this proposal is to assure that pesticide products claiming effectiveness against an invertebrate pest of significant public health or economic importance perform effectively. This action addresses both health concerns and economic consequences stemming from pesticide products that might not perform as claimed on the label. EPA acknowledges that use of the term arthropod would include all the pests identified in this document. However, product performance data for additional invertebrate species, such as (but not limited to) gastropods (snails and slugs) that serve as intermediate parasite hosts or invasive mussels of ecological concern could be needed in the future. To account for the potential for future data needs, EPA will use the terms invertebrates or invertebrate pests in reference to pests in all three categories (pests of significant public health importance, invasive species, and wood-destroying insects).

Consistent with the regulatory text in 40 CFR 158.400(e)(1) and as noted in PRN 2002-1 and PRN 96-7: Termiticide Labeling, (Ref. 3). EPA has regularly exercised its discretion to

require submission of product performance data for pesticides intended for use against invertebrate pests of significant public health importance and of product performance data on pesticides intended for use against invertebrate pests of significant economic importance. Since 1984, particularly for insect repellents, the awareness of the incidence and severity of mosquito- and tick-borne diseases in the U.S. has changed. Mosquitoes and ticks are not merely nuisance pests: The Centers for Disease Control and Prevention (CDC) has determined that a single bite can transmit sufficient infectious material, i.e., a sufficient amount of pathogen, to cause serious, and sometimes fatal, disease. (Ref. 4). This is true for both mosquito-borne diseases such as West Nile Virus, St. Louis Encephalitis, and the Zika virus, and tick-borne diseases such as Lyme Disease. (Refs. 5 and 6).

If a person can become ill because of a single insect bite, a person using an ineffective insect repellent may not have the opportunity to realize that the insect repellent did not work as expected and then correct the situation by purchasing another product. Given the nature of these and other mosquito- and tick-borne diseases, an ineffective insect repellent can have serious and sometimes fatal consequences to a person's health.

Consequences can also include both health and economic impacts. For example, the common bed bug (*Cimex lectularius*) has long been a pest, feeding on blood, causing itchy bites and generally irritating their human hosts. EPA, CDC, and the USDA all consider bed bugs a pest of significant public health importance. Bed bugs can cause a variety of negative physical health, mental health, and economic consequences. Effects can include:

• Allergic reactions to the bed bug bites, which can range from no reaction to a small bite mark to, in rare cases, anaphylaxis (severe, whole-body reaction).

• Secondary infections of the skin, such as impetigo, ecthyma, and lymphangitis.

• Mental health impacts on people living in infested homes. Reported effects include anxiety, insomnia and systemic reactions. (Refs. 7 and 8).

Bed bug infestations are also an economic burden on society. The economic losses from health care, lost wages, lost revenue and reduced productivity can be substantial. The cost of effectively eliminating bed bugs may be significantly more than the cost of eliminating other pests because bed bug control usually requires multiple visits by a licensed pest control operator and diligence on the part of those who are experiencing the infestation. Control in multi-family homes is much more difficult than in single family homes because bed bugs frequently travel between units, either by direct transport by humans or through voids in the walls. Thus, there are additional costs and complexities associated with coordinating and encouraging participation from multiple residents. Also, if the pesticide product claiming to treat bed bugs is not effective and families are forced into repeated (and expensive) cycles of re-treatment, then serious health and economic impacts can occur.

While wood-destroying insects/structural pests are not pests of significant public health importance, they are similar in that the consequences of ineffective treatments can be severe. Unfortunately, the effectiveness of a treatment to protect a wooden structure is not readily apparent to the applicator at the time of application or during the occupancy of the building or home. It is only after the damage becomes apparent that the extent of needed repairs is determined. There is a potential for significant financial loss to the property owner. Thus, demonstrating the efficacy of pesticides intended to control structural pests has a unique importance. Data on the level of economic damage caused by structural pests on an annual basis are difficult to obtain but several authors have attempted to quantify it. The economic costs of termite property damage, preventative treatments, and structural repairs can be quite severe, with

estimated cost at approximately $5 billion annually. (Refs. 9 and 10). While these estimates are indicative of the cost nationwide, the costs borne by an individual property owner can be significant in their own right, up to and including, loss of the structure.

B. Labels

1. *Label requirements*. Pesticide product labeling provides information to users on, among other things, the product's intended uses, and how to handle and apply the produEPA's labeling regulations are contained in 40 CFR part 156. EPA reviews pesticide labels to determine whether the labeling is consistent with EPA's regulations, and is accurate, clear and enforceable. The accuracy of the information on the labeling is of particular importance for products making a claim to kill or repel pests of significant public health importance and wood-destroying pests. Such pests, if uncontrolled, can transmit disease pathogens, thus posing a widely recognized and significant risk to human health, and can result in significant economic impacts.

Consumers purchase products that claim effectiveness against a pest of significant public health importance precisely to avoid the harm these pests can cause. Consumers have a reasonable expectation that the claims on the pesticide label have a scientific basis, i.e., are based on valid evidence, and are neither false nor misleading. Such claims should be expressed using wording or graphics that are easily understood and require little or no interpretation by the consumer. To ensure that labeling provides consumers with accurate information concerning how long and how well the product works, EPA reviews and evaluates product performance (efficacy) data. Once the data have been reviewed and evaluated, then the Agency works to ensure that the labeling use directions and labeling claims are clear and consistent with the results of the supporting product performance data.

EPA believes that having reliable information concerning the effectiveness of pesticide

products that claim effectiveness against invertebrate pests results in sound regulatory decisions and accurate information on the labeling. Accurate labeling claims provide consumers with information they need concerning the effectiveness of the pesticide.

2. *Label Review Manual*. Consistently, the Agency has in the Label Review Manual explained the historical need for product performance data for products intended for invertebrate control. The Label Review Manual has for some time summarized the Agency's current practice of requiring product performance data to support claims for pesticides intended for use in or on humans (or in or on pets for control of pests which attack humans such as fleas, ticks, mosquitoes, and biting flies) and in premises or in the environment to control pests of sanitary or significant public health importance such as termites, wasps, scorpions, poisonous spiders, fire ants, cockroaches, centipedes, and bedbugs. (Ref. 11).

C. EPA's Harmonized Test Guidelines for Invertebrate Product Performance

1. *Existing Guidelines*. EPA has established a unified library for test guidelines issued by the Office of Chemical Safety and Pollution Prevention (OCSPP) for use in testing chemical substances to develop data for submission to EPA under the Toxic Substances Control Act (TSCA) and FIFRA. This library of test guidelines represents an Agency effort that began in 1991 to harmonize the test guidelines within OCSPP, as well as to harmonize the OCSPP test guidelines with those of the Organization for Economic Cooperation and Development, which includes representation of countries, including the U.S., throughout the world. The process for developing and amending the test guidelines includes several opportunities for public participation and extensive involvement of the scientific community, including peer review by the FIFRA Scientific Advisory Panel (SAP), the Science Advisory Board (SAB), and other expert scientific organizations. New or revised guidelines are typically presented to SAP for peer

review. The purpose for harmonizing these guidelines into a single set of OCSPP guidelines is to standardize testing procedures that should be performed to meet the Agency's data requirements under FIFRA and TSCA. EPA's Invertebrate Control Agents, Product Performance Guidelines are listed in Table 2.

The guidelines themselves do not impose requirements. Instead, they provide recognized methods for conducting acceptable tests, guidance on reporting data, and definitions of terms. Since these are guidance, pesticide registrants are not required to use these guidelines to fulfill data requirements. Applicants may instead seek to fulfill the data requirements by other appropriate means or by using a non-guideline protocol. The applicant may submit a protocol of his own devising for the Agency to review. EPA notes that there is a PRIA fee category for submitting a protocol for EPA to review.

The guidelines identify thresholds for determining whether a product is effective. Since these thresholds are in guidance (not codified requirements), they are considered recommendations and not mandatory. EPA also acknowledges that the older (1998) guidelines, in particular, generally lack adequate, up-to-date guidance on efficacy data development, test protocols, and representative test species.

EPA notes that the Product Performance Guideline 810.1000 entitled, "Overview, Definitions, and General Considerations," discusses that product performance data are needed for any product that "bears a claim to control pests that may pose a threat to human health." This is specifically stated to include:

Public health uses of invertebrate control agents including, but not limited to, agents intended to control the following: Mosquitoes, biting flies, ticks, fleas, houseflies, cockroaches, fire ants, hornets, wasps, poisonous spiders, scorpions, biting midges, centipedes, bedbugs,

human lice, and dust mites. (Ref. 12).

Table 2—EPA's Series 810, Group C – Invertebrate Control Agents, Product Performance Guidelines

OCSPP Guideline Number	Guideline Title (Date)
810.3000	General Considerations for Efficacy of Invertebrate Control Agents (1998)
810.3100	Soil Treatments for Imported Fire Ants (1998)
810.3200	Livestock, Poultry, Fur- and Wool-Bearing Animal Treatment (1998)
810.3300	Treatments to Control Pests of Humans and Pets (March 1998)
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments (1998)
810.3500	Premise Treatments (2019)
810.3600	Structural Treatments (1998)
810.3700	Insect Repellents to Be Applied to Human Skin (2010)
810.3800	Methods for Efficacy Testing of Termite Baits (2004)
810.3900	Laboratory Product Performance Testing Methods for Bed Bug Pesticide Products (2017)

D. Guideline Modifications Needed for the Future

Those guidelines from 2004 and before require revision to remove any stated performance standards. Until the revisions can be made, this rule would supersede any species requirements or performance standards stated, or implied, in the guidelines applicable to invertebrate pests. EPA intends that any inconsistency that may exist between the guidelines and this rule should be resolved in favor of the regulations, once those regulations are finalized.

V. Selection of Pest Categories for Subpart R

EPA has selected three pest categories for this proposed rule: Pests of significant public health importance, wood-destroying insects, and invasive species. The rationale for selection of these three categories follows.

A. Pests of Significant Public Health Importance.

1. *Background.* As previously noted, in 2002, EPA issued Pesticide Registration Notice (PRN) 2002-1 (Ref. 2), which presented the "List of Pests of Significant Public Health Importance." This document is currently under revision within the Agency. The 2002 list was

derived in large part from review of the pesticide/pest combinations for which product performance data have been required on a case-by-case basis to be submitted and reviewed prior to registration. This list was developed cooperatively by the U.S. Department of Housing and Urban Development, USDA, and EPA, with input from some non-governmental entities. EPA's Office of Pesticide Programs coordinated the review by experts in public health and/or pesticide use patterns to compile this list.

As indicated in PRN 2002-1 (page 1), the criteria for inclusion on the list were defined "broadly, to include pests that pose a widely recognized risk to significant numbers of people."

The listing of invertebrate pests (pages 6-9) is specified by the taxonomic name, as not all members of a particular taxon may be considered a pest of significant public health importance. EPA takes this approach when only certain members of a taxonomic group may be of public health significance because labels usually do not identify specific individual species. However, even if the label did identify a specific species, most product users are not able to distinguish among the members of a taxonomic group (i.e., identifying one tick species from another).

The invertebrate species of significant public health importance identified in this proposed rule as requiring submission of product performance data are derived from the invertebrate pest list identified in PR Notice 2002-1. Differences that exist between the species identified in the PR Notice and this proposed rulemaking represent the evolution of our understanding of the testing required to support claims against pests of public health concern. These invertebrate pests pose a threat of injury, disease transmission and/or pathogen transfer, and allergen production. Table 3 provides the rationale for inclusion in this rule of an invertebrate pest as a pest of significant public health importance.

Table 3—Pests of Significant Public Health Importance from PRN 2002-1

Invertebrate Pest	Rationale for Inclusion

(Common Species Name)	
Mites	Produces allergens Triggers asthma Scabies Itching and skin irritation with risk of secondary infection
Chiggers	Itching and skin irritation with risk of secondary infection
Ticks	Rocky Mountain Spotted Fever Lyme Disease Ehrlichiosis
Scorpions	Venomous sting
Spiders	Venomous bite
Centipedes	Venomous bite
Lice	Skin irritation and rashes Epidemic typhus Trench fever
Fleas	Annoying bites, allergic reactions, and rash Plague
Cockroaches	Allergies Transmission of Salmonella Fecal contamination Hepatitis
Bot Flies	Infest host and live under the skin with risk of secondary infection
Filth Flies	Carry pathogens Food-borne illness
Mosquitoes	West Nile Virus Dengue Fever Malaria Encephalitis Yellow Fever Chikungunya Fever Zika
Biting Flies	Painful or annoying bites with allergic reactions
Sand Flies	Leishmaniasis
Triatomine Bugs	Allergic reactions Chagas disease
Bed Bugs	Bites and allergic reactions
Ants	Stings to painful stings; May be accompanied by severe or life-threatening reactions
Bees	Painful stings that may cause life-threatening reactions
Wasps, Hornets, and Yellowjackets	Painful stings that may cause life-threatening reactions

2. *Disease Pressures*. EPA's proposal to establish product performance data requirements

for pesticide products claiming to control invertebrate pests reflects the most up-to-date science and is responsive to the improved understanding of the diseases being transmitted by invertebrates and the prevalence of these diseases. Since 1984, additional vector borne diseases have emerged. Mosquitoes and ticks can no longer be considered as merely annoying insects.

West Nile Virus was first identified in the U.S. in New York in 1999. Since then, West Nile Virus spread throughout the country and cases have been reported in the 48 contiguous states. West Nile Virus is carried by common mosquitoes (primarily species of *Culex*, though *Aedes* and *Anopheles* can also carry the virus).

• Serious Symptoms in a Few People—Approximately one in 150 people infected with West Nile Virus will develop severe illness. The severe symptoms can include high fever, headache, neck stiffness, stupor, disorientation, coma, tremors, convulsions, muscle weakness, vision loss, numbness and paralysis. These symptoms may last several weeks, and neurological effects may be permanent. This is referred to as neuroinvasive West Nile disease and may result in death.

• Milder Symptoms in Some People—Up to 20 percent of the people who become infected have symptoms such as fever, headache, and body aches, nausea, vomiting, and sometimes swollen lymph glands or a skin rash on the chest, stomach and back. Symptoms can last for as short as a few days, though even healthy people have become sick for several weeks. This is referred to as West Nile Fever.

• No Symptoms in Most People—Approximately 80 percent of people (about 4 out of 5) who are infected with West Nile Virus will not show any symptoms at all.

Today, experts believe West Nile Virus is established as a seasonal epidemic in North America that flares up in the summer and continues into the fall. Persons over 50 years of age

have the highest risk of severe disease. (Ref. 13).

The Zika virus spreads to people primarily through the bite of an infected Aedes species mosquito (*Ae. aegypti* and *Ae. albopictus*). Zika can be passed from a pregnant woman to her fetus, which can cause certain birth defects. There is no vaccine for Zika. In 2015 and 2016, large outbreaks of Zika virus occurred in the Americas, resulting in an increase in travel-associated cases in the U.S., including widespread transmission in Puerto Rico and the U.S. Virgin Islands, and limited local transmission in Florida and Texas. In 2018 and 2019, there were no reports of Zika virus transmission by mosquitoes in the continental U.S. (Ref. 14).

In the past 20-25 years, Lyme Disease has increased in geographical distribution and in number of cases. The disease is carried by blacklegged (deer) ticks (*Ixodes scapularis* and *Ixodes pacificus*). The number and distribution of Lyme Disease cases correlates with the number and distribution of white tail deer, among other animal hosts. (Ref. 15). Deer populations have risen steadily in the last two decades, especially in suburban areas. (Refs. 16 and 17).

The first sign of infection is usually a circular rash, occurring in approximately 70 to 80% of infected persons. It begins at the site of a tick bite after a delay of 3-30 days and may gradually expand over a period of several days. The center of the rash may clear as it enlarges, resulting in a bull's-eye appearance. Patients also experience symptoms of fatigue, chills, fever, headache, and muscle and joint aches, and swollen lymph nodes. In some cases, these may be the only symptoms of infection.

Untreated, the infection may spread to other parts of the body within a few days to weeks, producing an array of discrete symptoms. These include loss of muscle tone on one or both sides of the face (called facial or Bell's palsy), severe headaches and neck stiffness due to meningitis, shooting pains that may interfere with sleep, heart palpitations and dizziness due to changes in

heartbeat, and pain that moves from joint to joint. Many of these symptoms will resolve, even without treatment.

After several months, approximately 60 percent of patients with untreated infection will begin to have intermittent bouts of arthritis, with severe joint pain and swelling. Large joints are most often affected, particularly the knees. In addition, up to 5 percent of untreated patients may develop chronic neurological complaints months to years after infection. These include shooting pains, numbness or tingling in the hands or feet, and problems with concentration and short-term memory.

Most cases of Lyme Disease can be cured with antibiotics, especially if treatment is begun early in the course of illness. However, a small percentage of patients with Lyme disease have symptoms that last months to years after treatment with antibiotics. (Refs. 18 and 19).

Rocky Mountain Spotted Fever is the most severe tick-borne rickettsial illness in the U.S. This disease is caused by infection with the bacterial organism *Rickettsia rickettsii*; it is carried primarily by dog ticks (*Dermacentor variabilis*) and wood ticks (*Dermacentor andersoni*). The initial symptoms of Rocky Mountain Spotted Fever include fever, nausea, vomiting, muscle pain, lack of appetite, and severe headache. Later symptoms include rash, abdominal pain, joint pain, and diarrhea. Pain and fluid loss can be so severe that hospitalization may be required. (Refs. 20 and 21).

EPA believes that tick and mosquito repellents have roles in disease prevention. Today, there is renewed interest in methods of preventing transmission of these diseases. CDC and other public health authorities have determined that efficacious insect repellents have a primary role in a multi-barrier approach in protecting the public from insect or tick-borne diseases. CDC recommends several personal protective practices to prevent tick and mosquito bites: one of the

most prominent and consistent messages is to use an insect repellent containing an EPA-registered active ingredient. (Refs. 22 and 23).

2. *Bed Bugs*. The U.S. has experienced a resurgence in the population of bed bugs. Bed bugs can impact people's physical and mental health. Physical impacts can include mild and severe allergic reactions to the bites, and secondary infections of the skin. Reported mental effects include anxiety and insomnia. (Refs. 7 and 8).

Both the EPA and the CDC believe that an integrated pest management program that combines both chemical and non-chemical treatments is the most effective way to control bed bugs. Among the integrated pest management methods, use of an effective pesticide product, labeled for use against bed bugs, applied according to the label directions is often necessary to control the population of bed bugs. (Ref. 8).

3. *Other pests of significant public health importance*. Other invertebrate pests cause painful bites and stings, provoke allergic responses, and transmit serious diseases. As discussed in PRN 2002-1, "cockroaches are controlled to halt the spread of asthma, allergy, and food contamination" and lice are controlled to prevent the "occurrence of louse-borne diseases such as epidemic typhus, trench fever, and epidemic relapsing fever in the United States." (Ref. 2).

B. Wood-destroying Insects

As previously explained, structural pests differ from pests of significant public health importance because health of individuals is not imperiled. However, the effectiveness of the treatment is not readily apparent to the applicator at the time of application or during the occupancy of the building or home, and a potential for significant financial loss to the property owner exists. EPA has generally required submission of product performance data for wood-destroying insects for over 40 years. USDA registered pesticides prior to establishment of the

EPA and also required product performance data in support of wood-destroying insects. The Agency issued PRN 96-7, entitled "Termiticide Labeling," (October 1, 1996) (Ref. 3) to provide guidance on label statements and minimum levels of product performance for soil treatment use of termiticide products. According to the PRN:

> The Agency believes that registration of a [termiticide] product demonstrating less than five (5) years of efficacy for control of termites is generally not appropriate from a safety or efficacy standpoint, considering the costs of treatment and the potential damage that could occur. The Agency does not believe that the homeowner should be subjected to such costly protection as would occur with products that are only efficacious for one year. Such products could, quite possibly, pose unreasonable adverse effects to the environment and/or humans because of higher risks than longer-acting alternatives. The more frequent treatments required could result in greater exposure and risk, or lower benefits, because of being less effective if not retreated, or more expensive if retreated.
> . . .
> EPA has always required efficacy data to be submitted by registrants to demonstrate that termiticides perform their intended function as claimed. EPA has reviewed such data prior to registration to assure that the benefits of the use would outweigh the potential risks.

C. Invasive Species

On February 8, 1999, President Clinton signed The Executive Order 13112 (64 FR 6183) (February 8. 1999), which is intended to "…to prevent the introduction of invasive species and provide for their control and to minimize the economic, ecological, and human health impacts that invasive species cause…." The Executive Order directed each federal agency to use relevant programs and authorities to:

• Prevent the introduction of invasive species;

• Detect and respond rapidly to and control populations of such species in a cost-effective and environmentally sound manner;

• Monitor invasive species populations accurately and reliably;

• Provide for restoration of native species and habitat conditions in ecosystems that have been invaded;

• Conduct research on invasive species and develop technologies to prevent introduction and provide for environmentally sound control of invasive species; and

• Promote public education on invasive species and the means to address them.

Invertebrate invasive species can impose serious economic costs by causing or vectoring diseases against native species that have little or no natural defenses. For example, an invasive species of significant note is the emerald ash borer, a wood boring beetle that is native to Asia. The emerald ash borer kills ash trees. Its presence was reported in southeast Michigan and Windsor, Ontario in 2002. Since then it has spread to at least 35 states and five Canadian provinces. Infested areas are under quarantine and restrictions have been imposed on moving fire wood. EPA has registered several pesticide products for use against the emerald ash borer after reviewing submitted efficacy data. (Ref. 24)

Another invasive invertebrate species, the Asian longhorned beetle, is also native to Asia and was first discovered in New York in 1996. The Asian longhorned beetle kills maple trees and other hardwoods. (Ref. 25). A very serious situation/crisis exists in New England, and USDA has established an extensive eradication program. EPA has also registered several products for use against the Asian longhorned beetle.

Invertebrates such as the emerald ash borer and the Asian longhorned beetle kill trees over very large geographic areas, thus, having substantial ecological and economic impacts by destroying both urban cover and forests used for recreation purposes and timber stands. According to a 2011 analysis (Ref. 26) entitled, "Economic Impacts of Non-Native Forest Insects in the Continental United States," the following five categories of expenditures and losses can be used to illustrate impacts on forests.

• Federal government expenditures (survey, research, regulation, management, and

outreach),

- Local government expenditures (tree removal, replacement, and treatment),
- Household expenditures (tree removal, replacement, and treatment),
- Residential property value losses, and
- Timber value losses to forest landowners.

Within the 2011 analysis were cost estimates using the five previously described categories of the damage caused by three types of invasive insects: borers, sap feeders, and foliage feeders. Since some of the economic categories overlap, the total sum of all economic categories would include some double counting. However, the total of the insect types can be summed without double counting, which means that it is appropriate to sum the columns, but not the rows. Table 4 shows that most of the costs are borne by local governments and households, and the total damage is several billion dollars.

Table 4—Annualized Invasive Species Damages in the U.S. ($ millions)

	Federal Government Expenditures	**Local Government Expenditures**	**Household Expenditures**	**Residential Property Value Loss**	**Forest Landowner Timber Costs**
Borers	$92	$1,700	$760	$830	$130
Sap Feeder	$14	$170	$130	$260	$4
Foliage Feeders	$110	$170	$160	$410	$18
Total	**$216**	**$2,040**	**$1,050**	**$1,500**	**$152**

Pesticide products are an important tool for managing the spread of an invertebrate invasive species and the related significant economic impacts. The availability of pesticide products with proven performance against an invasive species is important to slowing the spread of the invasive species. When circumstances necessitate the submission or citation of reliable data to support claims for controlling invasive species, EPA has the authority to require such product performance data.

Due to the sudden appearance and often rapid spread of invasive species, EPA does not

presently propose to codify a comprehensive list of all the specific invasive species for which product performance data might be deemed necessary. At this time, EPA is specifically proposing to codify product performance data submission requirements for the emerald ash borer and the Asian longhorned beetle. The submission of product performance data to support claims for effectiveness against other invasive invertebrate pests will be considered on a case-by-case basis.

VI. Development of Invertebrate Pest Groups and Subgroups

EPA has identified pest groupings on the basis of the biology and life history characteristics of the pests identified as public health or wood destroying pests. (Ref. 28). The groupings are taxonomically based. "Pest groups" and "pest sub-groups" are designations simply intended to convey the fact that some pests groups are part of larger groups. Therefore, when practical, "pest sub-groups" have been identified to define a meaningful subset of the larger group.

EPA developed the pest groups and pest sub-groups with the intention that product performance testing performed on a particular species can adequately represent all members of the pest group (or pest sub-group). The Agency intends these pest groupings to decrease data submission burdens on applicants and data review burden on the Agency as well as increasing the consistency, reliability, and integrity of data submitted to EPA. In some cases, EPA is proposing pest-specific claims, in addition to group and sub-group claims.

To develop these groupings, EPA considered species sensitivity. In certain cases, one member of a pest grouping is known to be significantly harder to kill, control, or repel than other members of the grouping. If product performance testing is performed using the species that is harder to kill, control, or repel, then logically, it can be assumed that the results of this testing

can be extrapolated to other members of the grouping. Additional considerations included the availability of species in a laboratory setting, the occurrence of species over wide areas and/or those species most commonly associated with transmission of diseases to humans.

VII. Introduction to Part 158, Subpart R

A. General

EPA is proposing to codify product performance data requirements pertaining to registration of pesticide products claiming efficacy against certain invertebrate pests. The proposed data requirements are consistent with the Agency's current practices concerning the data needed to register a pesticide product that claims effectiveness against invertebrate pests.

The proposed data requirements are presented, as appropriate, in table formats, with the needed data specified according to the claim on the label, the species to be tested, and the performance standards to be met. Once final, the regulations will provide the regulated community and other interested parties a better understanding of the data required to support registration of a pesticide product making a claim against an invertebrate pest identified to be a public health concern (e.g., ticks, mosquitoes, cockroaches, etc.), a wood-destroying insect (e.g. termites), or an invasive invertebrate species (e.g. Asian longhorned beetle).

The Agency is proposing to title the new subpart R in part 158, "Product Performance for Products Claiming Effectiveness Against Invertebrate Pests." The existing product performance data requirements in subpart E will be renamed "Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion-related Claims, and Products for Control of Organisms Producing Mycotoxins." Additionally, EPA is proposing conforming edits to subparts U, V, and W.

B. Contents of Proposed Subpart R

1. *General requirements*. Proposed 40 CFR 158.1700 contains the general requirements that would be applicable to any pesticide product that is making a claim(s) against an invertebrate pest, and describes how to use the data tables in proposed subpart R. These general requirements describe when product performance data may be required, specifically for products that bear a claim against a pest of significant public health importance or a pest of economic significance. The required tests must be conducted using the end-use product to ensure that the product's claims are supported in the form in which the user will be using the product.

Additionally, proposed 40 CFR 158.1700 provides a set of instructions on how to determine the product performance data required to support the pesticide product use for which registration is sought. This includes referring to all parts of subpart R, identifying the claims intended to be made on the product labeling, reviewing and understanding the performance standards that must be met or exceeded for the identified claims against the target pests, and understanding all applicable test notes.

2. *Definitions*. In order to ensure consistent implementation of proposed subpart R, EPA is proposing definitions specific to the subpart. Proposed 40 CFR 158.1701 and 158.1703 contain the definitions pertaining to subpart R. In particular, proposed 40 CFR 158.1701 defines many of the terms that are needed to assure a common understanding of the requirements and performance standards being proposed for codification under subpart R.

During the 2013 SAP, EPA received public comments and feedback from the SAP on the proposed definitions in the Technical Support Document (TSD) provided to the SAP. (Ref. 28). In addition, the SAP recommended several additional definitions that should be considered under this proposed rulemaking. After considering the comments provided, and based on the data requirements being proposed in this rulemaking, the proposed definitions represent those that are

most essential for understanding the requirements and regulatory text of the proposed subpart R. For those definitions that the SAP and public commenters provided feedback on or that were recommended then, but not included in this proposal, EPA intends to consider the utility of those definitions and will consider incorporating them into future guidance and rulemakings. The SAP and public comments on definitions associated with product performance data requirements are available in the docket for the SAP [EPA-HQ-OPP-2012-0574]. EPA's response to those comments are discussed in this document and associated docket. Other definitions included in the TSD have since been adopted in testing guidelines.

Where applicable, EPA derived the proposed subpart R definitions from existing guidelines. The definition for *Complete protection time* is very similar to the one found in Guideline 810.3700. The proposed definition of *Skin-applied insect repellent* is taken from Guideline 810.3700. The proposed definitions for *Soil-applied termiticides*, and *Bait treatment* were derived from information in Guidelines 810.3600 and 810.3800. For example, the *Bait treatment* proposed definition is similar to *Termite bait* in Guideline 810.3800. The definition of *Vector* is very similar to that in FIFRA 2(oo).

In the TSD presented to the 2013 SAP, EPA explained a pesticide for use against invertebrates and meeting one of the following circumstances might be characterized as making a public health pest claim requiring submission of product performance data:

• A claim is made to control, kill, knockdown, and/or repel specific invertebrate organisms that are directly or indirectly infectious or pathogenic or injurious to humans (or both humans and animals). For example: A claim is made to repel mosquitoes and/or ticks. Both mosquitoes and ticks transmit disease to humans. Or, a claim is made to kill bed bugs. Bed bugs are injurious to humans.

• The pesticide product is used in public health programs for vector control or for other recognized health protection uses to prevent or mitigate threats to public health.

• The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health organism and there is no other functional purpose for the ingredient in the product.

• The pesticide product is similar in composition to a registered pesticide product that makes explicit public health claims for control of invertebrate organisms.

EPA still agrees that these circumstances, in principle, identify the kinds of pesticides for which product performance data may be necessary. However, EPA is not proposing to codify the term "public health pest claim" as a means of identifying when data are required. Such a term is not necessary given the proposed regulatory text includes sections that specify the invertebrate pests and invertebrate pest groups/subgroups that would be subject to the proposed product performance data requirements if the pesticide is intended for use against those pests. EPA requests comment on whether there is utility in codifying an overarching definition of a "public health pest claim" for the purposes of subpart R, and if so, whether the definition presented to the SAP is appropriate.

In the 2013 TSD EPA wrote that:

> *A* ***public health claim*** is asserted if one or more of the following apply:
> --A claim is made to control, kill, knockdown, and/or repel specific invertebrate organisms that are directly or indirectly infectious or pathogenic or injurious to man (or both man and animals). For example: A claim is made to repel mosquitoes and/or ticks. Both mosquitoes and ticks transmit disease to man. Or, a claim is made to kill bedbugs. Bedbugs are injurious to man.
> --The pesticide product is used in public health programs for vector control or for other recognized health protection uses to prevent or mitigate threats to public health.
> --The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health organism and there is no other functional purpose for the ingredient in the product.
> --The pesticide product is similar in composition to a registered pesticide product that makes explicit public health claims for control of invertebrate organisms. (Ref. 28)

EPA believes that the circumstances presented in the 2013 TSD, in principle, identify the kinds of pesticides for which product performance data may be necessary. EPA also notes that existing regulations at 40 CFR 158.2204 provides definitions for a "public health claim" and a "nonpublic health claim" as they pertain to antimicrobial pesticide claims. EPA is not proposing to make any modifications to that provision, and any definition for a "public health pest claim" added to subpart R would be applicable only within proposed subpart R.

3. *Application Categories*. In proposed 40 CFR 158.1703, EPA is proposing to define a set of application categories to assist in defining the data needed to support registration. This section would only define application categories to the extent the terms appear in the proposed regulatory text and EPA believes they require definition. For example, the terms "bait treatments" and "spatial repellents" are defined. This section does not provide a listing of all application categories that would be covered by the proposed subpart R data submission requirements.

Application categories describe how and/or where the product is intended to be applied or used. The proposed application categories were derived after consideration of current practices and review of the application sites included in the Harmonized Test Guidelines (810.3000 through 810.3900). Oftentimes, these application categories will be used on pesticide product labeling, and, therefore, may be identified as a product performance labeling claim within the data requirement tables. Similar to the definitions in 40 CFR 158.1701, EPA received SAP feedback on some of the application category definitions. (Ref. 29). The application categories proposed in 40 CFR 158.1703 represent EPA's responses to that feedback for the application categories as applicable. These application categories are referred to in the portions of the

proposed regulatory text for the wood-destroying invertebrate pests.

4. *Performance Standards*. In proposed 40 CFR 158.1704, EPA is proposing a set of performance standards that, in the absence of performance standards specified elsewhere in subpart R, will apply generally and must be met for data cited to be considered acceptable in support of a specific labeling claim on the product's labeling.

a. *Performance standards for skin-applied insect repellents*: EPA is proposing that for skin-applied insect repellent labeling claims, the performance standard must be greater than or equal to 2-hours complete protection time.

Complete protection time (CPT) is defined in Guideline 810.3700 as "the time from application of a repellent until efficacy failure as it is defined in each study—for example, the time from application until the first efficacy failure event confirmed within 30 minutes by a second similar event." CPT has been the existing practice for determining efficacy of skin-applied insect repellents since the guideline was finalized in 2010. EPA presented this concept, along with a proposed minimum protection time of 2-hours, to the SAP in the TSD, as a means of ensuring that a skin-applied repellency product protects for a minimum amount of time given the potential variability of product results across different people.

The Agency believes that establishing a minimum CPT for skin-applied repellency products should be required because of the large variability in protection times experienced by susceptible individuals in the population. The SAP agreed that this was a reasonable standard, stating that "[i]f CPT is to be used, a minimum CPT of 2 hours was suggested by the Panel as a minimal criterion for product registration… A repellent of shorter duration may not provide sufficient, useful protection in practical terms and will give consumers a false sense of protection." (Ref. 29).

Additionally, EPA is proposing regulatory text for skin-applied products that reinforces that any testing required under part 158 which involves any human subjects must comply with all applicable requirements under 40 CFR part 26. For example, 40 CFR part 26 requirements are pertinent to 40 CFR part 158 testing requirements if the testing involves intentional exposure of human subjects. Protocols for such testing must be submitted to EPA for review prior to study initiation. Those protocols determined by EPA to involve intentional exposure of human subjects also require review by EPA's Human Studies Review Board (HSRB)) prior to study initiation.

b. *Performance standards for products other than skin-applied insect repellents*. Unless otherwise specified in the proposed 40 CFR 158.1700 – 158.1786, EPA proposes that the performance standard for a product performance claim against a pest must be greater than or equal to 90 percent. For non-wearable spatial repellents, the proposed performance standard is greater than or equal to 75%.

In the TSD presented to the SAP, EPA was considering performance standards of 95% for all other pest claims, with the exception of mites, lice, carpenter ants, wood destroying beetles, and termites. The 95% performance standards were initially chosen because they represented widely accepted standards at the time. (Refs. 28, 29, 30 and 31). EPA proposed these standards as a way to "define the levels of product performance that would need to be met in order for the studies to support product registration and labeling," and that proposing a specified threshold level or performance standard would be the "best means to assure that the products used to control invertebrate species are effective under conditions of use." (Ref. 28).

In response to the proposal, both the SAP and public commenters believed that a 95% performance standard would create a burden for unattainable results and would be cost prohibitive in most situations, particularly for large scale field trials, or in general, any field trial

using a 100% standard expectation. They argued that a minimum 90% performance under controlled laboratory conditions would be adequate. (Refs. 28 and 29). While they made this recommendation, the SAP stated that in special cases, EPA should retain the authority to overrule these standards if proper justification is provided by the applicants with regard to why the standards should not be applicable to a particular product. Additionally, the SAP stated that registrants should be allowed to compete by achieving higher than required performance standards, proving the superiority of their products.

After considering the SAP and public comments, with the exception of pests such as human mites, carpenter ants, termites, and wood-destroying beetles, EPA is proposing performance standards of 90% or greater instead of 95%. EPA believes that this standard will enable acceptance of registrations for products that provide a satisfactory level of control. Human mites and lice will retain a 100% standard, while the wood-destroying pests will have a 95% or greater standard for prevention of damage to wood, except for non-structural wood preservative treatments, which will have a standard of 100%. The standards for human mites, lice, and wood-destroying pests will be discussed in more detail in other sections of this proposed rule.

5. *Test Guidelines*. In proposed 40 CFR 158.1705, EPA is codifying a reference to EPA's Harmonized Test Guidelines, which set forth a recommended approach to generate the data required for product performance testing.

6. *Data Requirement Modifications*. In proposed 40 CFR 158.1707, EPA is proposing to state that on a case-by-case basis, the data requirements identified in subpart R may need to be adjusted for novel technologies or because a product's unusual physical, chemical, or biological properties or atypical use patterns would make particular data requirements inappropriate, either

because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. EPA recommends that registrants of novel technologies contact the Agency prior to conducting product performance testing. It should be noted that EPA has historically taken the position that data requirements can be adjusted or waived on a case-by-case basis per the procedures described in 40 CFR 158.45. This provision is not intended to supersede or alter the provisions at 40 CFR 158.45, but rather to clarify that EPA is proposing that the data requirements, including the performance standards, in subpart R may also be adjusted using the procedures consistent with those in 40 CFR 158.45.

7. *Invasive Species Claims*. In proposed 40 CFR 158.1708, EPA is proposing that when an application for registration or amended registration requests to put a claim(s) on its pesticide product's labeling for effectiveness against an invasive invertebrate species, then on a case-by-case basis, EPA may require submission of product performance data to support those claims for effectiveness. Due to the sudden appearance and often rapid spread of invasive species, EPA does not presently intend to codify a comprehensive list of the specific invasive species for which product performance data might be deemed necessary. USDA maintains a list of invasive species profiles, which can be used as guidance. (Ref. 32). EPA is specifically proposing to codify product performance data submission requirements for the emerald ash borer and the Asian longhorned beetle. The submission of product performance data to support claims for effectiveness against other invasive invertebrate pests will be considered on a case-by-case basis.

EPA notes that the Agency currently has authority to require data submission on a case-by-case basis when necessary to evaluate a pesticide product (see 40 CFR 158.75). This provision is intended to clarify that whether or not a claim is against an invasive species is a factor in determining whether product performance data is necessary to evaluate a pesticide.

8. *Invertebrate Disease Vector Claims*. In proposed 40 CFR 158.1709, EPA is proposing that if a registrant requests a labeling claim specific to a disease vector, additional testing conducted with the species specific to that disease vector claim is required if that species is not already required under subpart R as part of the pest group tested. For example, if a product claims to repel Asian longhorned ticks that may carry Japanese spotted fever, caused by *Rickettsia japonica*, then the registrant must generate data using the species that is known to carry the disease indicated, the Asian longhorned tick in this case. This requirement will ensure that all disease vector claims are supported by appropriate product performance data demonstrating the required performance standard should an unknown public health threat emerge in the future.

9. *Structural and Wood-destroying Pest Claims*. In proposed 40 CFR 158.1710, EPA is proposing that if an application for registration or amended registration requests a labeling claim specific to a structural or wood-destroying pest that is not identified in 40 CFR 158.1782 through 158.1786, EPA may require submission of product performance data to support those claims for effectiveness. This requirement will ensure that any claim against structural and wood-destroying pests that have not been accounted for at this time are supported by product performance data in the event that a new threat emerges.

10. *Pest Specific Claims*. EPA is proposing to codify product performance data submission requirements for pest groups, sub-groups, and some specific species. EPA uses the term "Pest group labeling claim" to mean a claim or statement on the labeling of the pesticide product that the product is effective against a group of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species for the entire assemblage of taxa. The term "Pest sub-group labeling

claim" means a claim or statement on the labeling of the pesticide product that the product is effective against a set of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species and part of a larger identified taxonomic grouping (e.g., Biting flies) that includes other pest species, which may or may not have a proposed pest group. The term "Pest-specific labeling claim" means a claim or statement on the labeling of the pesticide product that the product is effective against a particular arthropod species, such as German cockroach or house fly.

In addition to the group and sub-group claims, EPA is proposing to codify requiring product performance data for a number of pest-specific claims. As previously noted, the representative test species were selected on the basis of vigor of the pest species and the likely ability of the species to serve as an adequate surrogate for other pests in the group, as well as other factors including their availability for laboratory testing, ubiquity, and whether they are one of the primary drivers of the human health concerns within a grouping. (Ref. 1). The 2013 TSD envisioned that in many cases "[i]f representative taxa are provided, species specific data may not be required, as the group and any/all individual species within the group can be supported by supporting the general claim." (Ref. 28).

For pests that are not listed as a "pest-specific claim" in proposed subpart R, EPA proposes that the data required to support a group claim would also be sufficient to support pest-specific claims for species within that group. For example, the pavement ant (*Tetramorium caespitum*) is not listed as a pest-specific claim in proposed subpart R because it is not a pest of significant public-health importance (nor is it a wood-destroying insect) and no pest-specific product performance data would need to be submitted to add a claim against pavement ants to a label. In contrast, cluster flies (*Pollenia rudis*) are listed as a pest-specific claim in this proposed

rule because of their significant public health importance. These pest-specific claims are consistent with EPA's current practices. Thus, consistent with the Agency's current practices, pest-specific data would need to be submitted to add a pest-specific claim against cluster flies to a label in addition to any data submitted to support the group claim against "filth flies." EPA also notes that the provisions at 40 CFR 158.75 and proposed 40 CFR 158.1708 would also permit the EPA to require pest-specific data on a case-by-case basis when necessary to evaluate a pesticide product. These provisions allow EPA to address the Agency's data needs in the face of emergent invertebrate pest concerns.

EPA requests comment on the pest-specific claims covered by this proposed rule and whether there should be additional pest-specific claims added to subpart R, or if some of the ones included in the rule are unnecessary.

C. Data Requirements for Subpart R

The data requirements that EPA is proposing for codification are consistent with the Agency's current practices when considering the product performance data needed to register a pesticide product that bears a pesticidal claim against one or more of these pests or pest groups/sub-groups. FIFRA section 3(c)(2) directs EPA to specify the kinds of data that applicants and registrants must submit to EPA to support regulatory determinations under FIFRA. The data requirements for pesticide products are codified in 40 CFR part 158. Product performance data (efficacy studies) document how well the product performs the intended function (such as killing or repelling) against an invertebrate pest. The product performance data needs being considered in this rule would link the labeling claim for pesticide products claiming efficacy against an invertebrate pest with the data needed to substantiate that claim. EPA views these standards as performance standards for the acceptability of data, and

thus EPA views them as waivable under 40 CFR 158.45.

1. *Mites (excluding Chiggers)*. In 40 CFR 158.1712, EPA is proposing the required test species and performance standards in order to make a labeling claim against dog follicle mites, dust mites, and the human itch or scabies mite. EPA is proposing to list chiggers, which are mites, in a separate section.

As indicated in the TSD presented to the SAP, dog follicle mite infestations are typically commensal in nature, but can cause demodectic mange in susceptible animals. This can pose a serious risk to stricken individuals, which typically have pre-existing immune system issues. For this reason, a 100% performance standard is being considered for these applications.

Dust mites pose no direct threat of injury, disease transmission, or discomfort. However, dust mites are included as a pest of significant public health importance because they produce allergens in their feces and cast exoskeleton that can result in asthma and allergic reactions. EPA believes that it is impractical to expect complete elimination of the dust mite population in a structure. The focus should be to reduce the agent of concern (i.e., the allergen) to acceptable levels. This can be achieved through a reduction in the target pest that is less than is generally necessary for a pest that acts directly against its host. EPA initially proposed a 75% performance standard to the SAP for surface and fabric treatments, and a 95% performance standard for direct application to dust mites. However, after considering the responses received through the SAP and public comment, EPA is proposing a 90% performance standard for dust mites to be consistent with the recommendations provided on the performance standards for other species testing.

During the SAP, one commenter indicated that for mites, the proposed performance standard of 100%, as considered by EPA, was too high. Instead the commenter advocated for

90%, while indicating that 95% would be achievable. (Ref. 33). The 90% standard is being proposed for some labeling claims for the dog follicle and dust mites, but for human itch or scabies mites, EPA disagrees with lowering the performance standard since scabies mites directly infect and are easily transferred among hosts. A human skin-applied topical repellent performance standard of ≥ 2-hour complete protection time is also being proposed.

EPA also notes that any testing conducted with human subjects must comply with all applicable requirements under 40 CFR part 26.

2. *Chiggers*. In the proposed 40 CFR 158.1714, EPA is proposing to require testing for labeling claims against chiggers. Chiggers are being proposed in the rulemaking due to their bites causing itching and skin irritation with the risk of a secondary infection. Additionally, EPA is proposing the performance standards established under 40 CFR 158.1704 to apply to testing for chiggers.

During the SAP, the Panel noted that *Trombicula alfreddugesi* (as presented in the TSD) is now renamed as *Eutrombicula cinnibars*. EPA was unable to verify this and has maintained *Trombicula alfreddugesi* as was presented in the TSD. EPA requests comment on whether this is correct, and if the name has changed, EPA requests a reference to the revised name.

3. *Ticks*. In the proposed 40 CFR 158.1718, EPA is proposing to require the test species and performance standards to labeling claims against ticks, cattle ticks, and soft ticks. EPA is proposing several tick species due to their potential to transmit diseases, such as Rocky Mountain Spotted Fever, Lyme disease, and ehrlichiosis. For performance standards, EPA is proposing standards consistent with 40 CFR 158.1704.

To make a claim against "ticks," EPA is proposing to require a total of three hard tick species as representative of ticks in general. As presented in the TSD and based on

recommendations from the SAP, products claiming "ticks" must test for the blacklegged tick (*Ixodes scapularis*) and lone star tick (*Amblyomma americanum*), and a third species tested must be either the American dog tick (*Dermacentor variabilis*), the brown dog tick (*Rhipicephalus sanguineus*), or, as suggested by the SAP, the Rocky Mountain wood tick (*Dermacentor andersoni*). Because ticks are high stakes disease vectors and because consumers have difficulty differentiating between species, for a claim against any specific species of "ticks" all the representative species for the "ticks" claim must be tested. In addition, because these are pests of significant public health importance that the public strongly associates with the diseases they vector, EPA would also require submission of data on the specific pest claimed. EPA does not typically receive pest-specific claims for ticks other than those that are representative species for ticks. However, the Asian longhorn tick is an emergent pest in this category and EPA would require pest-specific data for a pest-specific claim against the Asian longhorn tick or any other pest specific tick claim. This would be in addition to testing on the representative species.

In addition to the required test species for a "tick" labeling claim, EPA is also proposing specific parameters regarding required species for "ticks" under certain testing circumstances. These specific parameters include:

i. For products intended to be applied to dogs, testing is required on three species: blacklegged tick (*Ixodes scapularis*), American dog tick (*Dermacentor variabilis*), and brown dog tick (*Rhipicephalus sanguineus*).

ii. For products intended to be applied to cats, testing is required on three species: blacklegged tick (*Ixodes scapularis*), lone star tick (*Amblyomma americanum*), and American dog tick (*Dermacentor variabilis*).

The species identified under each of these circumstances were identified as a result of

their occurrence on dogs and cats and the biology/behavior of the ticks.

For a claim against cattle ticks, EPA is proposing testing on either the Southern cattle tick (*Rhipicephalus microplus*) or the cattle fever tick (*Rhipicephalus annulatus*). When presented to the SAP, the SAP noted that if pests of veterinary importance are not the primary objective for this proposal, then pests such as cattle ticks should be removed from the tables. While the emphasis is on pests of significant public health importance and wood-destroying insects due to their significant economic impacts, EPA maintains that cattle ticks should be included in this proposal because of the potential for these ticks to carry diseases such as Texas cattle fever, which can result in significant economic losses to the cattle industry. (Ref. 34) Additionally, the cattle fever tick poses a risk to a small, but highly vulnerable population of humans. Specifically, those people that have had splenectomies are susceptible to a potentially fatal bovine babesiosis infection from an infected cattle fever tick. (Ref. 35).

For a claim against soft ticks, EPA is proposing testing on the species *Ornithodoros hermsi*. Humans typically come into contact with soft ticks when they sleep in rodent infested cabins. The ticks emerge at night and feed briefly while the person is sleeping. The bites are painless, and most people are unaware that they have been bitten. These ticks may transmit tick-borne relapsing fever (*Borrelia hermsii*, *B. parkerii*, or *B. turicatae*).

4. *Scorpions*. In proposed 40 CFR 158.1722, EPA is proposing to require data for a "scorpion" labeling claim due to their venomous sting. In the TSD to the SAP, EPA proposed to only require the striped bark scorpion (*Centruroides vittatus*). For scorpions, EPA is proposing the performance standards under proposed 40 CFR 158.1704.

One public commenter during the SAP questioned why EPA provided only one species for testing, stating that they believed this to be too restrictive. (Ref. 36). EPA chose the striped

bark scorpion as the required test species because it is a larger species of scorpion, and larger species can be harder to kill. Using such a species as the required test species means greater certainty that testing on one species would be representative of testing on other species. The commenter did not provide the name of a species that they consider suitable for testing. The Agency would welcome information to better inform the decision on selection of a suitable test species for scorpions.

5. *Spiders*. In proposed 40 CFR 158.1726, EPA is proposing data requirements for one pest group (Spiders), one pest sub-group (black widow spiders), and five pest-specific spider claims. EPA's current practice for spiders is to require product performance data to be submitted with certain species-specific claims (e.g. "Northern black widow spider"), certain pest-subgroup claims (e.g., "black widow spiders"), or pest-group claims for either "spiders" or "spiders unless the label expressly excludes black widow or brown recluse spiders." The black widow and the brown recluse spiders can deliver bites with potentially serious medical implications, and therefore are considered pests of significant public health importance. Thus, if an applicant submits a draft label with a labeling claim for "spiders (excluding black widow or brown recluse)," the applicant does not need to submit product performance data to EPA with an application for registration. Instead, the applicant would generate product performance data to confirm that the product is effective against these pests and hold those data in their files. In contrast, a general "kill spiders" claim encompasses pests of significant public health importance, i.e., the black widow and brown recluse spiders, and therefore, the applicant would need to submit two product performance studies to EPA to verify this claim, one study each for the brown recluse spider and black widow spider (either Northern black widow spider, the Southern black widow spider, or Western black widow spider).

For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

6. *Centipedes*. In proposed 40 CFR 158.1732, EPA is proposing data requirements for centipedes. EPA proposes testing on either the house centipede, the Florida blue centipede, or on one species from the *Scolopendra* genus. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

The SAP noted that centipedes are generally harmless and considered beneficial insects, behaving as active predators of other arthropod s within structures. Although a species such as the Florida blue centipede (*Hemicolopendra marginata*) can inflict a painful bite, the SAP questioned whether it was sufficient to include centipedes as a pest of significant public health importance. While some species of centipedes may be "harmless," species such as the Florida blue centipede can envenomate with painful bites, which can be categorized as similar to that of a bee sting. Effects can include anaphylactic shock in some individuals. EPA believes that these types of effects are sufficient to be considered as a pest of significant public health importance, and are thus included in this proposed rulemaking.

7. *Lice*. In proposed 40 CFR 158.1736, EPA is proposing data requirements on either the Head louse or the Body louse in order to make a labeling claim against lice. EPA is also proposing a performance standard of 100% for all efficacy claims made against lice. The SAP did not express any opinions on the proposed required test species or performance standards.

8. *Fleas*. In proposed 40 CFR 158.1740, EPA is proposing data requirements for one pest group (Fleas) and six pest-specific claims (cat flea, chigoe flea, dog flea, hen flea, human flea, and oriental rat flea). For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

Historically, EPA has only required testing on the cat flea in order to make a "flea" claim. The cat flea is common and easy to rear in the laboratory. Additionally, because the cat flea is the most common species that infests pets, most of the available pesticide products target the cat flea.

In the SAP response to the TSD, the Panel suggested adding the oriental rat flea (*Xenopsylla cheopis*) in addition to the cat flea for a "flea" labeling claim. The oriental rat flea (also known as the tropical rat flea) is a vector for bubonic plague (caused by *Yersinia pestis*), which is extremely rare in the U.S. EPA does not believe requiring this additional species provides immediate benefits at this time and would be an additional cost and burden on applicants to provide such data. EPA notes that 40 CFR 158.1709 would cover invertebrate diseases vector claims. In the future, if the plague becomes a significant issue in the U.S., then EPA would consider requiring the submission of data on the oriental rat flea in addition to the cat flea. Since the risk of the oriental rat flea is rare, EPA intends to continue with its existing practice to only require the larger cat flea for a "flea" claim, and is therefore proposing it as the only required test species at this time.

9. *Cockroaches*. In proposed 40 CFR 158.1744, EPA is proposing data requirements for one pest group (cockroaches) and seven pest-specific claims (American cockroach, Australian cockroach, brown cockroach, brownbanded cockroach, German cockroach, oriental cockroach, and the smokybrown cockroach). For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For the "Cockroach" pest group claim, EPA has historically required testing on both the American cockroach and the German cockroach, and is proposing to codify this requirement. These are the most common cockroaches requested on product labels and are commonly

controlled to halt the spread of asthma, allergy, and food contamination. The SAP was supportive of these species as the required test species for this pest group claim.

The SAP suggested adding *Periplaneta fuliginosa* and *P. brunnea* (smokybrown and brown cockroach, respectively) to the cockroach pest group. EPA is proposing these pests as a pest-specific labeling claims. Even with these additions, EPA continues to believe that for a general cockroach claim, the German and American cockroach are appropriate representative test species for the overarching pest group.

The Turkestan cockroach (*Blatta lateralis*) is thought to be displacing the Oriental cockroach in the southwestern U.S. and, like other cockroaches, can transfer food-borne pathogens. Because of this development, EPA is adding a pest-specific claim for the Turkestan cockroach to 40 CFR 158.1744.

10. *Keds, Screwworms, and Bot Flies*. In proposed 40 CFR 158.1748, EPA is proposing data requirements for bot flies (excluding human bot fly), the human bot fly, keds, and screwworms. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For bot flies (excluding human bot fly), EPA is proposing to require testing on one of the three following species: horse bot fly, throat bot fly, or the nose bot fly. The SAP suggested specifying the test species as *Gasterophilus* spp. instead of listing three specific *Gasterophilus* species, as specified in the TSD. EPA continues to believe that testing on either the horse bot fly, throat bot fly, or the nose bot fly were the most appropriate for efficacy testing because they are large and can be found throughout the U.S. While they are primarily pests of horses, larvae of these three species may occasionally parasitize humans.

For the human bot fly, EPA is proposing testing on the human bot fly (*Dermatobia*

hominis). The human bot fly is not known to vector disease, but the larvae will infest the skin of mammals and live out the larval stage in the subcutaneous layer, causing painful pustules that secrete fluids. The infestation of any fly larvae inside the body is known as myiasis. (Ref. 37). Under bot flies, the SAP stated that human bot fly should be retained as this is frequently introduced by travelers.

In addition to the three proposed options for bot flies, the SAP also suggested EPA consider the *Hypoderma* spp. and *Oestrus ovis* (the sheep bot fly) as additional options. EPA is not proposing to include these species since the Agency has not historically required or received data on these pests. However, EPA requests public comment on whether there is a need to codify product performance data requirements for *Hypoderma* spp. and *Oestrus ovis*.

For screwworms, EPA is proposing to require testing on either the screwworm (*Cochliomyia hominivorax*) or the secondary screwworm (*Cochliomyia macellaria*). The SAP indicated that *Cochliomyia hominivorax* is an eradicated species in the U.S. While EPA acknowledges that the sterile insect eradication program was a success, the species was recently found in Florida. If, in the future, an applicant wanted to make a label claim against screwworms, then *Cochliomyia hominivorax* would be the appropriate test species. Providing this option provides flexibility to the pesticide registrant. (Ref. 38).

For keds, EPA is proposing to require testing on the sheep ked. The sheep ked has historically been the representative species for a "keds" claim, and the SAP expressed general support of the Sheep ked as the required test species. Therefore, EPA is proposing to maintain this practice.

11. *Filth Flies*. In proposed 40 CFR 158.1752, EPA is proposing data requirements for one pest group claim against "Filth flies" and six pest-specific claims (blow fly, cluster fly, face

fly, flesh fly, house fly, and little house fly). For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For a "Filth Flies" pest group claim, EPA is proposing to require testing on the house fly (*Musca domestica*) and either one species of flesh fly (*Sarcophaga* spp., *Wohlfahrtia* spp., and other genera of flesh fly) or one species of blow fly (*Phaenicia* spp., *Calliphora* spp., and other genera of blow fly). One public commenter during the SAP questioned why EPA asked for testing in two species. The commenter indicated that for a direct spray application, only testing with the house fly is needed. The commenter suggested that testing with more than one species should only be needed for more specialized claims, such as fly baits. (Ref. 36).

In response, EPA included house flies and the option to select between blow flies and flesh flies because these types of flies move bacteria around from place-to-place when they land. This takes place by touching surfaces, as these flies generally do not bite. "Filth flies" is a large grouping and testing on two species provides greater assurance that the product would be effective against most members of the pest group. House flies are generally the smallest in size of these three groups and therefore may be more susceptible to insecticides. Testing against the larger filth flesh/blow flies reduces the likelihood of overestimating efficacy.

Additionally, the SAP suggested the cluster fly (*Pollenia rudis*) be deleted as a test species. Instead, flies in the genus *Fannia* can be included since they can be relatively easy to rear in laboratory conditions. *Fannia benjamini* complex and *Fannia scalaris* (canyon fly and latrine fly) were specifically mentioned. In response, the cluster fly was not listed as a required test species for a claim against "Filth Flies" in the TSD. The cluster fly was specified as a test species if an applicant makes a pest-specific claim against the cluster fly. Because house flies, blow flies, and flesh flies are considered better representative species for the pest group claim

against "Filth Flies," flies in the genus *Fannia* are not considered a representative alternative to cluster flies.

12. *Mosquitoes*. In proposed 40 CFR 158.1756, EPA is proposing data requirements for a pest group claim against "Mosquitoes." For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704. For the required test species, EPA is proposing that testing be required on at least one mosquito species from three different genera (i.e., one out of three proposed *Culex* spp.; one out of two proposed *Aedes* spp.; and one out of six proposed *Anopheles* spp.).

One public commenter during the SAP asked why the species *Anopheles stephensi* was missing from the list of species for mosquito testing in the TSD, as it is a common, representative lab insect. (Ref. 36). EPA agrees that the *Anopheles stephensi* could be used for testing, and has added *Anopheles stephensi* to the list of species for mosquito testing in EPA's proposal.

Additionally, the SAP comments were much more extensive regarding mosquitoes, as the SAP response covered both required test species as well as how one arrives at conducting the tests to collect the data. These comments are, as follows:

• Suggested having separate tables for killing and repelling and for field and lab testing

• Questioned the suitability of *Culex pipiens* and *C. quinquefasciatus* in repellent studies

• Suggested using *Culex* spp. instead of hybrids *C. pipiens* and *C. quinquefasciatus*

• Indicated *Anopheles freeborni* and *A. punctipennis* are suitable for field testing and not lab testing

• Indicated *Anopheles quadrimaculatus* is not suitable for indoor repellent testing

• Suggested adding *Anopheles albimanus* and *Anopheles stephensi*

• Indicated *Psorophora* is acceptable for field testing

The SAP also noted that for field testing of mosquitoes, certain species provided in EPA's list could not readily be obtained in a field test in the U.S.

In response, EPA agrees that a listing of specific mosquito test species as provided in the TSD was confusing when considered in the context of field testing. With lab testing and semi-field or "caged" testing a particular test species can be selected. The particular species selected for testing could depend on the colonies maintained by the laboratory, as well as the type of product being tested, and EPA believes providing a list of representative species that is comprehensive means that an appropriate species could be identified for a wide variety of product types or claims.

With regards to *Culex pipiens* and *Culex quinquefasciatus*, EPA is aware that these are now considered to be a hybrid mosquito complex. However, EPA believes that retaining the historical names of the *Culex* species provides more appropriate context, given the possibility of more name changes over time.

With regards to *Anopheles* mosquitoes, EPA has provided several species for the applicant to consider because some *Anopheles* mosquitoes may not be appropriate for all types of testing, or colonies of some *Anopheles* mosquitoes may be difficult to maintain in a laboratory. Additionally, EPA is proposing to add *Anopheles albimanus* and *A. stephensi*.

EPA agrees that *Psorophora* might be reported in a field study. Even though this is another genus of mosquito, *Psorophora* is not a major vector of diseases in the U.S. Other species may better inform the decisions that EPA needs to make.

For testing of skin-applied insect repellents, EPA's Guideline 810.3700, entitled, "Insect Repellents to be Applied to Human Skin" provides specific guidance (page 27) on the choice of

field testing sites. (Ref. 39). According to the Guidance, "Field tests for mosquito repellency should be conducted in at least two distinct habitats (e.g., forest, grassland, salt marsh, wetland, beach, barns, or urban environments) where the predominant mosquito species differ."

In field testing, a wide variety of species are encountered. Thus, for field testing, the applicant's submission will provide information on the species captured during the testing. EPA will review the data submitted to determine if a sufficient number and type of species were present. Generally, EPA expects three different genera to be present: *Culex*, *Aedes*, and *Anopheles*.

Claims against specific vector/disease combinations must be supported by testing of the specified vector. Additionally, because mosquitoes are high stakes vectors and because of the difficulty consumers have in differentiating between species, for a claim against any specific species of mosquito, all the required test genera must be tested.

EPA also agrees that certain species of the mosquitoes specified in the TSD might not be obtained in a field test. However, the purpose of providing multiple species is to offer flexibility in how one complies with the data requirements. In the proposal, EPA has not differentiated between what species may be more obtainable in a field versus laboratory test.

Additionally, two commenters provided other comments about how to obtain mosquito data, particularly in relation to using foreign data and foreign species as surrogate data. One commenter, for example, suggested that foreign data be considered acceptable as long as the study is conducted according to the 810.3700 guidelines. (Ref. 40). Another commenter indicated that foreign species could be useful if sufficient colonies of domestic species are not available (e.g., declining colonies of US anopheline mosquito species). (Ref. 41). EPA would like to note that conducting studies according to EPA guidelines is always recommended, but is

not enough to show that a foreign species is an acceptable surrogate for a domestic species. However, the Agency acknowledges that situations may arise where data showing efficacy of a product against foreign species can be useful. Therefore, the Agency will consider bridging data from foreign species to domestic species on a case-by-case basis. With this in mind, EPA is seeking comment on whether other species should be considered as part of the required test species.

13. *Biting Flies*. In proposed 40 CFR 158.1765, EPA is proposing data requirements for the pest group "Biting flies (excluding Sand flies)," the pest sub-groups "Large Biting Flies" and "Small Biting Flies (excluding Sand flies)," and nine pest-specific claims of biting flies. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

Since the SAP, the Agency has revised the proposed data requirements to be clearer than initially presented to the SAP. EPA proposed the pest group "Biting flies (excluding Sand flies)" to be consistent with experience on how the Agency receives labeling requests. Sand flies are vectors for Leishmaniasis, a parasitic disease that is found in parts of the tropics, subtropics, and southern Europe which can either cause skin sores or affect several internal organs (usually spleen, liver, and bone marrow). (Ref. 42). This differentiation improves the clarity and is consistent with how products have typically been labeled.

The Agency is also proposing to split the pest sub-groups further into "Large Biting Flies" and "Small Biting Flies (excluding Sand flies)." This is in response to the fact that periodically, the Agency receives requests for claims against large biting flies or claims against small biting flies. This proposal is to provide that flexibility in the codified data requirements.

During the SAP, the Panel suggested that the stable fly (*Stomoxys calcitrans*) and the horn fly (*Haematobia irritans*) be included in the filth fly category. The Panel also questioned

why both species need to be tested. In response, EPA considers both the stable fly and the horn fly to be biting flies. The Agency is proposing stable flies as one of the three representative species for the "Biting Fly (excluding sand flies)" pest group claim and one of the two required test species the "Large Biting Flies" pest sub-group claim. Testing of both species as described in the TSD to obtain a claim against stable flies was an error. Instead, in the absence of an appropriate pest group or pest sub-group representation, the Agency is proposing to require testing against stable flies for a pest-specific efficacy claim against stable flies and testing against horn flies for a pest-specific claim against horn flies.

The SAP suggested adding *Leptoconops kereszi* complex and *L. torrens* (black gnats) to pest sub-group biting midges in the TSD. For claims against biting midges, the Agency was proposing testing against one *Culicoides* species and one *Leptoconops* species. The specific species of *Leptoconops* required are not specified; therefore EPA would consider the species suggested by the commenter (*Leptoconops kereszi* complex and *L. torrens*) to be acceptable. The biting midges pest sub-group has since been revised to be represented as the "Small Biting Flies (excluding Sand flies)" pest sub-group claim. Both biting midges and black gnats are listed separately under the pest-specific claims.

14. *Bed Bugs*. In proposed 40 CFR 158.1768, EPA is proposing data requirements for the pest group claim "Bed bugs" and pest-specific claims for both the Common bed bug and the Tropical bed bug. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

For "Bed bugs," one commenter indicated that only one species is important to the vast majority of consumers and thus only one species needs to be tested to support this kind of product registration. For this proposal, EPA agrees that testing to include only the common bed

bug, *Cimex lectularius*, is appropriate as the lone required bed bug test species.

In the TSD, the EPA initially proposed a 95% performance standard for bed bug products. One commenter stated that the performance standard for bed bug control products that claim residual control and ovicidal control should be 90% rather the 95% standard in the TSD. Additionally, the commenter indicated that bed bug products need to have residual activity, because control of bed bugs is not possible via direct contact. They indicated that there must be residual activity in order for the product to claim "control" and if the product does not have residual activity, then this statement should be on the product label. The commenter also stated that a performance standard applicable to bed bug products that claim to kill bed bugs when bed bugs come into contact with a treated surface is needed. Therefore, EPA has decided to propose a performance standard of 90%, instead of the 95% in the TSD.

15. *Conenose Bugs and Kissing Bugs*. For proposed 40 CFR 158.1772, EPA is proposing data requirements for labeling claims against conenose bugs and kissing bugs. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704.

Initially proposed as "True bugs (excluding bed bugs)" in the TSD, EPA is proposing to focus primarily on the two required test species, the conenose bug and the kissing bug. This proposal has now separated them as pest-specific claims since experience has shown that labeling and data are usually submitted with the intent of labeling for the specific pest.

During the SAP, one commenter asked why the common stink bug species is missing from "true bugs." (Ref. 36). In response, the common stink bug is not a disease vector or otherwise a pest of significant public health importance, and therefore EPA did not include it as a test species in the TSD presented to the SAP. Since the "true bug" claims have changed in this group, stink bugs are no longer relevant to this group.

Similarly, the SAP suggested that both the conenose and the kissing bug be required test species. Both the kissing bug and the conenose bug (*Triatoma protracta* and *Triatoma sanguisuga*, respectively) are in the same genus and are both vectors of Chagas disease. Given these similarities and to reduce the number of studies to be submitted, EPA did not believe it was necessary to require both when a "true bug" claim was still in consideration. Based on experience, EPA has since opted to propose that they be separate pest-specific claims.

16. *Ants (excluding carpenter ants)*. In the proposed 40 CFR 158.1776, the EPA is proposing data requirements for pest group "Ants (excluding carpenter ants)," for the pest sub-groups "Fire and Harvester ants," "Fire and Harvester ant colonies," and "Fire ants," and for seven pest-specific claims in the absences of a pest group or sub-group claim.

For colony claims, testing must be done specific to the species listed. For colony claims against the red and/or black imported fire ants, testing may be done on the red imported fire ant (RIFA) (*Solenopsis invicta*), the black imported fire ant (*Solenopsis richteri*) or their hybrid.

Data for the pharaoh ant (*Monomorium pharaonis*) and red imported fire ant (*Solenopsis invicta*) would be required to support a general claim against ants, except carpenter ants. EPA proposes RIFA to receive a claim against fire and harvester ants for direct spray kill and residual surface application claims against foraging ants only (excluding colony claims). For bait products or claims involving outdoor use, testing must be specific to the species listed. For colony claims, testing must be specific to the species listed. For colony claims against the red and/or black imported fire ants, testing may be done on, *S. invicta*, *S. richteri*, or their hybrid.

Public comments on the 2013 SAP suggested that additional clarity was needed for categories such as "ants" where only certain members of the group would be considered pests of significant public health importance. (See, e.g., Ref. 40). Similar to EPA's current practice for

spiders, EPA requires product performance data for certain species-specific claims (e.g. "fire ants") and for general claims against "ants" or "ants, unless certain species are expressly excluded, i.e., fire, pharaoh, harvester, and carpenter ants." Fire and harvester ants are considered pests of significant public health importance, due to their painful stings that may result in anaphylaxis, while pharaoh ants are considered pests of significant public health importance because they can transfer numerous pathogens much like cockroaches. As discussed separately in more detail in Unit VII.C.18 of this proposal, Carpenter ants are structural pests which also require the submission of efficacy data. As a result, if an applicant submits a draft label with a claim against "ants (excluding fire, pharaoh, harvester, and carpenter ants)," the applicant does not need to provide product performance data to EPA. Instead, the applicant would generate efficacy data to confirm that the product is effective against these non-public health pests and then hold those data in their files. However, a label claim against "ants" encompasses, pests of significant public health importance and structural pests, and therefore for a "kills ants" label claim, the applicant would need to submit at least three product performance studies to EPA to verify this claim, one study each for the fire ant (which can be bridged to cover the harvester ant for a direct spray test), pharaoh ant, and carpenter ant. For a more detailed discussion of the "Carpenter ants" claim, see Unit VII.C.18 of this proposal.

The SAP also suggested adding the following ants to the "Ants (except carpenter ants)" group: European fire ant, odorous house ant, red imported fire ant (RIFA), tropical fire ant, thief ant, dark rover ant, hairy crazy ant, Caribbean crazy ant, yellow crazy ant, pavement ant, and *Crematogaster* spp. Fire ants (*Solenopsis* spp.). Some of the species suggested for inclusion are not pests of significant public health importance (odorous house ant, thief ant, dark rover ant, hairy crazy ant, Caribbean crazy ant, yellow crazy ant, and pavement ant), and thus EPA is not

proposing product performance data requirements specific to these species.

17. *Bees, Wasps, Yellowjackets, and Hornets*. For proposed 40 CFR 158.1780, EPA is proposing data requirement for a pest group claim "Bees, Wasps, Yellowjackets, and Hornets" and pest-specific claim for bald-faced hornet, mud dauber wasp, paper wasp, and yellowjackets. For the performance standards, EPA is proposing standards consistent with proposed 40 CFR 158.1704. For colony claims against *Vespula* spp. EPA is proposing a performance standard of 100%.

For the pest group claim, EPA is proposing data on two yellowjacket species (one *Vespula* sp. and the bald-faced hornet (*Dolichovespula maculata*)) and one paper wasp (*Polistes* sp.). These required test species were chosen based on their painful stings that may cause life-threatening reactions. The SAP was supportive of the selection of these species as representative to this pest group.

For the pest-specific claims that were proposed, one commenter indicated that stinging bees and wasps, solitary and ground nesting Hymenoptera such as mud daubers, digger wasps/bees, and spider wasps should not be included as pests of significant public health importance. The commenter believed that these females use their stingers for hunting, not defense, which means that it is unlikely such a pest would pose a public health threat. (Ref. 40). Another commenter added that they are also beneficial insects. (Ref. 41). However, these insects can inflict painful stings that may cause life-threatening allergic reactions and therefore are considered pests of significant public health importance and incorporated into the pest-specific claims.

The Asian giant hornet, *Vespa mandarinia*, has recently been sighted in the U.S. At the time EPA developed the pest grouping for "Bees, Wasps, Yellowjackets, and Hornets", this

species was not in the U.S. EPA requests comment on whether there are data to suggest the representative taxa should cover this species, or alternatively, data to suggest the opposite.

18. *Carpenter Ants*. Carpenter ants are structural pests which also require the submission of efficacy data. For proposed 40 CFR 158.1782, EPA is proposing data requirement for a pest group claim "Carpenter Ants." For the pest group claim, EPA is proposing requiring testing data on one of the following carpenter ant species: black carpenter ant (*Camponotus pennsylvanicus*), or Florida carpenter ant (*Camponotus floridanus*), or Western carpenter ant (*Camponotus modoc*).

For bait treatment EPA is proposing a performance standard of 95% prevention of damage to wood for ≥ 3 years. For "Non-Structural: Wood Preservative Treatment," EPA is proposing a 100% performance standard of prevention of damage to wood for ≥2 years. And for structural protection, EPA is proposing a performance standard of 95% prevention of damage to wood ≥ 5 years.

For carpenter ants, the SAP suggested adding the carpenter ant (*Camponotus neracticus*) as a test species. The Panel also indicated that more test species might be needed on the list because laboratories may experience hardship obtaining and maintaining colonies of some of the species on the list provided. In response EPA notes that there are three carpenter ant options for testing and that testing would need to be done on only one of the species. EPA notes that the *Camponotus neracticus* is significantly smaller than any of the three options. Thus, EPA believes that the three proposed test species are better choices for representative species.

19. *Wood-destroying beetles*. For proposed 40 CFR 158.1784, EPA is proposing data requirements for wood destroying beetles. For products making a claim against wood-destroying beetles or wood-boring beetles, EPA is proposing to require testing on three species: anobiid

beetle (*Anobiidae* sp.), bostrichid beetle (*Bostrichidae* sp.), and old house borer (*Hylotrupes bajulus*). For products making a claim against true powderpost beetles, EPA is proposing to require testing on one species from the Lyctinae subfamily.

For bait treatment EPA is proposing a performance standard of 95% prevention of damage to wood for ≥ 3 years. For "Non-Structural: Wood Preservative Treatment," EPA is proposing a 100% performance standard of prevention of damage to wood for ≥2 years. And for structural protection, EPA is proposing a performance standard of 95% prevention of damage to wood ≥ 5 years.

One public commenter suggested that EPA consider adding a fourth genus also known as the lyctid beetles (Lyctinae spp.) to represent the major wood-destroying beetle genera while allowing flexibility to test three of the four. (Ref. 43). The EPA does not believe that substituting a lyctid beetle as a representative test species is appropriate, as these beetles are not likely to cause structural damage.

20. *Termites*. For proposed 40 CFR 158.1786, EPA is proposing data requirements for the subterranean termite, desert subterranean termite, Formosan subterranean termite, drywood termite, and dampwood termite. For products making a claim against termites, EPA is proposing testing on species from four genera of termites. EPA is proposing to require testing on:

• *Coptotermes formosanus*

• And one of the following *Reticulitermes* species: *Reticulitermes flavipes*, or *Reticulitermes hesperus*, or *Reticulitermes virginicus*

• And one of the following arboreal termite species: *Nasutitermes coringer* (Motschulsky)

• And one of the following drywood termite species: *Cryptotermes brevis*, or

Cryptotermes cavifrons, or *Incisitermes minor*, or *Incisitermes snyderi*

For a claim against arboreal termites, EPA is proposing testing of one arboreal termite species: *Nasutitermes coringer* (Motschulsky). For a claim against dampwood termites, EPA is proposing testing of the following dampwood termite: *Zootermopsis* sp. For a claim against drywood termites, EPA is proposing testing of one of the following drywood termites: *Cryptotermes brevis*, or *Cryptotermes cavifrons*, or *Incisitermes minor* or *Incisitermes snyderi*. For a claim against subterranean termites, including formosan subterranean termites, EPA is proposing testing in two genera of termites. Specifically, EPA is proposing testing on the following *Coptotermes* species: *Coptotermes formosanus*; and one of the following *Reticulitermes* species: *Reticulitermes flavipes*, or *Reticulitermes hesperus*, or *Reticulitermes virginicus*.

For bait treatment, EPA is proposing a performance standard of 95% prevention of damage to wood for ≥ 3 years. For "Non-Structural: Wood Preservative Treatment" EPA is proposing a 100% performance standard of prevention of damage to wood for ≥2 years. And for structural protection, EPA is proposing a performance standard of 95% prevention of damage to wood ≥ 5 years.

The SAP suggested adding drywood termite (*Incisitermes synderi*) as a test species. EPA is proposing to add *Incisitermes snyderi* to the list of representative species for drywood termites. Additionally, *Cryptotermes cavifrons*, a species endemic to Florida, would also be an acceptable representative test species and EPA is proposing to add this organism as well.

The SAP and other commenters questioned the standard of "100% prevention of damage to wood" and thought that the lesser 95% or 90% would be more acceptable. EPA agrees with the comment and is proposing a 95% prevention of damage to wood standard. However, EPA

notes that what constitutes a 95% standard is dependent on the type of study being performed. For example, for the standard U.S. Forest Service Concrete Slab field study, the 95% would be calculated such that any damage greater than nibbles to surface etching would be considered a failure; if a single plot had more than one instance of nibbles to surface etching in any of the standard five evaluation periods, this would also be a failure. A 95% success rate for the U.S. Forest Service Concrete Slab (CS) tests would be determined by the combined data for a product, by rate, in a given year. For non-structural wood preservative treatments, EPA is proposing a standard of 100% prevention of damage to wood for ≥ 2 years. Additionally, to be consistent with the majority of other pests, EPA is proposing the termite standards for direct applications to pests, surface applications, and spatial applications will be changed to a performance standard of 90%, consistent with proposed 40 CFR 158.1704.

21. *Invasive Species*. EPA believes treating invasive species quickly and appropriately is critical, and EPA does not intend to preclude use of a pesticide product pursuant to FIFRA 2(ee) to treat an invasive species. EPA believes that pesticide products are an important tool for managing the spread of an invertebrate invasive species and the related public health concerns or significant economic impacts. The availability of pesticide products with proven performance against an invasive species is important to slowing the spread of the invasive species.

Due to the sudden appearance and often rapid spread of invasive species, except for the pests noted, EPA does not presently intend to list the specific invasive species for which product performance data might be deemed necessary. Instead, the submission of product performance data to support claims for effectiveness against invasive invertebrate pests will be considered on a case-by-case basis. Given the expectation of infrequent submission of such an application, a "case-by-case" approach is the most suitable. EPA recommends that applicants consult with the

Agency when first considering a submission to place an invasive species on the label of a pesticide product. As part of the consultation, EPA would be able to provide information on protocol development and selection of test species. EPA generally expects to require product performance data for invasive species that are similar to the Asian longhorned beetle and emerald ash borer in that they have the potential to cause significant economic or ecological damage and the efficacy of products used against them cannot readily be determined at the time of application.

This proposal specifies that the Asian longhorned beetle and the emerald ash borer are two invasive pests for which product performance data must be submitted. The efficacy of the products used for their control typically cannot be determined until the season after application, and the EPA believes it appropriate to continue the practice of reviewing efficacy data for these invasive species.

VIII. Updates to Subparts U and V

In addition to the inclusion of product performance data requirements under the new subpart R, EPA is also proposing to revise and update the product performance data requirements language for biochemical and microbial pesticides in subpart U, 40 CFR 158.2070 and subpart V, 40 CFR 158.2160, in order to clarify the requirements for products that would be subject to both proposed subpart R and also subpart U or subpart V.

Subpart U (biochemical pesticides) and subpart V (microbial pesticides) currently require that product performance data be developed, and that each applicant must ensure through testing that the pesticide product is efficacious when used in accordance with label directions and commonly accepted pest control practices. Both subparts also state that EPA may require, on a case-by-case basis, submission of product performance data for any pesticide product registered

or proposed for registration or amendment (see, 40 CFR 158.2070 and 40 CFR 158.2160). These requirements would not be modified by this proposal.

Subpart U (biochemical pesticides) and subpart V (microbial pesticides) also currently require that product performance data be submitted for each biochemical and microbial pesticide product that bears a claim to control public health pests, as the term is used in subparts U and V. This requirement is followed by a non-exhaustive list of public health pests. This includes pest microorganisms infectious to humans in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans.

This proposal adds additional clarity by including a provision in subpart U (biochemical pesticides) and subpart V (microbial pesticides) stating that product performance data must be submitted for each product that bears a claim against an invertebrate pest that is covered by subpart R. This provision is intended to be coextensive with the requirements of subpart R, and broader than the currently existing requirements in subparts U and V related to "public health pests" in that it would also cover the wood-destroying beetles and invasive exotic species claims covered by subpart R.

Additionally, EPA notes that data requirements and the performance standards that determine the acceptability of data may be modified on a case-by-case pursuant to the provisions in 40 CFR 158.45 and 40 CFR 158.1707.

IX. Impact of this Proposal on Future and Existing Registrations

This action, if finalized, will have no immediate effect on existing registrations unless new information indicates an existing registration includes claims that are not sufficiently

supported. When an application for registration or amended registration requests to put a claim(s) on its pesticide product's labeling for effectiveness against an invertebrate species that is covered by this action, the application would generally include submission of product performance data to support those claims for effectiveness.

X. Peer Review

A. Human Studies Review Board

1. *Background.* Research with human subjects that is conducted or supported by the U.S. government is subject to regulations for the protection of human subjects. These regulations are referred to as the Common Rule. EPA's codification of the Common Rule appears at 40 CFR part 26, subpart A. On February 6, 2006 (71 FR 6138) (FRL-7759-8), EPA published a final rule amending part 26 by adding new subparts (B-Q). This amendment added, among other parts, Subpart K, which applies standards similar to those in the Common Rule to third parties (i.e., those other than federal agencies and federally-funded researchers) conducting research with human subjects. Additional amendments to part 26 have been made, most recently in 2019 (84 FR 35315, July 23, 2019) (FRL-9996-48-ORD). Under EPA's regulation, if the research involves intentional exposure of a human subject and if the sponsor or investigator intends to submit the results of the research to EPA in connection with any action that may be performed by EPA under the pesticide laws (FIFRA or FFDCA), then the research must comply with the provisions of 40 CFR part 26; the requirements of EPA's human studies rule also apply to any research involving intentional exposure of a human subject to a pesticide, when the results are intended to be submitted in connection with a regulatory action under any other statute EPA administers. In addition to establishing protections for human subjects of research, EPA established the Human Studies Review Board (HSRB or Board) to review both proposals for

new research and reports of covered human research on which EPA proposes to rely under the pesticide laws. The HSRB is a federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App.2, section 9).

The HSRB typically includes independent experts in toxicology, exposure assessment, industrial hygiene, statistics, and bioethics, as well as an entomologist consultant. The HSRB provides EPA with advice, information, and recommendations on issues related to both the scientific and ethical aspects of human subjects research. The major objectives are to provide review and recommendations on the scientific and ethical aspects of research proposals and protocols, and reports of completed research with human subjects; and, when requested, advise on how to strengthen EPA's programs for protection of human subjects of research. EPA considers all recommendations from the HSRB before finalizing its reviews of proposed or final research.

The HSRB reports to the EPA Administrator through EPA's Science Advisor. Since 2006, the rigorous independent reviews conducted by EPA and the HSRB, as mandated by part 26, have resulted in research protocols designed to result in scientifically-sound data and to ensure the protection of human subjects involved in the research. In providing for the establishment of the HSRB, the regulations have reassured the public that all pesticide research involving intentional exposure to human subjects undergoes thorough independent and expert review based on scientific and ethical standards.

Under 40 CFR part 26, subpart K, protocols for research subject to the regulation's requirements must be submitted to EPA for review and evaluation before initiation of the study. The relevant information that must be included in the proposed research protocol is specified in 40 CFR 26.1125. EPA then evaluates the protocol and makes a determination about the scientific

validity and reliability of the research as well as examining the ethical aspects of the research, in accordance with the conditions in 40 CFR 26.1603. EPA submits the protocol and supporting materials, as well as EPA's science and ethics reviews of the proposed research to the HSRB for review and comment. The members of the HSRB review the proposed research. Then in an open and transparent manner at a public meeting, members of the HSRB ask additional questions, provide their individual comments, and participate in a discussion which is documented in meeting minutes. Each final HSRB report contains the Board's responses to charge questions posed by EPA, as well as the final, approved advice of the HSRB. The research cannot be initiated until EPA approves the protocol, following its consideration of the HSRB's input and recommendations. The protocol will only be approved if EPA determines that the research conducted according to the protocol would meet the standards of 40 CFR 26, Subparts K and L. Information on the HSRB, including materials reviewed and recommendations can be found on the HSRB webpage. (Ref. 44).

Once the research has been conducted, then all of the records relevant to the research, including raw data and records of ethical review, are submitted to EPA. EPA examines all submitted materials, considers the scientific and ethical conduct of the research, and provides the completed research and its evaluation of the completed research to the HSRB. The HSRB reviews the documents and discusses them at a public meeting in the same open and transparent manner. The HSRB issues a report of their findings following the meeting. EPA may rely on the results of completed human research involving intentional exposure of human subjects only if the research meets the standards referenced in part 26, subpart Q.

2. *Review of EPA's draft guideline 810.3700.* In October 2008, EPA presented to the HSRB a draft guideline titled "Insect Repellents to be applied to Human Skin" for review and

evaluation. (Ref. 46). The HSRB final report (Ref. 46) for that October 2008 meeting included the HSRB's comments and concerns about the statistical analysis plan included in the draft guideline.

Based on the HSRB review and comments, EPA revised the guideline and presented the revised guideline to the HSRB on June 23, 2010. EPA's Senior Policy Advisor for the Pesticide Program made a presentation titled, "OPP Policy Decisions Regarding Insect Repellent Efficacy Testing." (Ref. 31).

The HSRB recommended several changes or clarifications for the revised guideline in its final report, (Ref. 47) including:

• Removal of the maximum-likelihood method requirement in the data analysis section;

• Clarification of recommendations regarding the use of positive controls, particularly with respect to the number of controls and the rationale for including them in the study;

• Careful consideration of recommendations regarding the recruitment and inclusion of so-called 'vulnerable' populations; and

• Encouraging the use of study designs that will enable investigators to collect data that will allow quantitative measurement of repellent efficacy in addition to determining the complete protection time (CPT).

On August 6, 2010 (75 FR 47592), EPA announced the availability of the final guideline for Insect Repellents to be Applied to Human Skin (Guideline 810.3700).

3. *Overall impact of HSRB review*. As required by 40 CFR part 26, the HSRB has reviewed and commented on all protocols for conducting skin-applied insect repellents as well as the completed studies conducted according to those protocols. In its final reports, the HSRB provided recommendations to strengthen EPA's statistical approaches for calculating CPTs.

Additionally, the HSRB's feedback has resulted in EPA's development of a model to calculate sample sizes for field and lab testing with mosquitoes and lab testing with ticks, to support results. At the recommendation of the HSRB, EPA also elected not to require positive controls.

B. FIFRA Scientific Advisory Panel

On March 19-20, 2013, EPA presented to the SAP a variety of issues for their consideration and response concerning the Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance. The meeting announcement, the Agency's presentations and support documents, public comments, and the comments by the SAP are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2012-0574. Unit VII of this proposal discusses how comments from the SAP and public comments informed the data requirements of proposed subpart R.

In separate actions EPA has developed and revised testing guidelines and continues to do so. While this rule refers to these guidelines, and recommends their use, they are not the subject of today's proposal. For informational purposes, EPA is providing a description of SAP meetings relevant to those guidelines.

1. *1994 meeting*. In 1994, EPA held a 2-day meeting of the SAP to review the Agency's proposed amendments to the data requirements for pesticide registrations contained in 40 CFR part 158. The SAP was asked to comment on each data requirement and identify, in their opinion, which ones were necessary to fully and thoroughly evaluate the potential hazard of a chemical compound and which ones were not intrinsically useful in providing practical scientific information. The review included both comparative product performance data requirements along with product performance data requirements for public health and non-public health data

requirements. A very complete discussion of the 1994 SAP was presented in the proposed rule for conventional pesticides (March 11, 2005; 70 FR 12310) (FRL-6811-2).

2. *April 2000 meeting*. In April 2000 the SAP was asked to comment on a draft guideline regarding insect repellents for human skin and outdoor premises. (Ref. 48).

3. *July 2002 meeting*. On July 30-31, 2002, the SAP was asked to review the design and scientific soundness of the draft guideline entitled "Termite Bait Testing." EPA's presentations, the draft guideline, the charge questions, and the Panel's review of the guideline are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2002-0125.

4. *March 2012 meeting*. On March 6-7, 2012, EPA presented to the SAP, a draft guideline regarding bed bugs. The meeting announcement, the Agency's presentations and support documents, public comments, and the comments by the SAP are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2011-1017. After taking the SAP's feedback into consideration, EPA announced the availability of the final test guideline, Laboratory Product Performance Testing Methods for Bed Bug Pesticide Products; OCSPP Test Guideline 810.3900, on June 14, 2017 (82 FR 27254) (FRL-9959-78).

5. *May 2018 meeting*. On May 8-10, 2018, EPA presented to the SAP for their consideration and response scientific issues associated with proposed revisions to two EPA Test Guidelines 810.3100 (Soil Treatment for Imported Fire Ants), and Guideline 810.3500 (Premises Treatment), for Red Imported Fire Ants (RIFA). These guidelines were originally published in March 1998.

The proposed premises treatment guideline revisions presented to the SAP contained recommended test methodologies for a wide range of products intended to kill, control, flush, and/or knockdown invertebrate premises pests, such as cockroaches, ticks, mosquitoes, flies, and

wasps. The guideline did not cover treatment of livestock or pets, wide area-mosquito control, or bed bug products. In addition to guidance for testing efficacy of direct pesticide application to pests, residual treatments, and cockroach and fly baits in the laboratory, the proposed guideline also included field testing methods for outdoor misting systems, Hymenoptera nest treatments, and outdoor foggers. Methods for resistance ratio determination and characterization of pest population strain susceptibility were also described.

The proposed RIFA treatment guideline revisions contained recommended test methodologies for evaluating the performance of pesticide products for the treatment and control of red imported fire ant colonies/mounds. The guideline did not cover premises treatments for RIFA workers/foragers, such as direct application to pests. Field tests for both mound- and area-applied pesticide products were proposed, along with accompanying laboratory studies for baits, barrier treatments, and insect growth regulators.

The meeting announcement, the Agency's presentations and support documents, and public comments are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-2017-0693. In September of 2019, EPA published the final Product Performance Test Guidelines OCSPP 810.3500: Premises Treatments; Background information, the draft guideline, and charge questions developed by EPA are available at *https://archive.epa.gov/scipoly/sap/meetings/web/html/040500_mtg.html*.

7. *June 2019 meeting*. On June 11-14, 2019, the SAP reviewed EPA's proposed guidelines for Efficacy Testing of Topically Applied Pesticides Used Against Certain Ectoparasitic Pests on Pets. The meeting announcement, the Agency's presentations and support documents, public comments, and the comments by the SAP are available at *regulations.gov* using the docket identifier EPA-HQ-OPP-20190161.

XI. Request for Comments

The Agency invites the public to provide comment on the proposed requirements and their basis. Specifically included within the Agency's requests for comments are suggestions which can be supported by scientific data for the Agency to consider during the development of the final rule. Specific comments are requested for:

1. *Definitions*. The Agency welcomes comment on the proposed definitions. The Agency also welcomes suggestions on additional definitions that may be needed to help clarify what is required in the regulations.

2. *Representative test species*. The proposed rule includes taxonomic categories of invertebrates which require more than one species to be tested to support a general claim for that pest group. The representative taxa were selected on the basis of vigor of the pest species and the likely ability of the species to serve as an adequate surrogate for other pests in the group. The selection of representative taxa was informed by the 2013 SAP.

3. *Performance standards*. The Agency welcomes specific comments on performance standards. The Agency would need to see scientifically sound data to support any recommendations for performance standards that differ from those proposed. The Agency believes requiring data showing the pesticide meets a specified threshold level (performance standard) of efficacy is the best means of addressing potential consequences which could occur through the use of ineffective pesticides intended for use against pests that transmit disease.

4. *Economic analysis*. The Agency also welcomes public comment on its economic analysis of the proposed rule, as well as on its underlying assumptions, economic data, and high and low-cost options and alternatives. Describe any assumptions and provide any technical information and data used in preparing your comments. Explain estimates in sufficient detail to

allow for it to be reproduced for validation. EPA's underlying principle in developing the proposed revisions has been to strike an appropriate balance between the need for adequate data to make the statutorily mandated determinations and informed risk management decisions, while minimizing data collection burdens on regulated community required to support product performance data requirements. In particular, EPA would appreciate public comment on the magnitude of the savings in discovery costs discussed on page 29 of the cost analysis.

XII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. US EPA. Cost Analysis of the Proposed Product Performance Rule, prepared by the Biological and Economic Analysis Division, Office of Pesticide Programs, available in docket: EPA-HQ-OPP-2020-0124.

2. US EPA. Pesticide Registration (PR Notice) Notice 2002-1, available at https://www.epa.gov/sites/production/files/2014-04/documents/pr2002-1.pdf at 2 (accessed March 6, 2020); *see also* Public Review Draft: Pesticide Registration (PR Notice) 2020-[X], Draft List of Pests of Significant Public Health Importance—Revised 2020, docket EPA-HQ-OPP-2020-0260.

3. US EPA. PRN 96-7 Termiticide Labeling, available at https://www.epa.gov/pesticide-registration/prn-96-7-termiticide-labeling (accessed March 13, 2020).

4. United States Public Health Service. Public Health Report. 1923 Aug 3; 38(31): 1747–1814.

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7. US EPA. Bed Bugs, Get them out and Keep them Out, available at https://www.epa.gov/bedbugs (accessed March 6, 2020).

8. US EPA and CDC. Joint statement on bed bug control in the United States from the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Environmental Protection Agency (EPA); available at https://stacks.cdc.gov/view/cdc/21750/Email (accessed March 19, 2020).

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11. US EPA. Office of Pesticide Programs, Label Review Manual, available at *https://www.epa.gov/pesticide-registration/label-review-manual* (accessed March 13, 2020).

12. US EPA. Product Performance Guideline 810.1000, Overview, Definitions, and General Considerations, available at https://www.epa.gov/test-guidelines-pesticides-and-toxic-

substances/series-810-product-performance-test-guidelines (accessed March 6, 2020).

13. CDC. Division of Vector Borne Infectious Diseases: West Nile Virus Fact Sheet available at https://www.cdc.gov/westnile/resources/pdfs/wnvFactsheet_508.pdf, (accessed March 9, 2020).

14. CDC. Zika Virus, Statistics and Maps; available at https://www.cdc.gov/zika/reporting/index.html (accessed March 6, 2020); CDC, Zika Virus, available at https://www.cdc.gov/zika/index.html (accessed March 6, 2020).

15. CDC. Lyme Disease: Data and Surveillance, available at https://www.cdc.gov/lyme/datasurveillance/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Flyme%2Fstats%2Findex.html (accessed March 19, 2020).

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17. David Cameron Duffy, Scott R. Campbell, Dara Clark, Chris Dimotta, Susan Gurney. *Ixodes scapularis* (Acari: Ixodidae) Deer Tick Mesoscale Populations in Natural Areas: Effects of Deer, Area, and Location, Journal of Medical Entomology, Volume 31, Issue 1, 1 January 1994, Pages 152–158, https://doi.org/10.1093/jmedent/31.1.152.

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26. USDA. Asian Long-Horned Beetle, available at https://www.invasivespeciesinfo.gov/profile/asian-long-horned-beetle, (accessed March 9, 2020).

27. NRS. Economic Impacts of Non-Native Forest Insects in the Continental United States, available at https://www.nrs.fs.fed.us/pubs/38719 (accessed March 9, 2020).

28. US EPA. Technical Support Document Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance Submitted to the FIFRA Scientific Advisory Panel for Review and Comment March 19-21, 2013 (Hereinafter "TSD"), available in docket: EPA-HQ-OPP-2012-0574-0002, Appendix 1, Tables I and II.

29. US EPA. FIFRA Scientific Advisory Panel, Meeting Minutes and Final Report for the

March 19-21, 2013 Scientific Advisory Panel, available at https://www.epa.gov/sites/production/files/2015-06/documents/031913minutes.pdf (accessed April 9, 2020).

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31. US EPA. OPP Policy Decisions Regarding Insect Repellent Efficacy Testing, (prepared for June 23, 2010, Human Subjects Research Board Meeting.)

32. USDA. National Invasive Species Information Center, available at https://www.invasivespeciesinfo.gov/ (accessed April 29, 2020).

33. Consumer and Specialty Products Association (CSPA). Comment submitted by Beth Law, CSPA, March 15, 2013, EPA-HQ-OPP-2012-0574-0014.

34. USDA. Victor Borne Diseases: Cattle Fever Ticks, available at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/cattle-disease-information/cattle-vector-borne-diseases (accessed March 9, 2020).

35. Bovine Babesiosis, available at cfsph.iastate.edu/factsheets/pdfs/bovine_babesiosis.pdf (accessed March 24, 2020).

36. S.C. Johnson & Son, Inc. Comment submitted by Jill Geyser, S.C. Johnson & Son, Inc., March 9, 2013, EPA-HQ-OPP-2012-0574-0011.

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41. Comment submitted by Beth Law, Consumer and Specialty Products Association, March 15, 2013, EPA-HQ-OPP-2012-0574-0014.

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43. Comment submitted by Brian Forschler, Termiticide Scientific Review Panel, March 19,2013, EPA-HQ-OPP-2012-0574-0016.

44. US EPA. Science Adviser Programs: Human Studies Review Board, available at https://www.epa.gov/osa/human-studies-review-board (accessed April 1, 2010).

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April 14, 2020).

48. US EPA. Background Information, the Draft Guideline, and Charge Questions Developed by EPA, available at *https://archive.epa.gov/scipoly/sap/meetings/web/html/040500_mtg.html.*

49. US EPA. "Proposed Rule-related ICR Amendment for Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests" (RIN 2070-AJ49), EPA ICR No.: 0277.20 and OMB Control No.: 2070-[tbd]. November 2020.

XIII. FIFRA Review Requirements

Pursuant to FIFRA section 25(a), EPA submitted the draft proposed rule to the Secretary of Agriculture (USDA) and the FIFRA SAP for review. A draft of the proposed rule was also submitted to the appropriate Congressional Committees.

XIV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action (Ref. 1) which is summarized in more detail in Unit I.E. This analysis is available in the docket.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is expected to be a deregulatory action under EO 13771 (82 FR 9339, February 3, 2017). Details on the estimated cost savings of this proposed rule can be found in EPA's cost analysis (Ref. 1).

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq*. The Information Collection Request (ICR) document that EPA prepared is assigned EPA ICR No. 0277.20 and OMB Control No.: 2070-[tbd] (Ref. 49). You can find a copy of the ICR in the docket and it is briefly summarized here.

The information collection activities in this proposed rule are associated with the codification of efficacy data requirements against certain invertebrate pests. These information collection activities are activities associated with the application for a new or amended registration of a pesticide and are currently approved by OMB under OMB Control No. 2070-0060 (EPA ICR No. 0277). As such, this ICR is intended to amend that existing ICR at the final rule stage, incorporating the information collection activities attributable to this proposed rule, including a reduction in transaction costs associated with a clear codification of the product performance data requirements for certain invertebrate pests.

Respondents/affected entities: There are three groups impacted by the rule. Chemical producers (NAICS 32532), colleges, universities, and professional schools (NAICS code 611310), and research and development labs and services (NAICS code 541712).

Respondent's obligation to respond: These data must be submitted for the applicant to receive the desired pesticide registration or label claim. Authorizing legislation is contained in Section 3 of FIFRA (7 U.S.C. 136). The implementing regulations specific to the product

performance data requirements are contained in 40 CFR part 158.

Estimated number of respondents: EPA estimates that registrants submit 60 data packages to the Agency annually for efficacy review. Some registrants may submit multiple data packages per year. Under this rule the number of submissions may decline – and therefore the number of respondents may also decrease.

Frequency of response: On occasion

Total estimated burden: The proposed rule is expected to reduce burden hours by 4,683 annually, including 4,515 hours from reduced paperwork burden associated with data generation and 168 hours from reduced paperwork burden associated with the application process. Burden is defined at 5 CFR 1320.3(b). EPA already accounts for the activities associated with the proposed rule in the currently approved ICR, which covers most activities associated with new and amended registrations; EPA estimates a total annual respondent burden of 1.5 million hours for all these activities. As discussed in the Proposed Rule-related ICR Amendment (Ref. 49), 483,000 of those hours are paperwork burden from data generation for new products, and 102,000 of those hours are paperwork burden from application for new and amended products.

Total estimated cost: The estimated burden reduction is expected to reduce burden cost by $330,000 annually, including $315,000 from reduced paperwork burden associated with data generation and $15,000 from reduced paperwork burden associated with the application process, which includes $0 annualized capital or operation and maintenance costs. EPA already accounts for the activities associated with the proposed rule in the currently approved ICR, which covers most activities associated with new and amended registrations; EPA estimates a total annual respondent burden of $109 million for all these activities. As discussed in the Proposed Rule ICR (Ref. 49), $33.7 million of that cost is paperwork burden from data generation for new products,

and $9.3 million of that cost is paperwork burden from application for new and amended products.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov*, Attention: Desk Officer for the EPA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq*. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. EPA's small entity analysis suggests that the greatest impact, and the most potential cost savings, would accrue to small entities and new registrants. While large, established registrants have experience with the registration process and are aware of EPA's data requirements or have the means to determine the appropriate studies, new and small registrants without that experience may bear significant costs of acquiring this information. The registrants would have easier access to the data requirements, and the reduction in information acquisition costs would be largest for those registrants with the greatest

information acquisition needs. Thus, EPA anticipates that the proposed rule would result in cost savings, particularly for small and first-time registrants. While the affected NAICS codes contain up to 5,438 small entities, EPA does not expect all entities to experience cost savings in all years as a result of this proposed rule. As the cost analysis (Ref. 1) describes, a sample of 30 applications was selected at random. These applications were submitted by 16 different firms, four of which EPA was able to identify as small businesses according to the Small Business Administration Employees or Revenue Thresholds. About 60 packages are received annually by EPA for control claims. Therefore, EPA expects that, on average, approximately ten small entities will experience cost savings each year as a result of this proposed rule.

While not every element of the proposed rule would result in savings for registrants, EPA conservatively estimates that the rule would result in $1 million in annual reductions in registrant expenditures on the process of receiving label claims against public health, wood destroying, and invasive species pests, equivalent to about $17,000 in savings per data package submitted to the Agency and about $5,500 per registrant in annual savings I have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities. The basis for this determination is presented in the small entity analysis prepared as part of the cost analysis for the proposed rule (Ref. 1), which is summarized in Unit I.E, and a copy is available in the docket for this rulemaking. We have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and will not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments. The proposed rule would primarily

affect the private sector, i.e., pesticide registrants. The rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this proposed rule is not subject to the requirements of sections 202, 203, or 205 of UMRA. The cost analysis for this action is summarized in Unit I.E. and is available in the docket.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. At present, no Tribal governments hold, or have applied for, a pesticide registration. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered

regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

Lists of Subjects in 40 CFR Part 158

Environmental protection, administrative practice and procedure, agricultural and non-agricultural, pesticides and pests, reporting and recordkeeping requirements.

Dated: _____.

Andrew Wheeler,

Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 158 as follows:

PART 158 - [AMENDED]

1. The authority citation for part 158 continues to read as follows:

Authority: 7 U.S.C. 136-136y; 21 U.S.C. 346(a)

PART 158 DATA REQUIREMENTS FOR PESTICIDES

2. In § 158.1, revise paragraph (c) to read as follows:

§ 158.1 Purpose and scope.

* * * * *

(c) *Scope of individual subparts*.

(1) *Conventional pesticides*. Subparts A, B, C, D, E, F, G, K, L, N, O, and R apply to conventional pesticides.

(2) *Biochemical pesticides*. Subparts A, B, E, R, and U apply to biochemical pesticides.

(3) *Microbial pesticides*. Subparts A, B, E, R, and V apply to microbial pesticides.

(4) *Antimicrobial pesticides*. Subparts A, B, C, D, E, R, and W of this part apply to antimicrobial pesticides.

3. Revise the heading for subpart E to read as follows:

Subpart E—Product Performance for Products Claiming Effectiveness Against Vertebrate Pests, Products with Prion-related Claims, and Products for Control of Organisms Producing Mycotoxins

4. Add section subpart R to read as follows:

Subpart R—Product Performance for Products Claiming Effectiveness Against Invertebrate Pests

Sec.

158.1700 General requirements.
158.1701 Definitions.
158.1703 Application Categories.
158.1704 Performance standards for data acceptability.
158.1705 Test Guidelines.
158.1707 Data Requirement Modifications.
158.1708 Invasive species claims.
158.1709 Invertebrate disease vector claims.
158.1710 Structural and wood-destroying pest claims.
158.1712 Mites (excluding Chiggers).
158.1714 Chiggers.
158.1718 Ticks.
158.1722 Scorpions.
158.1726 Spiders.
158.1732 Centipedes.
158.1736 Lice.
158.1740 Fleas.
158.1744 Cockroaches.
158.1748 Keds, Screwworms, and Bot Flies.
158.1752 Filth Flies.
158.1756 Mosquitoes.
158.1760 Biting Flies.
158.1768 Bed Bugs.
158.1772 Conenose Bugs and Kissing Bugs.
158.1776 Ants (excluding carpenter ants).
158.1780 Bees, Wasps, Yellowjackets, and Hornets.
158.1782 Carpenter Ants.
158.1784 Wood-destroying beetles.
158.1786 Termites.

Subpart R—Product Performance for Products Claiming Effectiveness Against Invertebrate Pests

§ 158.1700 General requirements.

(a) *General.* Each applicant must ensure through testing that their product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, as specified herein and on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(1) *Test substance*. All product performance testing is performed using the end-use product.

(2) *Test organism*. All product performance testing must report the species tested.

(3) *Testing*. All products are to be tested to support the claim(s) made on the labeling of the pesticide product.

(4) To determine the specific product performance data required to support the registration of each pesticide product, the applicant must refer to the applicable sections of this subpart.

(b) *Product performance data submission*. Each product that bears a claim subject to this subpart, must be supported by submission of product performance data, as listed in this subpart. This product performance data must be submitted with any application for registration or amended registration. For the pest-specific claims listed in this subpart, data must be for the species specified to support the claim.

§ 158.1701 Definitions.

Definitions. The following terms are defined for purposes of this subpart.

Complete protection time (CPT) means the time from application of a skin-applied insect repellent until efficacy failure, which is described in Product Performance Test Guideline 810.3700 – Insect Repellents to be Applied to Human Skin.

Introduction means the intentional or unintentional escape, release, dissemination, or placement of a species into an ecosystem as a result of human activity.

Invasive species means with respect to a particular ecosystem, any species that is not native to that ecosystem, and whose introduction does or is likely to cause economic or environmental harm or harm to human health. .

Performance standard means a benchmark or reference against which the efficacy of the pesticide is compared (including, but not limited to, the ability of the pesticide product to control, kill, or repel an invertebrate pest species).

Pest group labeling claim means a claim or statement on the labeling of the pesticide product that the product is effective against a group of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species for the entire assemblage of taxa.

Pest-specific labeling claim means a claim or statement on the labeling of the pesticide product that the product is effective against a particular arthropod species, such as German cockroach or house fly.

Pest sub-group labeling claim means a claim or statement on the labeling of the pesticide product that the product is effective against a set of related species or taxa demonstrating adequate similarity in basic biology and life history characteristics to permit identification of representative test species and part of a larger identified taxonomic grouping (e.g., Biting flies) that includes other pest species, which may or may not have a proposed pest group.

Skin-applied insect repellent means a product intended to disrupt the host-seeking behavior of insects or other arthropods, driving or keeping them away from treated human skin. The repellent product, such as liquid, lotion, or spray, is intended to be applied directly to human skin. Efficacy of skin-applied insect repellents is expressed as complete protection time.

Species means a group of organisms all of which have a high degree of physical and genetic similarity, generally interbreed only among themselves, and show persistent differences from members of allied groups of organisms.

Wood-destroying applies to pests that feed on or nest in wood, and therefore are highly

destructive to wood buildings or structures, and stored lumber. The impact on the structural integrity of buildings can represent significant economic or safety concerns given the costs of remediation.

Vector means any organism capable of transmitting the causative agent of human and/or animal disease, including but not limited to mosquitoes and ticks

§ 158.1703 Application Categories.

Application Categories. The following terms are defined for purposes of this subpart.

Bait treatment means a pesticide product intended to be ingested by the target pest that kills or controls an invertebrate pest such as ants, cockroaches, or termites. This is normally through the insect feeding on the product directly, but may also include products which the target will contact and later ingest during grooming/cleaning. The attractiveness of these products is through the use of a palatable food base, however they may also incorporate an attractant (e.g. pheromone) which is intended to attract the target pests over a greater distance.

Soil-applied termiticides means pesticide products that are applied to the soil beneath and/or adjacent to the structure, pre- or post-construction, to kill or control termites. Treatments can be preventive (i.e., to provide structural protection before a termite infestation is present) or remedial (i.e., to kill and control a termite infestation when present).

Spatial repellents include treatments of both indoor and outdoor sites where the product is applied into the air rather than onto a surface or the skin in order to drive away insects or other arthropods from that space. They are intended to repel the target pest through the dispersal of pesticide into the atmosphere of a room or other open space.

Structural protection means the prevention of termite or other wood-destroying pest activity in an entire structure as the result of an application of a pesticide product.

§ 158.1704 Performance standards for data acceptability.

(a) *General.* The claim stated on the pesticide product labeling (such as knockdown, control, mortality, or repellency) determines the performance standard that must be met. In the absence of specific pest/labeling claims/performance standards specified in §§ 158.1708 through 158.1799, the performance standards of paragraphs (b) and (c) apply.

(b) *Skin-applied insect repellent labeling claims.* (1) For skin-applied insect repellent labeling claims, the performance standard must be greater than or equal to 2-hours complete protection time.

(2) Any testing required under 40 CFR part 158 which involves any human subjects must comply with all applicable requirements under 40 CFR part 26. For example, 40 CFR part 26 requirements are pertinent to the 40 CFR part 158 testing requirement if the testing involves intentional exposure of human subjects. Protocols for such testing must be submitted to EPA for review prior to study initiation. Those protocols determined by EPA to involve intentional exposure of human subjects also require review by EPA's Human Studies Review Board (HSRB)) prior to study initiation. If you are uncertain about the applicability of the 40 CFR part 26 requirements to this 40 CFR part 158 testing requirement or uncertain about the nature of your planned testing (such as, for example, whether the testing would involve intentional exposure of human subjects or whether the testing would be an observational study), you should contact the Agency prior to initiating the testing.

(c) *Labeling claims for products other than skin-applied insect repellents.* Unless otherwise specified in §§ 158.1710 through 158.1786, for pesticides other than skin-applied insect repellents, the performance standard for a product performance claim against a pest must be greater than or equal to 90 percent, except for non-wearable spatial repellents where the

performance standard is greater than or equal to 75 percent.

§ 158.1705 Test Guidelines.

EPA has published the Harmonized Test Guidelines, which set forth the recommended approach to generate the data required in this subpart. The Product Performance Guidelines (Series 810, Group C -- Invertebrate Control Agent Test Guidelines) are available on the Agency's website. These guidelines cover some, but not all, of the tests that would be used to generate data under this subpart. In instances where there is a conflict between one of the Harmonized Test Guidelines and the provisions of this subpart, this subpart will control.

§ 158.1707 Data Requirement Modifications.

The data requirements (including the performance standards associated with the data requirements) specified in this subpart as applicable to a category of products will not always be appropriate for every product in that category. Data requirements may, on a case-by-case basis, be adjusted by EPA in response to requests for novel technologies or products that have unusual physical, chemical, or biological properties or atypical use patterns which would make a particular data requirement, or data performance standard, inappropriate. Requests for such data requirement modifications must be submitted the same manner as waiver requests submitted under 40 CFR 158.45. EPA will respond in writing to those requests. The Agency may modify data requirements it finds are inappropriate for the pesticide in question, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

§ 158.1708 Invasive species claims.

(a) *General*. In addition to those species specified in paragraph (b) of this section, if an application for registration or amended registration requests a labeling claim for effectiveness

against an invasive invertebrate species, then on a case-by-case basis, EPA may require submission of product performance data and establish performance standards for those data to support those claims for effectiveness.

(b) *Specific*. Applications for registration or amended registration requests for a labeling claim for the emerald ash borer, *Agrilus planipennis*, or Asian longhorned beetle, *Anoplophora glabripennis*, must be accompanied by product performance data to support those claims for effectiveness.

§ 158.1709 Invertebrate disease vector claims.

If an application for registration or amended registration requests a labeling claim specific to a disease vector (such as repels mosquitoes that may carry West Nile virus), then submission of testing conducted with the species specific to the disease vector claim and subject to specific performance standards is required even if the test species is not specifically required in §§ 158.1712 through 158.1786.

§ 158.1710 Structural and wood-destroying pest claims.

If an application for registration or amended registration requests a labeling claim specific to a structural or wood-destroying pest not identified in §§ 158.1782 through 158.1786, EPA may require submission of product performance data, with testing on that specific pest and subject to specific performance standards, to support those claims for effectiveness.

§ 158.1712 Mites (excluding Chiggers).

(a) *General*. The tables and test notes in this section apply to dust, human itch or scabies, and dog follicle mites. The claim stated on the pesticide product labeling determines the required test species. The required test species for a specific type of mite claim appear in paragraph (b) of this section and the required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For pesticide products making a claim against mites, the required test species appear in the following table.

Table 1 of 158.1712—Required Test Species for Products Making a Claim Against Mites (excluding Chiggers)

Labeling Claim	Required Test Species
Dog Follicle Mite	Dog follicle mite (*Demodex canis*)
Dust Mite	Testing on one of the following species is required: American house dust mite (*Dermatophagoides farinae*) OR European house dust mite (*Dermatophagoides pteronyssinus*)
Human Itch or Scabies Mite	Human itch mite (*Sarcoptes scabiei*)

(c) *Performance standards*. (1) For the dog follicle mite, a performance standard of 100 percent is required.

(2) For the human itch or scabies mite, a performance standard of 100 percent is required.

§ 158.1714 Chiggers.

If the pesticide product labeling makes a claim against chiggers, then testing is required using the following test species: Chigger (*Trombicula alfreddugesi*).

§ 158.1718 Ticks.

(a) *General*. The table and test notes in this section apply to hard ticks (including cattle ticks) and soft ticks. The claim stated on the pesticide product labeling determines the required test species. The required test species for a specific type of tick claim appear in paragraph (b) of this section. Specific parameters that apply to individual tests appear in paragraph (c) of this section. For a claim against any specific species of "ticks" that individual species and all the listed representative species for "ticks" must be tested, but not the representative species for cattle ticks or soft ticks. Claims against ticks in association with tick borne diseases are also subject to the requirements in § 158.1709.

(b) *Test species*. For pesticide products making a claim against ticks, the required test

species appear in the following table.

Table 1 of 158.1718—Required Test Species for Products Making a Claim Against Ticks

Labeling Claim	Required Test Species
Ticks	Testing on a total of three hard tick species is required: Blacklegged tick (*Ixodes scapularis*) AND Lone star tick (*Amblyomma americanum*) AND One of the following three species: American dog tick (*Dermacentor variabilis*) OR Brown dog tick (*Rhipicephalus sanguineus*) OR Rocky Mountain wood tick (*Dermacentor andersoni*)
Cattle Ticks	Testing on one of the following species is required: Southern cattle tick (*Rhipicephalus microplus*) OR Cattle fever tick (*Rhipicephalus annulatus*)
Soft Ticks	Soft tick (*Ornithodoros hermsi*)

(c) *Specific parameters*. The following parameters are required.

1. For products applied to dogs, testing is required on three species: Blacklegged tick (*Ixodes scapularis*), American dog tick (*Dermacentor variabilis*), and Brown dog tick (*Rhipicephalus sanguineus*).

2. For products applied to cats, testing is required on three species: Blacklegged tick (*Ixodes scapularis*), Lone star tick (*Amblyomma americanum*), and American dog tick (*Dermacentor variabilis*).

§ 158.1722 Scorpions.

If the pesticide product labeling makes a claim against scorpions, then testing is required using the following test species: Striped bark scorpion (*Centruroides vittatus*).

§ 158.1726 Spiders.

(a) *General*. The table in this section applies to spiders. The product labeling claim determines the required test species. The required test species for spider labeling claims appear

in paragraph (b) of this section.

(b) *Test species*. For products making a claim against spiders, the test species for labeling claims appear in the following table.

Table 1 of 158.1726—Required Test Species for Products Making a Claim Against Spiders

Labeling Claim	Required Test Species
Pest Group Claim	
Spiders	Testing on two species is required: Brown recluse spider (*Loxosceles reclusa*) AND One of the following species is required: Northern black widow spider (*Latrodectus variolus*) OR Southern black widow spider (*Latrodectus mactans*) OR Western black widow spider (*Latrodectus hesperus*)
Pest Sub-Group Claims	
Black Widow Spiders	Testing on one of the following species is required: Northern black widow spider (*Latrodectus variolus*) OR Southern black widow spider (*Latrodectus mactans*) OR Western black widow spider (*Latrodectus hesperus*)
Pest-Specific Claims	
Brown recluse spider	Brown recluse spider (*Loxosceles reclusa*)
Brown widow spider	Brown widow spider (*Latrodectus geometricus*)
Northern black widow spider	Northern black widow spider (*Latrodectus variolus*)
Southern black widow spider	Southern black widow spider (*Latrodectus mactans*)
Western black widow spider	Western black widow spider (*Latrodectus hesperus*)

§ 158.1732 Centipedes.

(a) *General*. The table in this section applies to centipedes. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of the section.

(b) *Test species*. For products making a claim against centipedes, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1732—Required Test Species for Products Making a Claim Against Centipedes

Labeling Claim	Required Test Species
Centipedes	Testing on one of the following species is required: House centipede (*Scutigera coleoptrata*) OR Florida blue centipede (*Hemiscolopendra marginata*) OR *Scolopendra* sp.

§ 158.1736 Lice.

(a) *General*. The table in this section applies to human lice. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against lice, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1736—Required Test Species for Products Making a Claim Against Lice

Labeling Claim	Required Test Species
Lice	Testing on one of the following species is required: Head louse (*Pediculus humanus capitis*) OR Body louse (*Pediculus humanus humanus*)

(c) *Performance standards*. For labeling claims against lice, a performance standard of 100 percent is required.

§ 158.1740 Fleas.

(a) *General*. The table in this section applies to fleas. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section.

(b) *Test species*. For products making a claim against fleas, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1740—Required Test Species for Products Making a Claim Against Fleas

Labeling Claim	Required Test Species
Pest Group Claim	
Fleas	Testing on the following species is required: Cat flea (*Ctenocephalides felis*)
Pest-Specific Claims	
Cat flea	Cat flea (*Ctenocephalides felis*)
Chigoe flea	Chigoe flea (*Tunga penetrans*)
Dog flea	Dog Flea (*Ctenocephalides canis*)
Hen flea	Hen flea (*Ceratophyllus gallinae*)
Human flea	Human flea (*Pulex irritans*)
Oriental rat flea	Oriental rat flea (*Xenopsylla cheopis*)

§ 158.1744 Cockroaches.

(a) *General*. The table in this section applies to cockroaches. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section. Specific parameters that apply to individual tests and labeling claims appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against cockroaches, the required test species for a labeling claim for cockroaches and the test species for pest-specific label claims appear in the following table.

Table 1 of 158.1744—Required Test Species for Products Making a Claim Against Cockroaches

Labeling Claim	Required Test Species
Pest Group Claims	
Cockroaches	Testing on two species is required: American cockroach (*Periplaneta americana*) AND German cockroach (*Blattella germanica*)
Pest-Specific Claims	
American cockroach	American cockroach (*Periplaneta americana*)
Australian cockroach	Australian cockroach (*Periplaneta australasiae*)
Brown cockroach	Brown cockroach (*Periplaneta brunnea*)
Brownbanded cockroach	Brownbanded cockroach (*Supella longipalpa*)
German cockroach	German cockroach (*Blattella germanica*)
Oriental cockroach	Oriental cockroach (*Blatta orientalis*)
Smokybrown cockroach	Smokybrown cockroach (*Periplaneta fuliginosa)*
Turkestan cockroach	Turkestan cockroach (*Blatta lateralis*)

§ 158.1748 Keds, Screwworms, and Bot Flies.

(a) *General*. The table in this section applies to keds, screwworms, and bot flies. The product labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against keds, screwworms, and bot flies, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1748—Required Test Species for Products Making a Claim Against Keds, Screwworms, and Bot Flies

Labeling Claim	Required Test Species
Bot Flies (excluding Human bot fly)	Testing is required on one of the following species: Horse bot fly (*Gasterophilus intestinalis*) OR Throat bot fly (*Gasterophilus nasalis*) OR Nose bot fly (*Gasterophilus haemorrhoidalis*)
Human bot fly	Human bot fly (*Dermatobia hominis*)
Keds	Testing is required on the following species: Sheep ked (*Melophagus ovinus*)
Screwworms	Testing is required on one of the following species: Screwworm (*Cochliomyia hominivorax*) OR Secondary screwworm (*Cochliomyia macellaria*)

§ 158.1752 Filth Flies.

(a) *General*. The table in this section applies to filth flies. The product labeling claim determines the required test species. The required test species for a labeling claim against filth flies or specific species of filth flies appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against filth flies, the required test species for a labeling claim against filth flies appear in the following tables.

Table 1 of 158.1752—Required Test Species for Products Making a Claim Against Filth Flies

Labeling Claim	Required Test Species
Pest Group Claim	
Filth Flies	Testing on two species is required:

	House fly (*Musca domestica*) AND One of the following species is required: Flesh fly (*Sarcophaga* sp., *Wohlfahrtia* sp., and other *genera* of flesh flies) OR Blow fly (*Phaenicia* sp., *Calliphora* sp., and other *genera* of blow flies)
Pest-Specific Claims	
Blow fly	Blow fly (*Phaenicia* sp., *Calliphora* sp., and other *genera* of blow flies)
Cluster fly	Cluster fly (*Pollenia rudis*)
Face fly	Face fly (*Musca autumnalis*)
Flesh fly	Flesh fly (*Sarcophaga* sp., *Wohlfahrtia* sp., and other *genera* of flesh flies)
House fly	House fly (*Musca domestica*)
Little house fly	Little house fly (*Fannia canicularis*)

§ 158.1756 Mosquitoes.

(a) *General*. The tables and test notes in this section apply to mosquitoes. The required test species for a labeling claim against mosquitoes appears in paragraph (b) of this section. For a claim against any specific species of mosquito, that individual species and all the required test genera must be tested. Claims against mosquitos in association with mosquito-borne diseases are also subject to the requirements in § 158.1709.

(b) *Test species*. For products making a claim against mosquitoes, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1756—Required Test Species for Products Making a Claim Against Mosquitoes

Labeling Claim	Required Test Species
Mosquitoes	Testing in three genera (*Culex*, *Aedes*, and *Anopheles*) of mosquitoes is required. One of the following *Culex* species: *Culex pipiens* OR *Culex quinquefasciatus* OR *Culex tarsalis* AND one of the following *Aedes* species: *Aedes aegypti*

	OR *Aedes albopictus* AND one of the following *Anopheles* species: *Anopheles albimanus* OR *Anopheles freeborni* OR *Anopheles gambiae* OR *Anopheles punctipennis* OR *Anopheles quadrimaculatus* OR *Anopheles stephensi*

§ 158.1760 Biting Flies.

(a) *General*. The tables in this section apply to biting flies, which includes biting midges and black flies. The product labeling claim determines the required test species. The required test species for biting fly labeling claims and the test species for pest-specific labeling claims appear in paragraphs (b) of this section.

(b) *Test species*. For products making a claim against biting flies, the required test species for a labeling claim and the test species for pest-specific label claims appear in the following table.

Table 1 of 158.1760—Required Test Species for Products Making a Claim Against Biting Flies

Labeling Claim	Required Test Species
Pest Group Claim	
Biting flies (excluding Sand flies)	Testing is required on three species: Stable fly (*Stomoxys calcitrans*) AND one of the large biting fly species: Black horse fly (*Tabanus atratus*) OR Deer fly (*Chrysops* sp.) OR Striped horse fly (*Tabanus lineola*) AND one of the small biting fly species: Biting midge (punkie, granny nipper, no-see-um) (any

	Culicoides sp.) OR Black fly (any *Simulium* sp. or *Prosimulium* sp.) OR Black gnat (any *Leptoconops* sp.)
Pest Sub-Group Claims	
Large Biting Flies	Testing is required on two species: Stable fly (*Stomoxys calcitrans*) AND one of the following species: Black horse fly (*Tabanus atratus*) OR Deer fly (*Chrysops* sp.) OR Striped horse fly (*Tabanus lineola*)
Small Biting Flies (excluding Sand flies)	Testing is required on one of the following species: Biting midge (punkie, granny nipper, no-see-um) (*Culicoides* sp.) OR Black fly (*Simulium* sp. OR *Prosimulium* sp.) OR Black gnat (*Leptoconops* sp.)
Pest-Specific Claims	
Biting midges (punkie, granny nipper, no-see-um)	Biting midge (punkie, granny nipper, no-see-um) (*Culicoides* sp.)
Black flies	Testing on one of the following species is required: *Simulium* sp. OR *Prosimulium* sp.
Black gnats	Black gnat (*Leptoconops* sp.)
Deer flies	Deer fly (*Chrysops* sp.)
Greenhead	Greenhead (*Tabanus nigrovittatus*)
Horn fly	Horn fly (*Haematobia irritans*)
Horse flies	Testing on one of the following species is required: Black horse fly (*Tabanus atratus*), OR Striped horse fly (*Tabanus lineola*)
Sand flies	Testing on one of the following species is required: *Lutzomyia* sp. OR *Phlebotomus* sp.
Stable fly	Stable fly (*Stomoxys calcitrans*)

§ 158.1768 Bed Bugs.

(a) *General*. The table in this section applies to bed bugs. The product labeling claim

determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section.

(b) *Test species*. For products making a claim against bed bugs, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1768—Required Test Species for Products Making a Claim Against Bed Bugs

Labeling Claim	**Required Test Species**
Pest Group Claim	
Bed bugs	Common bed bug (*Cimex lectularius*)
Pest-Specific Claims	
Common bed bug	Common bed bug (*Cimex lectularius*)
Tropical bed bug	Tropical bed bug (*Cimex hemipterus*)

§ 158.1772 Conenose Bugs and Kissing Bugs.

(a) *General*. The table in this section applies to Conenose bugs and Kissing bugs. The product labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section.

(b) *Test species*. For products making a claim against either the conenose and/or kissing bugs, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1772—Required Test Species for Products Making a Claim Conenose and Kissing Bugs

Labeling Claim	**Required Test Species**
Conenose bug	Conenose bug (*Triatoma sanguisuga*)
Kissing bug	Kissing bug (*Triatoma protracta*)

§ 158.1776 Ants (excluding carpenter ants).

(a) *General*. The table in this section applies to ants (excluding carpenter ants). The product labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against ants (excluding carpenter ants), the required test species for a labeling claim appear in the following table, unless otherwise specified

in paragraphs (c) or (d).

Table 1 of 158.1776—Required Test Species for Products Making a Claim Against Ants (excluding carpenter ants)

Labeling Claim	Required Test Species
Pest Group Claim	
Ants (excluding carpenter ants)	Testing is required on the following two species: Pharaoh ant (*Monomorium pharaonis*) AND Red imported fire ant (*Solenopsis invicta*)
Pest Sub-Group Claim	
Fire and Harvester	Testing is required on the following species: Red imported fire ant (*Solenopsis invicta*)
Fire ants	Testing is required on the following species: Red imported fire ant (*Solenopsis invicta*)
Pest-Specific Claims	
European fire ant	European fire ant (*Myrmica rubra*)
Harvester ant	Harvester ant (*Pogonomyrmex* sp.)
Pharaoh ant	Pharaoh ant (*Monomorium pharaonis*)
Red imported fire ant	Red imported fire ant (*Solenopsis invicta*)
Southern fire ant	Southern fire ant (*Solenopsis xylon*i)
Tropical fire ant	Tropical fire ant (*Solenopsis geminat*a)
Black imported fire ant	Black imported fire ant (*Solenopsis richteri*)

(c) *Colony Claims*. For colony claims, testing must be done specific to the species listed. For colony claims against the red and/or black imported fire ants, testing may be done on, *S. invicta*, *S. richteri*, or their hybrid.

(d) *Bait products or claims involving outdoor use*. The group and sub-group claims in paragraph (b) are for direct kill and residual surface application claims against foraging ants only (excluding colony claims). For bait products or claims involving outdoor use, testing must be specific to the species listed.

§ 158.1780 Bees, Wasps, Yellowjackets, and Hornets.

(a) *General*. The table in this section applies to bees, wasps, yellowjackets, and hornets. The labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section.

(b) *Test species*. For products making a claim against bees, wasps, yellowjackets, and hornets, the required test species for a labeling claim appear in the following table, unless otherwise specified in paragraph (c).

Table 1 of 158.1780—Required Test Species for Products Making a Claim Against Bees, Wasps, Yellowjackets, and Hornets

Labeling Claim	Required Test Species
Pest Group Claims	
Bees, Wasps, Yellowjackets, and Hornets	Testing on three species is required: Two Yellowjacket species (one *Vespula* sp. AND the Bald-faced hornet (*Dolichovespula maculata*)) AND one Paper wasp (*Polistes* sp.)
Pest-Specific Claims	
Bald-faced hornet	Bald-faced hornet (*Dolichovespula maculata*)
Mud dauber wasp	Mud dauber wasp (*Sphecidae* sp.)
Paper wasp	Paper wasp (*Polistes* sp.)
Yellowjackets	Yellowjacket (*Vespula* sp.)

c) *Colony Claims*. For colony claims, except *Vespula* spp., testing must be specific to the species listed. Acceptable data for any *Vespula* species may support a yellowjacket colony claim for ground nesting *Vespula* species; however, species-specific claims need to be supported by data from testing of the specific species. Colony claims against *Vespula* spp. have a performance standard of 100%.

§ 158.1782 Carpenter Ants.

(a) *General*. The table in this section applies to carpenter ants. The product labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against carpenter ants, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1782—Required Test Species for Products Making a Claim Against Carpenter Ants

Labeling Claim	Required Test Species
Carpenter ants	Testing on one of the following carpenter ant species is required: Black carpenter ant (*Camponotus pennsylvanicus*) OR Florida carpenter ant (*Camponotus floridanus*) OR Western carpenter ant (*Camponotus modoc*)

(c) *Performance standards*. The performance standards for pesticide products making certain claims against carpenter ants appear in the following table. The performance standards for labeling claims that are not specifically provided in the following table appear in § 158.1704.

Table 2 of 158.1782—Performance Standards for Certain Claims Against Carpenter Ants

Application Category	Performance Standard
Bait Treatment	95% prevention of damage to wood for ≥ 3 years
Non-Structural: Wood Preservative Treatment	100% prevention of damage to wood for ≥ 2 years
Structural Protection	95% prevention of damage to wood ≥ 5 years

§ 158.1784 Wood-destroying beetles.

(a) *General*. The tables and test notes in this section apply to wood-destroying beetles. The labeling claim determines the required test species. The required test species for a labeling claim appears in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against wood-destroying beetles, the required test species for a labeling claim is set forth in the following table.

Table 1 of 158.1784—Required Test Species for Products Making a Claim Against Wood-Destroying Beetles

Labeling Claim	Required Test Species
True powderpost beetles	Testing on one species from the Lyctinae subfamily is required.

Wood-destroying or wood-boring beetles	Testing on three species is required: Anobiid beetle (*Anobiidae* sp.) AND Bostrichid beetle (*Bostrichidae* sp.) AND Old house borer (*Hylotrupes bajulus*)

(c) *Performance standards*. The performance standards for pesticide products making certain claims against wood-destroying beetles appear in the following table. The performance standards for labeling claims that are not specifically provided in the following table appear in § 158.1704.

Table 2 of 158.1784—Performance Standards for Certain Claims against Wood-Destroying Beetles

Application Category	Performance Standard
Bait Treatment	95% prevention of damage to wood ≥ 3 years
Non-Structural: Wood Preservative Treatment	100% prevention of damage to wood for ≥ 2 years
Structural Protection	95% prevention of damage to wood ≥ 5 years

§ 158.1786 Termites.

(a) *General*. The tables and test notes in this section apply to the subterranean termite, desert subterranean termite, Formosan subterranean termite, drywood termite, and dampwood termite. The labeling claim determines the required test species. The required test species for labeling claims appear in paragraph (b) of this section. The required performance standards appear in paragraph (c) of this section.

(b) *Test species*. For products making a claim against termites, the required test species for a labeling claim appear in the following table.

Table 1 of 158.1786—Required Test Species for Products Making a Claim Against Termites

Labeling Claim	Required Test Species
Pest Group Claim	
Termites	Testing on species from four genera of termites is required: Testing is required on the following *Coptotermes* termite: *Coptotermes formosanus*

	AND one of the following *Reticulitermes* species: *Reticulitermes flavipes* OR *Reticulitermes hesperus* OR *Reticulitermes virginicus* AND one of the following arboreal termite species: *Nasutitermes coringer* (Motschulsky) AND one of the following drywood termite species: *Cryptotermes brevis* OR *Cryptotermes cavifrons* OR *Incisitermes minor* OR *Incisitermes snyderi*
Pest Sub-Group Claim	
Arboreal Termites	Testing of one arboreal termite species is required: *Nasutitermes coringer* (Motschulsky)
Dampwood Termites	Testing of the following dampwood termite is required: *Zootermopsis* sp.
Drywood Termites	Testing of one of the following drywood termites is required: *Cryptotermes brevis* OR *Cryptotermes cavifrons* OR *Incisitermes minor* OR *Incisitermes snyderi*
Subterranean Termites, including Formosan Subterranean Termites	Testing in two genera of termites is required: Testing on the following *Coptotermes* species is required: *Coptotermes formosanus* AND one of the following *Reticulitermes* species: *Reticulitermes flavipes* OR *Reticulitermes hesperus* OR *Reticulitermes virginicus*

(c) *Performance standards*. The performance standards for pesticide products making certain claims against termites appear in the following table. The performance standards for labeling claims not provided in the following table appear in § 158.1704.

Table 2 of 158.1786—Performance Standards for Certain Claims Against Termites

Application Category	Performance Standard
Bait Treatment	95% prevention of damage to wood ≥3 years
Non-Structural: Wood Preservative Treatment	100% Prevention of damage to wood for ≥ 2 years
Structural Protection	95% prevention of damage to wood ≥ 5 years

5. Revise § 158.2070 in subpart U to read as follows:

§ 158.2070 Biochemical Pesticides Product Performance Data Requirements.

(a) *General*. Product performance data must be developed for all biochemical pesticides. Each applicant must ensure through testing that the product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(b) *Product performance data for each product that bears a claim against an invertebrate pest that is covered by subpart R of this Part*. The product performance data requirements of subpart R of this part apply to biochemical products covered by this subpart. Product performance data must be submitted with any application for registration or amended registration. The performance standards required in subpart R of this part also apply to biochemical pesticide products. However, data requirements and the performance standards that determine the acceptability of data may be modified on a case-by-case basis pursuant to the waiver provisions in 40 CFR 158.45 and the provisions in 40 CFR 158.1707.

(c) *Product performance data for each product that bears a public health claim, excluding those covered under paragraph (b)*. Product performance data must be submitted with any application for registration or amended registration, if the product bears a claim to control public health pests, such as pest microorganisms infectious to humans in any area of the inanimate environment, or a claim to control vertebrates, including but not limited to, rodents,

birds, bats, canids, and skunks.

6. Revise § 158.2160 in subpart V to read as follows:

§ 158.2160 Microbial Pesticides Product Performance Data Requirements.

(a) *General*. Product performance data must be developed for all microbial pesticides. Each applicant must ensure through testing that the product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(b) *Product performance data for each product that bears a claim against an invertebrate pest that is covered by subpart R of this part*. The product performance data requirements of subpart R of this part apply to microbial products covered by this subpart. Product performance data must be submitted with any application for registration or amended registration. However, data requirements and the performance standards that determine the acceptability of data may be modified on a case-by-case basis pursuant to the waiver provisions in 40 CFR 158.45 and the provisions in 40 CFR 158.1707.

(c) *Product performance data for each product that bears a public health claim, excluding those covered under paragraph (b)*. Product performance data must be submitted with any application for registration or amended registration, if the product bears a claim to control public health pests, such as pest microorganisms infectious to humans in any area of the inanimate environment, or a claim to control vertebrates, including but not limited to, rodents, birds, bats, canids, and skunks.

7. In § 158.2200, revise paragraph (b) in subpart W to read as follows:

§ 158.2200 Applicability.

* * * * *

(b) *A product that bears both antimicrobial and non-antimicrobial uses or claims*. Such a product is subject to the data requirements for pesticides in subparts C through O, R, and U or V of this part with respect to its non-antimicrobial uses and claims, and to the requirements of this subpart with respect to its antimicrobial uses and claims.

* * * * *

Message

From: Ross, David P [ross.davidp@epa.gov]
Sent: 1/7/2021 1:23:59 AM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
CC: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Bolen, Brittany [bolen.brittany@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]
Subject: RE: Nutrient Trading Policy Document & OMB

Thank you.

From: adm15.arwheeler.email <adm15.arwheeler.email@epa.gov>
Sent: Wednesday, January 6, 2021 8:02 PM
To: Ross, David P <ross.davidp@epa.gov>
Cc: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Wildeman, Anna <wildeman.anna@epa.gov>
Subject: Re: Nutrient Trading Policy Document & OMB

Put it through

Sent from my iPhone

On Jan 6, 2021, at 4:46 PM, Ross, David P <ross.davidp@epa.gov> wrote:

Confidential/Deliberative

Administrator,

Anna and I have one last nutrient trading policy document that we'd like to get on the street, further advancing our Feb. 2019 trading policy mentioned in the water subcab EO. The final document was developed with the benefit of public comment (prior to the new guidance rule taking effect). As the

Ex. 5 Deliberative Process (DP)

But, this document was inadvertently left off our priorities list for you (as was getting UCMR5 out of OMB, which cleared this week!), so Brittany needs your approval to communicate to OMB that this final policy document can get processed to and through OMB. We'd appreciate that approval so that we can get this processed and posted to our nutrients website.

Dave

David P. Ross
Assistant Administrator
Office of Water, EPA
ross.davidp@epa.gov

Message

From: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
Sent: 1/7/2021 1:28:20 AM
To: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
CC: Reisman, Larry [Reisman.Larry@epa.gov]
Subject: Detail/Temporary Promotion - Join OPPT's Team: Acting Team Lead in OPPT/DGAD/DCB

The **Office of Chemical Safety and Pollution Prevention, Office of Pollution Prevention and Toxics, Data Gathering and Analysis Division**, has an exciting 120-day opportunity to serve as the **Acting Team Lead of the Data Collection Branch**. The Acting Team Lead of DCB will support the Branch Chief in managing the workload of DCB, including the assignment of work, tracking progress on projects, and coordinating with the other divisions in the newly reorganized OPPT responsible for TSCA determinations and deliverables. No more than 25% of the Acting Team Lead's duties will be supervisory.

To view the full Talent Hub announcement and to apply, click the following link:
https://usepa.sharepoint.com/sites/OARM/talenthub/details/sitepages/home.aspx#!/positions/2281.

Title	Acting Team Lead
Duration	120 days
Position Type	Applications will be considered from current GS-13s and 14s EPA-Wide. A temporary promotion will be considered for the GS-13s that are eligible
Location of Position	Washington, D.C.
Closing Date	Tuesday, January 19, 2021

Please do not respond to this email. For questions regarding this opportunity, please contact Larry Reisman at 202-566-0751 or reisman.larry@epa.gov

Message

From: Bolen, Brittany [bolen.brittany@epa.gov]
Sent: 1/7/2021 4:39:10 AM
To: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
CC: Molina, Michael [molina.michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: Re: 111B

No problem. Thank you

Sent from my iPhone

On Jan 6, 2021, at 11:17 PM, adm15.arwheeler.email <adm15.arwheeler.email@epa.gov> wrote:

Sorry, we had problems, I'll have to do it first thing in the morning. Corey isn't available right now

Sent from my iPhone

On Jan 6, 2021, at 9:11 PM, Bolen, Brittany <bolen.brittany@epa.gov> wrote:

This does not include a signature. Can you please try again?

From: adm15.arwheeler.email <adm15.arwheeler.email@epa.gov>
Sent: Wednesday, January 6, 2021 9:37 PM
To: Bolen, Brittany <bolen.brittany@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Gunasekara, Mandy <gunasekara.Mandy@epa.gov>
Subject: 111B

2B or not 2B

Message

From: adm15.arwheeler.email [adm15.arwheeler.email@epa.gov]
Sent: 1/7/2021 2:37:11 AM
To: Bolen, Brittany [bolen.brittany@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: 111B
Attachments: 111(b) EGU Preamble and Rule 01_06_2021_Admin.docx

2B or not 2B

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA-HQ-OAR-2013-0495; FRL-10019-30-OAR]

RIN 2060-AT56

Pollutant-Specific Significant Contribution Finding for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units, and Process for Determining Significance of Other New Source Performance Standards Source Categories

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this final action, the U.S. Environmental Protection Agency (EPA) is finalizing a significant contribution finding (SCF) for purposes of regulating source categories for greenhouse gas (GHG) emissions, under section 111(b) of the Clean Air Act (CAA) for electric generating units (EGUs), and in doing so, reaffirming that EGUs remain a listed source category. The EPA has reached that conclusion by articulating a framework under which source categories are considered to contribute significantly to dangerous air pollution due to their GHG emissions if the amount of those emissions exceeds 3 percent of total U.S. GHG emissions. The EPA is applying the 3-percent threshold to the EGU source category to demonstrate that GHG emissions from the EGU source category would contribute significantly to dangerous air pollution. While EGU GHG emissions exceed this threshold by a sufficient magnitude to warrant an SCF without more ado, the EPA has also, for completeness, analyzed EGU emissions under a secondary criteria framework, which also demonstrates the propriety of the SCF.

DATES: The final rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2013-0495. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. With the exception of such material, publicly available docket materials are available electronically through *https://www.regulations.gov/*. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Mr. Christopher Werner, Sector Policies and Programs Division (D243-01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5133; fax number: (919) 541-4991; and email address: *werner.christopher@epa.gov*.

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. The EPA uses multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

AEO	Annual Energy Outlook
BSER	best system of emission reduction
°C	degrees Celsius
CAA	Clean Air Act
CFR	Code of Federal Regulations
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
D.C. Cir.	United States Court of Appeals for the District of Columbia Circuit
DOE	Department of Energy
EGU	electric utility generating unit
EIA	U.S. Energy Information Administration
EPA	Environmental Protection Agency
°F	degrees Fahrenheit
GHG	greenhouse gas
HAP	hazardous air pollutant(s)
HFC	hydrofluorocarbon
km	kilometers
M	million
N_2O	nitrous oxide
NAICS	North American Industry Classification System
NGCC	natural gas combined cycle
NOx	nitrogen oxides
NSPS	new source performance standards
OMB	Office of Management and Budget
PC	pulverized coal
PFC	perfluorocarbon
PM	particulate matter
SF_6	sulfur hexafluoride
SO_2	sulfur dioxide
U.S.	United States
U.S.C.	United States Code

Organization of this document. The information in this preamble is organized as follows:

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C. What are the costs and benefits?
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I. General Information

A. Does this action apply to me?

Categories and entities potentially impacted by this rule include sources subject to new source performance standards (NSPS) requirements under section 111 of the CAA. While this rule informs all NSPS source categories, the EPA is finalizing a SCF specific to electric generating units regulated under 40 CFR part 60, subpart TTTT. The North American Industry Classification System (NAICS) code for the industrial, federal government, and state/local government electric generating units is 221112. The NAICS code for tribal government electric generating units is 921150.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action is available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at *https://www.epa.gov/stationary-sources-air-pollution/nsps-ghg-emissions-new-modified-and-reconstructed-electric-utility*. Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the final rule and key technical documents at this same website.

C. Judicial Review

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the D.C. Circuit) by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Moreover, under section 307(b)(2) of the CAA, the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce these requirements. The Administrator has determined that this action is subject to section 307(d) of the CAA (42 U.S.C. 7607(d)(1)(V)). Section 307(d)(7)(B) of the CAA further provides that "[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review." This section also provides a mechanism for the EPA to convene a proceeding for reconsideration "[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment, (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule." Any person seeking to make such a demonstration

to us should submit a Petition for Reconsideration to the Office of the Administrator, U.S. Environmental Protection Agency, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

II. Executive Summary

A. What is the purpose of this regulatory action?

In Executive Order 13783 (Promoting Energy Independence and Economic Growth), all executive departments and agencies, including the EPA, were directed to "immediately review existing regulations that potentially burden the development or use of domestically produced energy resources and appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources beyond the degree necessary to protect the public interest or otherwise comply with the law."[1] Moreover, the Executive Order directed the EPA to undertake this process of review with regard to the "Standards of Performance for Greenhouse Gas Emissions from New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units," 80 FR 64510 (October 23, 2015) (2015 Rule).

In a document signed the same day as Executive Order 13783 and published in the **Federal Register** at 82 FR 16330 (April 4, 2017), the EPA announced that, consistent with the Executive Order, it was initiating a review of the 2015 Rule and providing notice of a forthcoming proposed rulemaking consistent with the Executive Order. After due deliberation, the EPA issued a proposed rulemaking, "Review of Standards of Performance for Greenhouse

[1] Executive Order 13783, Section 1(c), 82 FR 16093, March 31, 2017.

Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units—Proposed Rule," 83 FR 65424 (December 20, 2018) (2018 Proposal). Here the EPA is finalizing a rulemaking with respect to whether GHG emissions from EGUs contribute significantly to dangerous air pollution, in reliance on a methodology articulated herein for determining whether GHG emissions from other NSPS source categories contribute significantly to dangerous air pollution. Any action regarding the proposal to revise the standards of performance, including the underlying determinations of the BSER, for new, reconstructed, and modified coal-fired EGUs, including certain technical issues, is beyond the scope of this final rule and comments received on the 2018 Proposal will be addressed in a separate future action.

B. What is the summary of the major provisions in this action?

The EPA is finalizing a pollutant-specific SCF for GHG emissions from EGUs. That finding is based on an emissions threshold framework for determining significance, as well as secondary criteria to be applied in certain circumstances, for other NSPS source categories.

C. What are the costs and benefits?

In 2015, the EPA promulgated "Standards of Performance for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units," 80 FR 64510 (October 23, 2015) (2015 Rule). When the EPA promulgated the 2015 Rule, it took note of both utility announcements and U.S. Energy Information Administration (EIA) modeling and, based on that information, concluded that even in the absence of this rule, (1) existing and anticipated economic conditions are such that few, if any, coal-fired EGUs will be built in the foreseeable future, and that (2) utilities and project developers are expected to choose new generation technologies (primarily natural gas combined cycle (NGCC)) that would meet the

final standards and also renewable generating sources that are not affected by these final standards. *See* 80 FR 64515 (October 23, 2015). The EPA, therefore, projected that the 2015 Rule would "result in negligible CO_2 emission changes, quantified benefits, and costs by 2022 as a result of the performance standards for newly constructed EGUs." *Id.* The Agency went on to say that it had been "notified of few power sector new source performance standards (NSPS) modifications or reconstructions." Based on that additional information, the EPA said it "expects that few EGUs will trigger either the modification or the reconstruction provisions" of the 2015 Rule. *Id.* at 64516.

The EPA has concluded that the projections described in the 2015 Rule remain generally correct.[2] In the period of analysis,[3] the EPA expects there to be few, if any, newly constructed, reconstructed, or modified sources that will trigger the provisions the EPA is promulgating in this action. Consequently, the EPA projects that there will be no significant changes in carbon dioxide (CO_2) emissions or in compliance costs as a result of this final rule.

III. Summary of Previous Rulemaking Actions

On December 20, 2018, the EPA published a proposal to revise certain parts of the 2015 Rule; "Review of Standards of Performance for Greenhouse Gas Emissions From New, Modified, and Reconstructed Stationary Sources: Electric Utility Generating Units." 83 FR 65424 (2018 Proposal). The majority of that proposal was dedicated to the issue of the best system of emission reduction (BSER) for newly constructed, modified, and reconstructed coal-fired EGUs. Comments received on that issue are not being addressed in this rule and will be addressed in any future EPA action. In that proposal, the EPA solicited comment on whether to

[2] In the reference case for the most recent Annual Energy Outlook (AEO2020), the EIA projected no additions of new planned or unplanned coal capacity through 2050 (*www.eia.gov/aeo2020*; Table 9. Electricity Generating Capacity).
[3] Standards developed under the NSPS program must, by statutory requirement, be reviewed, at least, every 8 years.

make a pollutant-specific significant contribution determination for GHG emissions from EGUs, 83 FR 65432 n. 25, which is the subject of this action.

IV. Pollutant-Specific Significant Contribution Finding (SCF)

A. Background

CAA section 111(b)(1)(A) states that "[The Administrator] shall include a category of sources in such list if in his judgment it causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare."

In the 2015 Rule, the EPA promulgated standards for GHG (measured CO_2 emissions) from fossil fuel-fired steam generating EGUs and combustion turbines, a pollutant that the Administrator had not considered when he listed the categories of those sources - fossil fuel-fired steam generators[4] and stationary gas turbines.[5] *See* 80 FR 64510. Similarly, in 2016, the EPA promulgated an NSPS for GHG (measured by methane (CH_4) emissions) from oil and gas sources, a pollutant that the Administrator had not considered when he listed the category for those sources - the Crude Oil and Natural Gas Production source category.[6] *See* 81 FR 35824 (June 3, 2016) (2016 Oil & Gas Rule).

In each rule, the EPA interpreted CAA section 111(b) to require that an SCF and endangerment finding be made only with respect to the source category, at the time the EPA lists the category, and to authorize the EPA to promulgate NSPS for GHG, as long as the EPA

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[4] *See* "List of Categories of Stationary Sources," 36 FR 5931 (March 31, 1971) (listing source category); "Standards of Performance for New Stationary Sources," 36 FR 24376 (December 31, 1971) (promulgating NSPS for source category).

[5] *See* "Standards of Performance for New Stationary Sources; Gas Turbines," 44 FR 52792 (September 10, 1979) (listing and promulgating NSPS for source category).

[6] *See* "Priority List and Additions to the List of Categories of Stationary Sources," 49 FR 49222 (August 21, 1979) (listing source category); "Standards of Performance for New Stationary Sources; Equipment Leaks of VOC From Onshore Natural Gas Processing Plants," 50 FR 26124 (June 23, 1985), and "Standards of Performance for New Stationary Sources; Onshore Natural Gas Processing SO_2 Emissions," 50 FR 40160 (October 1, 1985) (promulgating standards of performance).

provides a rational basis for doing so. However, in each rule, the EPA acknowledged that some stakeholders had argued that the EPA first needed to make a pollutant-specific SCF, that is, a finding that GHG from the source category contributes significantly to dangerous air pollution. In each rule, the EPA stated that it disagreed with those stakeholders, but nevertheless, in the alternative, did make a pollutant-specific SCF for GHG, supported by the same reasons that the EPA had used to determine that it had a rational basis to regulate GHG. *See* 80 FR 64529 through 64531 (2015 EGU Rule); 81 FR 35840 through 35843 (2016 Oil & Gas Rule).

In the 2018 Proposal, in which the EPA proposed to revise the 2015 Rule, the EPA solicited comment on whether to adopt the interpretation that it was required to make an SCF for GHG from the EGU source category before it could promulgate an NSPS for CO_2. Some commenters stated that the EPA must make pollutant-specific findings of endangerment and significant contribution in order to establish an NSPS for that pollutant. These commenters explained that in their view, CAA section 111(b)(1)(A) requires the EPA to make two specific findings: (1) the specific "air pollution" to be regulated is "reasonably … anticipated to endanger public health or welfare;" and (2) the specific source category "causes or contributes significantly to" that air pollution. Commenters asserted that CAA section 111(b)(1)(A) is not ambiguous in this respect, and, therefore, the Agency's interpretation in the 2015 Rule directly contradicts the plain language of that section.

Other commenters stated that the EPA's approach in the 2015 Rule, that it needs to determine only that it has a rational basis to regulate GHGs emitted by this source category as a prerequisite to regulation, is sound. They said in the context of CAA section 111, the SCF and endangerment finding are made with respect to the source category, and not as to specific pollutants. These commenters supported the conclusion in the 2015 Rule that the EPA possesses

authority to regulate GHG emissions from fossil fuel-fired EGUs under CAA section 111 because there was no new evidence calling into question its determination that GHG air pollution may reasonably be anticipated to endanger public health and welfare and fossil fuel-fired EGUs have a high level of GHG emissions. The commenters stated that these considerations hew closely to the statutory factors that inform the decision whether to list a source category in the first place—namely, whether the category "causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare," under CAA section 111(b)(1)(A). The commenters added that this approach, which closely parallels the listing analysis but does not require a formal endangerment finding or SCF, is legally sound. They also added that the statute is clear that a formal endangerment finding is required to initially list a sector to be regulated under CAA section 111; but it is also clear that such a finding is not required before regulating additional harmful pollutants from a previously-listed sector.[7]

[7] Some commenters on the 2018 Proposal also said that, in the 2009 Endangerment Finding, the EPA specifically defined air pollution, as referred to in section 202(a) of the CAA, to be the mix of six well-mixed, long-lived, and directly emitted GHGs: CO_2, CH_4, N_2O, HFCs, PFCs, and SF_6. 74 FR 66497. They commented that the EPA needs to make, but has never made, a separate finding that CO_2 alone is reasonably anticipated to endanger the public health or welfare. The Agency disagrees with commenters. The air pollutant that the 2015 Rule regulates is GHG, and that air pollutant contributes to the same GHG air pollution that was addressed by the Endangerment Finding. The standards of performance adopted in the 2015 Rule take the form of an emission limitation on only one constituent gas of this air pollutant, CO_2. *See* 40 CFR 60.5515(a) ("The pollutants regulated by this subpart are greenhouse gases. The greenhouse gas standard in this subpart is in the form of a limitation on emission of carbon dioxide."). This is reasonable, given that CO_2 is the constituent gas emitted in the largest volume by the source category and for which there are available controls that are technically feasible and cost effective. There is no requirement that standards of performance address each component of an air pollutant. CAA section 111(b)(1)(B) requires the EPA to establish "standards of performance" for listed source categories, and the definition of "standard of performance" in CAA section 111(a)(1) does not specify which air pollutants must be controlled. Moreover, as the EPA noted in the 2015 Rule, the information considered in the 2009 Endangerment Finding and its supporting record, together with additional discussion of GHG impacts in the 2015 Rule, makes clear that GHG air pollution may reasonably be anticipated to endanger public health or welfare. *See* 80 FR 64517, 64530 and 31. Because the 2015 Rule followed the same approach as in the 2009 findings and regulated the same pollutant as contributing to the same air pollution (to reiterate, both the air pollutant and the air pollution are GHG as the group of six well-mixed gases, including CO_2), it was not necessary to evaluate CO_2 separately. The EPA took the same position in the 2016 Oil & Gas Rule in response to a similar comment concerning CH_4. *See* 81 FR 35843.

Similarly, in a 2019 proposal to revise the 2016 Oil & Gas Rule, the EPA solicited comment on whether to adopt the interpretation that it was required to make an SCF for GHG from the Oil and Gas source category before it could promulgate a CH_4 NSPS. Recently, the EPA completed the final rule to revise the 2016 Oil & Gas Rule, "Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review: Final Rule," 85 FR 57018 (September 14, 2020) (2020 Oil & Gas Rule). There, the EPA determined that a pollutant-specific SCF is required. In addition, the EPA further determined that the pollutant-specific SCF in the 2016 Oil & Gas Rule was invalid on grounds, in part, that the EPA had not established a threshold or criteria by which to determine whether an amount of emissions contributes significantly to dangerous air pollution, and to distinguish from an amount of emissions that simply contributes to dangerous air pollution. The EPA stated that section 111(b) of the CAA requires, or at least authorizes, a pollutant-specific SCF, and such an SCF must be based on defined criteria or thresholds. *Id.* at 57033-40.

B. What is a Significant Contribution Finding (SCF)?

1. Significant Contribution Finding and Key Comments Received

CAA section 111 directs the EPA to regulate, through a multi-step process, air pollutants from categories of stationary sources. CAA section 111(b)(1)(A) requires the initial action, which is that the Administrator must "publish … a list of categories of stationary sources. He shall include a category of sources in such list if in his judgment it causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare." Therefore, the first action that the EPA must take, specified in CAA section 111(b)(1)(A), is to list a source category for regulation on the basis of a determination that the category contributes significantly to dangerous air pollution. This provision makes clear that

although Congress designed CAA section 111 to apply broadly to source categories of all types wherever located, Congress also imposed a constraint: The EPA is authorized to regulate only sources that it finds cause or contribute significantly to air pollution that the EPA finds to be dangerous. Because CAA section 111(b)(1)(A) refers to air *pollution*, the EPA's determination that a source category should be listed for regulation can be based on all pollutants emitted by the category (*i.e.*, collective contribution), or for a specific pollutant.

After the EPA lists a source category, CAA section 111(b)(1)(B) then directs the EPA to propose regulations "establishing Federal standards of performance" for new sources within the source category, to allow public comment, and to "promulgate … such standards with such modifications as he deems appropriate." CAA section 111(a)(1) defines the term "standard of performance" as "a standard for emissions of air pollutants which [the Administrator is required to determine through a specified methodology]." These provisions read together make clear that the standards of performance that CAA section 111(b)(1)(A) directs the Administrator to promulgate must concern air pollutants emitted from the sources in the source category. However, industrial sources of the type subject to CAA section 111(b)(1)(A) invariably emit more than one air pollutant, and neither CAA section 111(b)(1)(B) nor CAA section 111(a)(1), by their terms, specifies for which of those air pollutants the EPA must promulgate standards of performance.

In the past, the EPA has interpreted CAA section 111(b)(1)(B) to authorize it to promulgate standards of performance for any air pollutant that the EPA identified in listing the source category and any additional air pollutant for which the EPA has identified a rational basis for regulation. 81 FR 35843 (2016 Oil & Gas Rule); 80 FR 64510 (2015 Rule). Inherent in this approach is the recognition that CAA section 111(b)(1)(A) does not, by its terms, necessarily

require the EPA to promulgate standards of performance for all air pollutants emitting from the source category. The EPA could list a source category on grounds that it emits numerous air pollutants that, taken together, significantly contribute to air pollution that may reasonably be anticipated to endanger public health or welfare, and proceed to regulate each of those pollutants, without ever finding that each (or any) of those air pollutants by itself causes or contributes significantly to—or, in terms of the text of other provisions, causes or contributes to—air pollution that may reasonably be anticipated to endanger public health or welfare.

As described in the 2020 Oil and Gas Policy Rule, CAA section 111(b)(1)(A) does not provide or suggest any criteria to define the rational basis approach, the EPA has not articulated any criteria in its previous applications in the EGU CO_2 NSPS and the 2016 40 CFR part 60, subpart OOOOa rules, and in instances before those rules in which the EPA has relied on the "rational basis" approach, the EPA has done so to justify not setting a standard for a given pollutant, rather than to justify setting such a standard. 85 FR 77037, December 1, 2020. Thus, the rational basis test allows the EPA virtually unfettered discretion in determining which air pollutants to regulate. As a result, the rational basis standard creates the possibility that the EPA could seek to promulgate NSPS for pollutants that may be emitted in relatively minor amounts.

In contrast, CAA section 111(b)(1)(A) is clear that the EPA may list a source category for regulation only if the EPA determines that the source category "causes or contributes *significantly*" (emphasis added) to dangerous air pollution. As described in the 2020 Oil and Gas Policy Rule, in light of the stringency of this statutory requirement for listing a source category, it would be unreasonable to interpret CAA section 111(b)(1)(B) to allow the Agency to regulate air pollutants from the source category merely by making an administrative determination under the open-ended and undefined rational basis test. The EPA, therefore, determined it is logical to

interpret CAA section 111(b)(1)(B) to require that the Agency apply the same degree of rigor in determining which air pollutants to regulate as it does in determining which source categories to list for regulation, and, therefore, must make a pollutant-specific SCF. *Id.*

Requiring a pollutant-specific SCF necessitates the establishment of a clearer framework for assessing which air pollutants merit regulatory attention that will require sources to bear control costs. The establishment of such a framework or criteria promotes regulatory certainty for stakeholders and consistency in the EPA's identification of which air pollutants to regulate and reduces the risk that air pollutants that do not merit regulation will nevertheless become subject to regulation due to an unduly vague standard.

As previously described, CAA section 111(b)(1)(B) requires the EPA to establish an NSPS for a source category listed under CAA section 111(b)(1)(A). For a source category previously listed under CAA section 111(b)(1)(A), in order to subsequently promulgate an NSPS for a pollutant that the EPA did not evaluate the source category for at the time of listing, the EPA must make a pollutant-specific SCF for the reasons described above. As part of making an SCF, the EPA concluded in the 2020 Oil and Gas Policy Rule that, "a standard or an established set of a criteria, or perhaps both, are necessary to identify what is significant and what is not." 85 FR 57039. The EPA did not finalize or take a position in the 2020 Oil and Gas Policy Rule on potential criteria, stating that it was deferring the identification of such criteria to a future rulemaking. *Id.* CAA section 111(b) itself does not specify what the criteria for a pollutant-specific SCF.

The "contributes significantly" provision in CAA section 111(b)(1)(A) is ambiguous as to what level of contribution is considered to be significant. *See* 84 FR 50267 and 50268, September 24, 2019 (citing *EPA* v. *EME Homer City Generation, L.P.*, 572 U.S. 489 (2014)

(holding that a similar provision in CAA section 110(a)(2)(D)(i), often termed the "good neighbor" provision, is ambiguous)). Accordingly, the EPA has authority to interpret that provision. *Id.* at 50268. As noted above, the EPA reads CAA section 111(b)(1)(B) in light of CAA sections 111(b)(1)(A) and 111(a)(1) to incorporate the "contributes significantly" standard in connection with promulgating NSPS for particular air pollutants. The EPA has concluded that to allow the EPA to distinguish between a *contribution* and a *significant contribution* to dangerous pollution, some type of (reasonably explained and intelligible) standard and/or established set of criteria that can be consistently applied is necessary.

A supporting basis for this conclusion can be found by looking at the EPA's interpretation of the similarly worded "contribute significantly" provisions of CAA section 189(e), concerning major stationary sources of particulate matter with a diameter of 10 micrometers or less (PM_{10}). This provision requires that the control requirements applicable to major stationary sources of PM_{10} also apply to major stationary sources of PM_{10} precursors "except where the Administrator determines that such sources [of precursors] do not contribute significantly to PM_{10} levels which exceed the standard in the area." As the EPA noted in the 2019 Oil and Gas Policy Rule proposal, in CAA section 189(e), Congress intended that, in order to be subject to regulation, the emissions must have a greater impact than a simple contribution not characterized as a significant contribution. However, Congress did not quantify how much greater. Therefore, the EPA developed criteria for identifying whether the impact of a particular precursor would "contribute significantly" to a NAAQS exceedance. 84 FR 50268. These criteria included numerical thresholds. *Id.* The EPA concluded similarly that, under CAA section 111(b), a standard or an established set of a criteria, or perhaps both, are necessary to identify what is significant and what is not.

These criteria help ensure that the EPA's decision-making is well-reasoned and consistent. The EPA considers it particularly important to develop a set of criteria and/or a standard in order to determine when a *significant* contribution occurs, in order, as noted above, to distinguish it from a simple contribution. A contribution can be greater or lesser and remain a contribution, but a significant contribution determination necessarily involves a judgment about the degree of the contribution that rises to the level of significance. For such a judgment to be meaningful (and, of critical importance, to be understood by regulated parties and by the public), the Agency must identify the criteria it will use to determine significance.

2. Other Comments Received on the EPA's Basis for Regulating GHG Emissions from EGUs

Comment: Commenters stated that the EPA must make the specific pollutant findings of endangerment and significant contribution that are required in listing a source category in order to establish a NSPS for that pollutant. Commenters stated they are not arguing that the EPA could not or should not make these findings. Rather, that the Clean Air Act (CAA) requires the EPA to make two specific findings: (i) the specific "air pollution" to be regulated is "reasonably … anticipated to endanger public health or welfare"; and (ii) the specific source category "causes or contributes significantly to" that endangering air pollution. CAA section 111(b)(1)(A). The commenters said section 111(b)(1)A) is not ambiguous at all in this respect, and therefore the Agency's interpretation in the 2015 Rule directly contradicts the plain language of this section. Additionally, they said that in the 2009 Endangerment Finding, the EPA specifically defined air pollution, as referred to in section 202(a) of the CAA, to be the mix of six long-lived and directly emitted GHGs: CO_2, CH_4, N_2O, HFCs, PFCs, and SF_6 (74 FR 66497, December 15, 2009). They commented that the EPA did not make a separate finding then, or now, that CO_2 alone is a danger to the public health or welfare and the EPA has argued that because CO_2 is the "dominant

anthropogenic GHG," it is not required to "make an endangerment finding with respect to a particular pollutant." (*Id*). They argued that this view does not satisfy the statutory standard and said the GHG endangerment determination in section 111(b)(1)(A) is fundamentally different than that in section 202(a) and other CAA sections, in part because it: (i) is source-category based; and (ii) requires a finding of significance.

These commenters stated that in the 2015 Rule, the EPA made three arguments as to why it believed it had met its statutory obligations. The commenters stated that none of these arguments are correct as a legal matter for the following primary reasons: (1) the EPA was wrong in claiming that new CO_2-specific findings were unnecessary, as the 2015 Rule was for a new category of electric utility generating unit (EGUs) emitting CO_2—a specific pollutant for which an endangerment finding had not been made. EPA's prior listings of "steam generators" and "stationary gas turbines" covered only emissions of NO_X, SO_2, and particulate matter. Because EPA's findings in earlier listings addressed different pollutants, those listings triggered and authorized only regulation of NO_X, SO_2, and particulate matter. *Cf. Nat'l Asphalt Pavement Ass'n v. Train*, 539 F.2d 775 (D.C. Cir. 1976). EPA has asserted the authority to regulate under section 111 any pollutant for which EPA believes it has a "rational basis" to regulate (see 83 FR 65432; 80 FR 64530). But this "rational basis" standard is not the one authorized by section 111; the endangerment and significant contribution standard governs section 111 regulation. EPA cannot rewrite the statute to circumvent the endangerment and significant contribution standard that Congress prescribed for section 111 regulation.; (2) the EPA cannot rely on its 2009 finding regarding GHG emissions from automobiles which determined that "six well-mixed GHGs" in the "aggregate" endanger public health or welfare, as this "combined mix" is different air pollutant than the single pollutant controlled here (CO_2 alone). EPA has never found that CO_2

alone endangers public health or welfare, much less that CO_2 from fossil fuel-fired steam generating units (as opposed to motor vehicles) has that effect; and (3) the EPA's attempt to rely on "information and conclusions" contained in the 2015 Rule does not satisfy the CAA. Simply identifying the evidence that might support a finding is not the same as completing the administrative process of distilling and analyzing that data in the context of the Agency's statutory obligations and its failure to make the requisite findings of endangerment and significant contribution in the 2015 Rule violated the CAA. They said the CAA grants the EPA narrowly bounded authority to regulate stationary sources that emit pollutants that may reasonably be anticipated to endanger public health or welfare *for those pollutants* which led to the endangerment finding and to which the source category significantly contributes. The CAA does not grant the Agency unlimited authority to regulate any pollutant emitted by that source. Accordingly, before the EPA finalizes the 2018 Proposal, it must make a specific and supportable finding that CO_2 emissions from fossil fuel-fired EGUs pose a danger to public health and welfare. They said the EPA should reject its ill-founded "rational basis test" for imposing performance standards without endangerment and contribution findings. The Agency's rational basis test is not in the CAA. They argued that section 111 never uses the term and the case law on which the EPA relied for this test addresses agency authority under a different statute, the Administrative Procedure Act (APA). The APA does not define the scope of the EPA's authority to undertake this rulemaking.

Commenters added that as a textual matter, the endangerment requirement modifies, and relates back to, "air pollution," not "sources": The provision requires the EPA to determine whether a source causes or contributes significantly to "air pollution which may reasonably be anticipated to endanger public health or welfare." 42 United States Code (U.S.C.) section

7411(b)(1)(A). Only after the EPA determines that a pollutant poses a threat to "public health or welfare" must it inquire whether the particular category of sources "contributes significantly" to that pollution. *Id.* The idea that an endangerment finding is "one and done" on a source level also cannot be squared with the surrounding statutory requirements. Section 111(b)(1)(B) provides that the EPA may issue performance standards after a source category is listed pursuant to section 111(b)(1)(A). *Id.* section 7411(b)(1)(B). Yet by definition, a "standard of performance" is tied to specific pollutants for which an endangerment finding has been made. *Id.* section 7411 (a)(1) (defining a "standard of performance" as "a standard for emissions of air pollutants). Commenters said that as such, the approach in the 2015 Rule would give the EPA unfettered authority to regulate any air pollutant emitted by a source regardless of whether it endangers health or welfare and the 2015 Rule's approach of mixing and matching elements of endangerment findings would allow the EPA to impose stringent regulations on sources that do not "contribute significantly" to emissions of a pollutant. In summary, the commenters argued that if the EPA "retain[s]" the "statutory interpretation" of section 111 as set out in the 2015 Rule, 83 FR 65432 n. 25, it will once again be setting standards beyond the scope of its authority and it may be that the EPA can make the findings section 111(b)(1)(A) requires for CO_2 emissions from fossil-fuel-fired electricity generating units, but unless and until the EPA makes those determinations under the proper legal standard, the Proposed Rule will rest on a flawed foundation.

Commenters stated that the previous endangerment findings the EPA listed in the 2015 Rule did not relate to "fossil fuel-fired electricity generating units." (80 FR 64527 nn.86 & 87). Rather, one related to "steam generators," (36 FR 5931, March 31, 1971, -cited at 80 FR 64527 n.86), and the other to "stationary gas turbines," (42 FR 53657. October 3, 1977, - cited at 80 FR

64527 n.87). The commenters stated that this failing should prevent the EPA's ability to move forward with proposed regulation because the Agency has not issued the required endangerment finding for the specific source category, it becomes irrelevant whether it may rely on that (nonexistent) finding to justify setting standards of performance for different emissions from sources in the category.

Commenters stated that in the 2016 subpart OOOOa rulemaking, the EPA established NSPS for CH_4 without making an endangerment finding for CH_4 emissions from oil and gas sources. Commenters and other industry groups filed comments pointing out the EPA's omission in failing to make a section 111(b) endangerment finding for the new pollutant subject to regulation under NSPS. By imposing NSPS requirements for a new pollutant without first establishing that that pollutant "may reasonably be anticipated to endanger public health or welfare" *(i.e.,* making an endangerment finding), commenters urged the EPA to reject and withdraw the interpretation that the EPA may skip the endangerment finding step in this context. The commenters further urged the EPA to clarify that a statutory prerequisite for regulation of a new pollutant under the NSPS program is an endangerment finding for that particular pollutant. Finally, and as a separate matter, the commenters urged the EPA to revisit the legal underpinnings for the subpart OOOOa standards as the commenters asserted the EPA did not follow the statutory prerequisites for the adoption of such standards. According to the commenters, those standards are illegal as being outside of the agency's authority, and as such should now be withdrawn.

Other commenters stated that the EPA's previous approach in the 2015 Rule to determining that it has a rational basis to regulate GHGs emitted by this source category is sound. The Agency has correctly not reopened this approach, nor has it proposed any alternatives

to it. They said in the context of section 111, the endangerment finding is made with respect to the source category, and not as to specific pollutants (80 FR 64530). It would be unlawful for the Agency to finalize any alternative approach. In 2015, the EPA concluded that it possesses authority to regulate GHG emissions from fossil fuel-fired EGUs under section 111 for two reasons: (1) there was no new evidence calling into question its determination that "GHG air pollution may reasonably be anticipated to endanger public health and welfare"; and (2) fossil fuel-fired EGUs have a "high level of GHG emissions." These considerations hew closely to the statutory factors that inform the decision whether to list a source category in the first place—namely, whether the category "causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare." In fact, in 2015 the Agency confirmed that, even if it were required to issue endangerment and significant contribution findings under this provision in order to regulate GHGs emitted by EGUs, the same information that underpinned its rational basis conclusion would support such findings (80 FR 64530). This approach, which closely parallels the listing analysis but does not require formal endangerment or cause-or-contribute findings, is legally sound. The statute is clear that a formal endangerment finding is required to initially list a sector to be regulated under section 111—and is also clear that such a finding is not required before regulating additional harmful pollutants from a previously-listed sector. Because Congress did not provide specific criteria for regulating additional pollutants from a source category that is already listed under section 111, it is reasonable to look to the statutory factors that trigger regulation initially when deciding whether to require reductions of other pollutants. They said the statutory factors for listing a source category—the endangerment and cause-or-contribute findings—provide a floor for when EPA *must* regulate an additional pollutant from a listed source category under the rational basis

inquiry. It would be irrational to fail to regulate an additional pollutant simply because a source category was already listed, if the same evidence regarding that pollutant would have triggered a formal listing of that source category had the source category not previously been listed. Thus, it would be arbitrary for the agency to decline to regulate a pollutant on the basis of considerations wholly unrelated to the harms that pollutant poses or the quantities in which it is emitted from a particular source category.

Other commenters also stated that any effort to reverse the EPA's decision to regulate CO_2 from power plants would require, among other things, that the EPA fully contend with each step of the statutory and legal analysis of section 111 it undertook in the 2015 Rule, and explain why each of them has become invalid. They said promulgating a final rule contrary to the 2015 Rule without the requisite record-based, factual analysis and reasoned explanation would yield "an unexplained inconsistency in agency policy" that is arbitrary, capricious, and unlawful. Commenters stated that that while the most comprehensive approach to sensible GHG regulation remains through congressional action, and while the CAA is far from the perfect tool for regulating GHGs, it is preferable to protracted legal battles and to the potential patchwork of judicial and regulatory outcomes. As a result, the Agency should retain the existing endangerment finding. They said that if the EPA fails to regulate GHG emissions from new coal-fired EGUs it would be wholly unreasonable and contrary to the endangerment finding.

Response: The EPA addressed the substance of these comments in a lengthy discussion in "Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Review: Final Rule," 85 FR 57018, 57033-40, 57052-58 (September 14, 2020). That discussion is incorporated by reference here. That discussion further elaborates the rationale for EPA's determination that a pollutant-specific significant contribution determination is

appropriate, and EPA's related determinations. That discussion also responds in full to the comments on the present rule.

It should be noted that in the 2015 Rule, EPA combined the steam generating source category and combustion turbine source category into a single source category for purposes of GHG emission regulation, 80 FR 64510, 64521-32 (October 23, 2015), and determined, in the alternative, that GHG emissions from the combined source category contribute significantly to dangerous air pollution. *Id.* at 64531. In today's rulemaking, the EPA is not revising the source category determination in the 2015 Rule and, by the same token, the significant contribution finding that EPA is making in the present rulemaking for GHG emissions concerns emissions from the same, combined source category.

Comment: Commenters stated that if the Endangerment Finding is overturned, the electric power sector could be broadly exposed to tort and nuisance suits brought by citizens and states—as was the case prior to the EPA regulation of GHGs (*e.g.*, *American Electric Power Co. v. Connecticut*, 564 U.S. 610 (2011)). Accordingly, these efforts would create more uncertainty about the future of GHG regulations applicable to new EGUs—uncertainty that likely would not be resolved for years and could undermine any potential for generation owners and operators to consider new coal-based generation as a viable option. They said as a result, the Agency should retain the existing endangerment finding.

Response: The Agency has not proposed to overturn the existing Endangerment Finding and is not overturning it in this final rule.

Comment: Commenters stated that to the extent that emissions of CO_2 from new, modified, or reconstructed electric utility generating units are to be subjected by the EPA to regulation under the CAA, the proper path would be to regulate such emissions as part of a

broader effort to regulate CO_2 emissions from "numerous or diverse" sources under sections 108-110 of the CAA. Alternatively, if the EPA is adamant in engaging in regulating such emissions under section 111(b), at the very least the EPA must complete a specific endangerment finding for CO_2 emissions from such facilities under the applicable criteria set forth in section 111(b), which the EPA has failed to do to date. Either way, commenters stated that the proposed rule amendment is beyond the legal authority of the CAA.

Response: EPA is making a pollutant-specific significant contribution finding in this action.

Comment: Commenters quoted the NSPS proposal as stating that "the Agency will consider comments on the correctness of the EPA's interpretations and determinations, and whether there are alternative interpretations that may be permissible, either as a general matter or specifically as applied to GHG emissions" (83 FR 65242, 65432 n.25). Commenters then stated that they filed a petition in 2017 contending that the EPA should commence a new rulemaking on the subject of the Agency's 2009 endangerment finding. They provided the following arguments of the 2017 petition: 1) there had been no statistically significant atmospheric warming despite a continued increase in atmospheric CO_2 levels; 2) changes in global temperatures in recent decades were far from unusual; 3) new balloon and satellite data showed that the atmosphere was far less sensitive to CO_2 forcing than the climate models had predicted; and 4) there was mounting evidence that the EPA's GHG rules would have no discernible climate impact. For these reasons, they said there was a need to reexamine both the three lines of evidence for the EPA's endangerment finding as well as its underlying rationale. Regarding the proposal, the commenters stated that in addition to their still pending petition, they are providing new evidence for why the Agency should proceed with this petition and with similar petitions

pending before it. They submitted references (titles, weblinks, and synopses) to nine research papers published since filing their initial petition which they argue add additional support. They stated that given the points and data outlined in this newer research, in addition to those set forth in their 2017 petition, the EPA should commence a new proceeding to reexamine its 2009 endangerment finding.

Response: The Agency is retaining the existing endangerment finding. The submitted material is out of scope for this rulemaking. With regards to the claim that EPA was soliciting comments on this subject, the footnote quoted by the commenters goes on to specifically outline examples of the kind of comments referred to: this further elaboration made clear that EPA was not soliciting comments on the science of climate change but rather regarding interpretation of statutory language and legal opinion as to whether the Agency would need to make an endangerment finding for previously listed source categories ("For example, the Agency will consider comments on the issue of whether it is correct to interpret the "endangerment finding" as a finding that is only made once for each source category at the time that the EPA lists the source category or whether the EPA must make a new endangerment finding each time the Agency regulates an additional pollutant by an already-listed source category. Further, the EPA will consider comments on the issue of whether GHG emissions are different in salient respects from traditional emissions such that it would be appropriate to conduct a new "endangerment finding" with respect to GHG emissions from a previously listed source category. In addition, the EPA solicits comment on whether the Agency does have a rational basis for regulating CO_2 emissions from new coal-fired electric utility steam generating units and whether it would have a rational basis for declining to do so at this time" 83 FR 65242, 65432 n.25).

Comment: Commenters also said that the Agency suggestion in footnote 25 of the Proposal is unreasonable in that the Agency seems to presume that it might not be appropriate to regulate GHGs from new coal-fired power plants because the Agency projects that few such plants will be built in coming years. They said this approach asks the wrong question. The question should be whether there is a rational basis to regulate GHGs from power plants – not just new coal-fired plants. This is because, once new sources are regulated under section 111(b), the obligation to regulate existing sources under section 111(d) is triggered. If new sources in a source category could not be regulated under section 111(b), no sources in the category could be regulated. Commenters further stated that the EPA cannot reverse its position merely by asking for comments on whether it should adopt a new position diametrically opposed to both current law and the position it maintains in the Proposed Rule.

Commenters stated that using footnote 25 as a means of requesting public comment is misleading and violates administrative procedures. They said that it appears that the EPA is seeking rationale or justification to under the legal basis for this rule while claiming that is retaining its legal basis. The EPA cannot have it both ways: either EPA is using its legal basis, or it is looking for alternatives. If it is looking for alternatives, then EPA has not met its responsibilities under the Administrative Procedures Act for fair notice of the nature and scope of this rulemaking.

Commenters stated that in the endangerment finding footnote of the 2018 Proposal (83 FR 65432 n 25), the EPA suggests that it may consider whether it would have a rational basis to decline to regulate given that "no more than a few new coal-fired EGUs can be expected to be built." The commenters said this suggestion is not legally or factually sound and does not provides a valid reason not to regulate GHGs from fossil fuel-fired EGUs under section 111.

They said the statute is unambiguous: the EPA must consider pollution from both new and existing sources when deciding whether to regulate a pollutant within a source category. To the extent that the statute contains any ambiguity, a decision not to regulate based solely on projected levels of emissions from new sources would be disallowed as an impermissible construction. They argued that section 111(b) unambiguously expresses Congress's concern with pollution emitted from a source category as a whole, not just new sources and 111(b) directs the Administrator to base decisions about whether to list a source category on an analysis of the entire category, including existing sources. Section 111(b)(1)(A) does not distinguish between "new" and "existing" sources but rather conveys Congress's directive to address pollution across the source category.

The commenters also stated that Footnote 25 of the proposal raises the prospect that, on the question of regulating a pollutant from a listed source category, Congress inexplicably intended for the EPA to consider pollution from new sources only, irrespective of the harm caused by pollution from existing sources—and even though Congress directed the EPA to consider the air pollution from the sector as a whole, that plain language should be ignored. They said the Agency presents no support for this theory, which is contrary to both the clear terms and the evident objective of the statute. The commenters argued that Footnote 25's suggested interpretation disregards statutory language in other ways as well. For example, section 111(b)(1) provides that the Administrator "shall include a category of sources in such list if in his judgment it *causes, or contributes significantly to*, air pollution which may reasonably be anticipated to endanger public health or welfare." (42 U.S.C. section 7411(b)(1)(A)). Yet as of the date of when the EPA determines to list a source category, there are no "new" sources in existence. Section 111(a)(2) provides: "The term "new source" means any stationary source, the

construction or modification of which is commenced *after the publication of regulations (or, if earlier, proposed regulations) prescribing a standard of performance under this section* which will be applicable to such source." (*Id.* section 7411(a)(2)). They said under section 111, listing *precedes* promulgation of standards. So, when the EPA decides whether to list a category, by definition it has not yet *proposed* section 111 standards for that category and because it has not proposed such standards, no sources qualify as "new" sources under section 111(a)(2). Basing a decision not to list (and therefore not to regulate) a source category solely on the absence of emissions from as yet nonexistent "new" sources—while ignoring sources that already exist and are emitting pollutants that threaten harm to public health and welfare—is not a tenable reading of the statutory language.

Response: In this rule, EPA takes the position that GHG emissions from new and existing EGUs contribute significantly to dangerous air pollution. While EPA proposed to retain the position that it stated in the 2015 Rule that a pollutant-specific significant contribution finding is not required, it solicited comment on whether such a finding is required, and that comment solicitation provided adequate notice.

Comment: Commenters stated that though the EPA notes that it is not proposing to revisit its 2009 endangerment finding for greenhouse gases, the proposed NSPS revisions request comment on whether recent and projected power sector trends present a rational basis to decline to regulate CO_2 emissions from the power sector. The suggested comment area, presented in footnote 25, cites power sector trend projections from the Energy Information Administration's (EIA's) 2018 Annual Energy Outlook and findings from the EPA's proposed Affordable Clean Energy (ACE) rule as potential support for this position. Commenters also stated that the EIA's 2018 Annual Energy Outlook does not indicate that power sector CO_2 emissions will decline

significantly in the future. Instead, the estimates referenced by the EPA in the proposal project that CO_2 emissions from the power sector will remain the single largest sector-based source of CO_2 emissions over the long term, totaling 1.72 billion tons in 2020, 1.71 billion tons in 2030, and 1.78 billion tons in 2050. Commenters said though the EPA found that the transportation sector overtook the power sector as the largest sector-based source of GHG emissions in 2017, the 2018 Annual Energy Outlook projects that power sector emissions will regain the top ranking in 2026 and maintain a lead over the transportation sector by growing modestly through 2050. Commenters stated while newer EIA projections that were unavailable at the time of the EPA's proposal indicate slightly lower power sector CO_2 emissions, EIA still projects significant and sustained power sector GHG emissions through 2050, not a steady decline. Commenters said a report from the Rhodium Group based on preliminary EIA data for 2018 and released a few weeks after the EPA's proposal estimates that power sector-related GHG emissions increased 3.4 percent in 2018, breaking a three-year trend of decreases. Commenters added still more recent EPA data reveals the same pattern. Commenters stated preliminary 2018 emissions data compiled by EPA's Clean Air Markets Division (CAMD), also released after the proposed NSPS revisions were published in the *Federal Register*, show power sector CO_2 emissions rising from 1.92 billion tons in 2017 to 1.93 billion tons in 2018. Commenters said prior to the 2018 release, EPA's CAMD data had shown flat or declining CO_2 emissions for every year since 2013.

Commenters stated it would be unlawful and arbitrary for the EPA to use declining power sector emissions as reason for not regulating. They argued that even if power sector emissions are declining—which is not at all clear—they are far higher than levels necessary to keep CO_2 concentrations from rising further, let alone to achieve the necessary net-zero balance. CO_2 pollution accumulates in the atmosphere, where it lingers for centuries, such that a year-to-year

decline in emissions does not prevent atmospheric concentrations from continuing to rise, exacerbating the impacts of climate change. "[T]he urgency of reducing emissions now," (80 FR 64520) which the EPA acknowledged in the 2015 Rule, has only increased in recent years. Commenters said reliance on recent emission trends is even more unfounded because U.S. climate pollution significantly increased in 2018, including a 1.9 percent increase in power sector carbon pollution. Even before the 2018 data were available, U.S. Energy Information Administration (EIA) had recognized long-term market and economic uncertainty, which could potentially drive some shift back to coal generation. EIA projections now show that the general trend toward declining carbon pollution from the power sector is likely to flatten out in the early 2020s. Commenters stated standards that even if pollution levels were declining more steadily, that would not authorize the EPA to ignore its obligation to protect the public from what will continue to be a major threat to public health and the environment. The CAA is not concerned merely with whether pollution levels are currently below their historic peak. To the contrary, the Agency must ensure that pollution is controlled to the degree the statute requires—*i.e.*, in accordance with a standard of performance that reflects the best system of emission reduction (BSER) (42 U.S.C. section 7411(a)(1)).

The commenters also said that there may be other reasons why a developer would be willing to pay a premium to build a new coal-fired plant that the models do not consider (80 FR 64559-64562). Thus, it is unreasonable not to establish standards of performance on the assumption that coal-fired power plants will never again be built (or modified). They said that the Agency does not even consider the fact that the source category includes not only new sources but also existing sources that undergo certain "modifications," and that such modified sources have significant CO_2 emissions.

Commenters said that by asking whether the Agency has a rational basis for regulating CO_2 emissions from new coal-fired EGUs "in light of" the projections cited in footnote 25, the EPA is setting itself up to conduct continual market evaluations for all the EPA regulations for which regulation is premised on a similar type of prerequisite determination. An interpretation of section 111 that leads to that result is unreasonable and impractical. They said that there is no indication in the CAA that Congress intended the Agency to undertake a continual market assessment of this nature.

Commenters stated that the endangerment finding footnote of the 2018 Proposal (83 FR 65432 footnote 25) contains a fatal factual deficiency in that it suggests that the rational basis finding might be reversed because "no more than a few new coal-fired EGUs can be expected to be built, which raises questions about whether new coal-fired EGUs contribute significantly to atmospheric CO_2 levels." The commenters said that not only does this suggestion disregard the EPA's 2015 acknowledgment that "the CO_2 emissions from even a single new coal-fired power plant may amount to millions of tons each year," but it entirely ignores natural gas-fired power plants, which are also included in the source category. In making the 2015 determination, the EPA specifically observed that "the CO_2 emissions from even a single natural gas combined cycle (NGCC) unit may amount to one million or more tons per year." They said natural gas-fired power plants continue to be built at a steady clip as evidenced by the first ten months of 2018 in which 14.9 gigawatts (GW) of natural gas-fired EGU capacity was added to the grid. New gas plants must be accounted for and by failing to do so, the Agency would forfeit any "rational connection between the facts found and the choice made," and would fail to provide "a reasoned explanation . . . for disregarding facts and circumstances that underlay . . . the prior policy." Each of those flaws would render the decision arbitrary and capricious. Commenters

said that even if the EPA legally could regulate CO_2 emissions from new natural gas plants without regulating CO_2 emissions from new coal-fired power plants, the EPA should not do so because such partial regulation would provide an inadvertent subsidy to new coal-fired plants.

Response: In this rule, the EPA is determining that GHG emissions from EGUs contribute significantly to dangerous air pollution and is promulgating revised standards of performance for EGU GHG emissions. To the extent it is useful or necessary in this rulemaking for the EPA to further address whether long-term emission trends, or related considerations, are relevant for a significant contribution determination, the EPA does so elsewhere in this document.

C. Primary Criteria for Determining Significance

In this section, the EPA describes criteria for determining when GHG emissions from a source category contribute significantly to dangerous air pollution in response to comments submitted on this rule. The EPA indicated in the 2020 Oil and Gas Policy Rule that it would finalize these criteria in a separate rulemaking. 85 FR 57039.

1. GHG Emissions

The criteria discussed herein only apply to GHG in the context of the EPA's SCF under CAA section 111(b)(1)(B). This action does not discuss criteria for pollutants other than GHGs. Under this framework, the EPA is determining that the quantity of GHG emissions from a source category is the primary criterion in determining significance for purposes of regulation of GHGs from a source category under CAA section 111(b). Gross GHG emissions are important for this set of pollutants because GHGs are global long-lived pollutants and do not have the local, near-term ramifications found with other pollutants (*e.g.*, criteria pollutants). Unlike other pollutants where both the location and quantity of pollution emissions are factors in determining the impact

of the emissions, GHGs' impact (*i.e.*, climate change) is based on a cumulative global loading and the location of emissions is not nearly as important a factor as it is for assessing local, near-term impacts associated with criteria pollutants. It is for this reason that, when the EPA is assessing GHGs impact in contributing significantly to air pollution which may reasonably be anticipated to endanger public health and welfare, the quantity of emissions should be the primary criterion that the EPA should evaluate.

The GHG emissions are the best, but not necessarily only, indicator of significance because the quantity of emissions emitted from a source category correlates directly with impacts. Calculations using the Model for the Assessment of Greenhouse Gas Induced Climate Change (MAGICC model) to investigate the impact of including or eliminating a single sector's emissions from 2020 through 2100 have shown that the magnitude of emissions from that single sector is very close to being linearly related to the projected temperature change in 2100 resulting from eliminating that sector's emissions. This is consistent with the results of a number of peer reviewed publications in the past decade: *e.g.*, Matthews *et al.* found that the temperature change is roughly proportional to the total quantity of CO_2 emissions over a wide range of potential scenarios.[8]

A threshold of GHG emissions from the source category compared to the rest of the U.S. GHG emissions (*i.e.*, the percent of total U.S. GHG emissions) can be used to demonstrate significance. Emissions can be large enough from a source category that the evaluation of GHG emissions in isolation is sufficient for making a finding of significance for the source category. Conversely, the EPA believes that some source categories are sufficiently small in GHG

[8] H. Damon Matthews, Nathan P. Gillett, Peter A. Stott & Kirsten Zickfeld, The Proportionality of Global Warming to Cumulative Carbon Emissions. Nature 459, 829-832 (2009), available at *https://www.nature.com/articles/nature08047*.

emissions that a finding of insignificance can be made by only evaluating the GHG emissions from the source category. For many source categories, the evaluation of GHG emissions alone will be sufficient for determining whether there is significant contribution.

It should be noted that under section 111(b)(1)(A), the EPA is required to make a significance finding on a category-by-category basis. That provision requires the Administrator to list "*a* category of sources" for regulation if he determines that "*it* causes or contributes significantly to" dangerous air pollution. Section 111(b)(1)(A) (emphasis. added). As a result, the text of 111(b)(1)(A) compels or is at least best read to require the EPA to make the significance determination for a particular source category on the basis of the emissions (or other relevant attributes) of that particular source category. In contrast, the EPA may not combine source categories that individually would not meet the significance criteria and determine that, when combined, the source categories do meet the significance criteria.[9]

2. Using a Threshold in Significance Determination

Under this framework, the EPA is determining a threshold for the evaluation of significance of GHG emissions from source categories. The use of a clear threshold provides certainty regarding the EPA's process and allows the regulated entities to have insight into how the EPA will make determinations on significance for their respective source category. The threshold introduced in this rulemaking is a reflection of the EPA's best understanding of the landscape of the U.S. GHG emissions from stationary sources. The EPA is introducing a methodology to evaluate significance with respect to the U.S. GHG emissions that can be applied

[9] By the same token, as the EPA explained in the 2020 Oil & Gas Rule, there are limits to the EPA's ability to expand a source category to include other sources. As the EPA stated in that rule, "the authority to revise the scope of a source category must be exercised within reasonable boundaries and cannot be employed in a way that results in an unreasonable expansion of an existing source category.... [T]he EPA is not authorized to expand the scope of a listed source category to cover a new set of sources that are not sufficiently related to the sources in the pre-existing category...." 85 FR 57027.

for any source category, and that application of the methodology is only being directly applied to the EGU source category in this action as further introduction of this approach. It is important to note that a significance determination for the U.S. GHG emissions will be needed before the EPA may regulate any other source category under CAA section 111(b) for GHG emissions.

As Table 1, below, makes clear, there are at least two natural breakpoints between groups of emitting source categories. The first natural breakpoint is between EGUs and all other source categories. EGUs stand out as by far the largest stationary source of the U.S. GHG emissions, emitting over 25 percent of all the U.S. GHG emissions. Based on available data, the next largest source category, Oil and Natural Gas, emits just under 3 percent of U.S. GHG emissions. Two other source categories, Boilers and Petroleum Refineries, also fall between 2.5 percent and 3.0 percent of U.S. emissions. Between 1.5 percent and 2.5 percent of U.S. GHG emissions there is another natural breakpoint and all of the remaining source categories fall below 1.5 percent of the U.S. GHG emissions. Note that source category emissions in Table 1 are an estimate of what the Agency currently understands about the emissions from CAA section 111 source categories. If the EPA were to do a rulemaking and a significance determination for a specific source category, the EPA would do a thorough analysis of the available and attributable GHG emissions data to ensure appropriate determinations and assessments.

TABLE 1. EXAMINATION OF GHG EMISSIONS FROM LARGE STATIONARY SOURCES OF GHG EMISSIONS

% of Total US GHG Emissions	Emissions in that Range (MMT CO_2e)*	Source Categories Affected at Different Thresholds	Percent of US GHG Emissions from Stationary Sources Covered at Given Threshold
Above 25%	>1670 MMT	EGUs (1778 MMT/27% of total US GHG Emissions, 3.6% of Global emissions)	43%

3% to 25%	200 MMT-1670 MMT	No categories identified	43%
2.5% to 3.0%	167-200 MMT	Oil/Gas Production and Processing^; Refineries; Boilers	56%
2.0% to 2.5%	134-167 MMT	No categories identified	56%
1.5% to 2.0%	100-134 MMT	No categories identified	56%
1.0% to 1.5%	67-100 MMT	Landfills[1]; Iron and Steel	60%

** MMT CO_2e = Million metric tons of carbon dioxide equivalent*
^ Note that the oil and gas production and processing GHG emissions are very close to the 3% value and thus there is a possibility that this source category may be above the threshold in the near term.
[1] Note that the Landfills source category has already been regulated under CAA section 111 and the level of the emissions in Table 1. reflects reductions in GHG emissions as a result of that regulation as a co-benefit.

The EPA is introducing a threshold of 3 percent of U.S. GHG emissions to evaluate a source category's emissions to determine significance for purposes of CAA section 111(b). The EPA is also determining that source categories that are less than this value (*i.e.*, 3 percent or less) are necessarily insignificant without consideration of any other factors. The reasoning for choosing this threshold is presented later in this document.

The EPA acknowledges that, when interpreting other CAA provisions, the EPA has used different thresholds to define "significant contribution," but it is appropriate to select a threshold based on the nature of the problem being addressed. For example, to address the problem of interstate transport under CAA section 111(a)(2)(D)(i)(I) -- which concerns criteria pollutants, *i.e.,* pollutants that affect the NAAQS -- the EPA selected a threshold of 1 percent based on analysis of air quality modeling specific to the criteria pollutant at issue. 76 FR 48208, 48236 (August 8, 2011) (Cross-State Air Pollution Rule (CSAPR)). For criteria pollutants, both the location and quantity of emissions are factors in determining their impact. In contrast, the impact of GHGs (*e.g.*, climate change) is based on a cumulative global loading, and the location of emissions is not nearly as important a factor as it is for assessing local impacts associated with criteria pollutants. Because GHGs do not have the local near-term impacts that criteria pollutants

tend to have, a larger value is appropriate to use in determining significance as it still addresses the health and welfare impacts of GHG emissions without specifically evaluating local near-term impacts, which is analytically unreasonable to do given the global nature of GHGs. While the 3 percent threshold will be applied against domestic emissions, source categories exceeding that threshold represent a much smaller fraction of global GHG emissions.[10]

By determining a threshold, the EPA is setting a clear indication of how source categories will be evaluated for significance based on GHG emissions. For those source categories that are below the 3 percent threshold, the EPA would make a determination (through future rulemaking) of insignificance. This means that if a source category collectively emits 3 percent or less of the total U.S. GHG emissions, it will be considered to be insignificant. For those source categories that are above the threshold, a more detailed evaluation of other criteria can be used to make a determination of significance. This is described in section IV.D below. It is important for the EPA to make this clear indication as it allows source categories and the general public a level of transparency as to how the EPA will be evaluating source categories for significance. The threshold in this action will provide a degree of certainty regarding whether a source category will later be found significant or insignificant based on the threshold.[11]

After evaluating the two natural break points in GHG emissions, the EPA determined that 3 percent of the U.S. GHG emissions was the best threshold for determining significance. As

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[10] The EPA recognizes that in the 2016 Oil & Gas Rule, it determined that GHG emissions from the oil and natural gas source category contribute significantly to dangerous air pollution, in part, on the grounds that those emissions exceeded the total amount of emissions from various foreign countries. 81 FR 35824, 35840 (June 3, 2016). The EPA believes that its current approach of identifying a threshold for significance based on a percentage of U.S. emissions is better reasoned than the 2016 Oil & Gas Rule's approach of drawing comparisons to the absolute emissions of other countries.

[11] The EPA does not currently have a comprehensive inventory of the U.S. GHG emissions for all of the NSPS source categories. For the EPA to make determinations of significance for a source category, a more comprehensive emissions profile of a source category should be used. The EPA will make determinations of significance for other source categories in the future.

noted above, there is currently only one source category above this threshold, EGUs, and the evaluation of significance for the EGU source category has been a topic explored and discussed by the Agency in great detail over the course of the last decade.[12] Just below the 3 percent threshold are three source categories: Oil and Natural Gas, Petroleum Refineries, and Industrial-Commercial-Institutional Steam Generating Units (*i.e.*, "Boilers"). There are no other source categories with GHG emissions between 1.5 percent and the 3 percent. By using a threshold of 3 percent of the U.S. GHG emissions (*i.e.*, only including EGUs above the threshold), the EPA will effectively be covering 43 percent of the U.S. stationary source GHG emissions via regulation of a single source category. If the EPA were to instead set a threshold between the other identified breakpoint – between 1.5 percent and 2.5 percent of U.S. GHG emissions – the EPA observes that this threshold would lead to a relatively modest increase in the stationary source U.S. GHG emissions that would be regulated of an additional 13 percent (for a total of 56 percent of U.S. stationary source GHG emissions).[13] In addition, regulation of the additional source categories that comprise 13 percent of U.S. emissions would eliminate only a portion of those emissions. With an even lower threshold of significance set at 1.0 percent of U.S. GHG emissions, there would be significantly more source categories covered (about 10 based on the EPA estimates) above the threshold but likely would include an even more modest increase in stationary source GHGs that would cover 60 percent of U.S. stationary source GHGs. Under this framework, the EPA is basing a decision to apply a threshold of 3 percent on the relative contribution of regulating source categories that contribute significantly to the overall impact of climate change. To that end, the temperature impact associated with the hypothetical elimination

[12] *See* 79 FR 34960 and 80 FR 64510.

[13] Note that one of those "next three largest" source categories is oil and natural gas. In the recently finalized policy package, the EPA found that regulation of GHGs from this source category is unnecessary as it is currently being controlled by regulation of volatile organic compounds. See 85 FR 57018, 57030 (September 14, 2020).

of all source categories above a 3 percent threshold corresponds to a hypothetical global mean temperature reduction of 0.049 degrees Celsius (°C) (approximately 0.1 degree Fahrenheit, the calculated effect in 2100 of removing 1,780 million metric tons (MMT) of CO_2 emissions each year from 2020 through 2100) from source categories above that threshold (*i.e.,* just EGUs). Eliminating the next largest source category (*i.e.*, Oil and Gas Processing and Production) would only generate an additional hypothetical global mean temperature reduction of less than 0.01°C and even smaller source categories correspondingly contribute less to global temperature. The EPA is making the decision that the threshold for a significance determination for U.S. GHG emissions to be in the form of a percentage. A percentage is a metric that measures the relative contribution to the whole and, in this action, the EPA believes that it is appropriate to measure and evaluate significant contribution of U.S. GHG emissions as a relative contribution to the whole of GHG emissions in the U.S. The EPA is determining that a threshold in the form of a percentage is both reasonable and more appropriate for making the significance determination in this rule based on a percent's relative nature. This is important because the trajectory of U.S. GHG emissions is trending down. As overall emissions decrease over the course of time, a source category's relative contribution to GHGs may not have changed or may have even increased based on GHG reductions in other source categories and sectors. A relative percentage threshold recognizes that the EPA may later determine a source category is significant based on these circumstances, because a source category's emissions may eventually exceed the threshold even though it is currently below the threshold. Accordingly, a percentage threshold allows the EPA, over time, to always focus on the source categories with the potential to have the greatest impact. The framework on which EPA bases its decision today is, therefore, amenable to future use, which augurs in favor of the framework's use to make today's finding.

The EPA is introducing in this action that a threshold in the form of a percentage is both reasonable and more appropriate for making a significance determination for GHGs based on a percent's relative nature. A tonnage threshold is a static metric that would not change over time. As previously described, the trajectory of U.S. GHG emissions is trending down. As emissions decrease over the course of time, it is likely that source categories that were once above any static threshold will fall below such a threshold. Even though a source category may reduce overall U.S. GHG emissions, that source category's relative contribution to GHGs may not have changed or may have even increased based on GHG reductions in other source categories and sectors. Additionally, if emissions do decrease over time, the use of a tonnage threshold potentially results in no source category meeting the criteria for significance, even if collectively the U.S.GHG emissions continue to pose a danger to public health or welfare.

It should be noted that the U.S. GHG emissions of the EGU source category are more than an order of magnitude larger than the emissions threshold in the framework, representing 43 percent of U.S. stationary source GHG emissions. The EPA believes that it is possible for source categories with GHG emissions substantially larger than the threshold to be deemed significant on the basis of the primary criterion alone (*i.e.*, magnitude of emissions) and without consideration of the secondary criteria described elsewhere in this notice.

3. Tiers of Source Categories Based on GHG Emissions

As noted previously, the primary criterion in evaluating the significance of a source category is, again, the relative magnitude of the U.S. GHG emissions. The EPA believes that NSPS source categories may be grouped into three tiers on the basis of magnitude of the U.S. GHG emissions, as follows:

(1) *Source category with GHG emissions substantially above the threshold.* This source category has emissions of a large enough magnitude that a determination of significance can be made on the basis of the magnitude of emissions alone. As discussed later in this document, this tier is comprised solely of the EGUs source category; in other words, EGUs do not require consideration of the secondary criteria in order to determine significance.

(2) Source categories with an intermediate magnitude of the U.S. GHG emissions (i.e., those with emissions above the threshold but less than the quantity emitted by the EGU source category). For source categories with emissions above the threshold, evaluation of the magnitude of the U.S. GHG emissions is inconclusive. Rather, a significance determination requires an examination of the source category's magnitude of emissions combined with a more detailed look at the secondary criteria discussed elsewhere in this document.

(3) *Source categories with a small magnitude of GHG emissions (i.e., those with emissions below the threshold).* Source categories with a small magnitude of emissions will be deemed insignificant based on evaluation of the primary criterion alone, without detailed consideration of any secondary criteria.

D. Secondary Criteria for Determining Significance

As described above, the EPA is determining that the U.S. GHG emissions from a source category are the primary and most important criterion for making a determination of significance for a source category. However, there may be instances where the U.S. GHG emissions from a source category do not give a comprehensive enough picture to make a determination of significance. The threshold that the EPA has described above in Section IV.B would provide a

clear indication that the U.S. GHG emissions from source categories below that threshold are necessarily insignificant. However, under this framework, for any source category that is above that threshold, there are other source-category specific considerations that should be evaluated in addition to GHG emissions when making a determination of significance.[14] For that reason, the EPA will consider other, secondary, criteria in the evaluation of significance for certain source categories. These other criteria are described in the subsequent subsections. It is important for the EPA to consider secondary criteria in the evaluation of significance for certain source categories because the criteria provide unique context to the source category beyond the information provided by the magnitude of the source category's GHG emissions.

1. Evaluation and Context of GHG Emissions

Under the introduced framework, the evaluation of the magnitude of the U.S. GHG emissions from a source category is a substantial indicator of whether a source category is significant, but in the specific instance of source categories that have greater GHG emissions than the threshold, an evaluation based on the magnitude of the U.S. GHG emissions may be inconclusive. Within the introduced framework, there are other emissions-based metrics that must be evaluated to clarify and make a significance determination for these source categories.

a. *Source Category Trends*

An important criterion that can help illuminate and contextualize a significance determination is an evaluation of the trends in emissions and number of designated facilities within a source category. Primarily, the EPA is evaluating whether a source category is on a trajectory of the U.S. GHG emission decline. If the source category, as a whole, is decreasing its

[14] Although there is no source category other than EGUs above the 3% threshold, because the threshold is a percentage and as previously described, other source categories may move into this tier as overall GHG emissions decrease and other source category emissions increase.

GHG emissions, an explanation for why it is on the decline may aid in making a significance determination. In one scenario, if the source category is decreasing emissions because the source category is declining in production or other output (*e.g.*, due to decreasing demand for goods or other market conditions, due to relocation overseas, or due to the cumulative effect of regulations), it may lend towards an insignificance determination as the emissions are already declining and expected to continue to decline even without further regulation. In a separate scenario, if a source category's GHG emissions are declining due to increased efficiency and updated technology, it may lend towards a determination of significance. This would allow the EPA the ability to regulate the source category in order to ensure that efficiency and technology improvements become standard across the source category through both an NSPS (111(b) regulation) for new, modified and reconstructed sources and an emission guidelines (111(d) regulation) for existing sources.

In a scenario in which the EPA were to find a source category to be growing in either emissions or number of designated facilities (or both), it could lend towards that source category being found to be significant. This would allow EPA to regulate and mitigate emissions from new, modified and/or reconstructed designated facilities within that source category under CAA section 111(b) (*i.e.*, via a NSPS).

If the EPA were to evaluate the trend in the number of designated facilities and emissions of a source category, it might show a static number of existing facilities with a constant or slightly increasing quantity of the U.S. GHG emissions. In this scenario, there may be little utility in determining significance for that source category and consequentially developing a NSPS as there are little to no emissions that would be subject to such a standard. However, creating a NSPS for a source category and pollutant is a necessary predicate to regulating

existing sources under CAA section 111(d). Hence, in the scenario of a static number of existing facilities, a finding of significance for the source category may be warranted as it would allow eventual regulation of a group of existing source categories. Under this framework, the EPA expects the prospect of regulating a source category under CAA section 111(d) for existing sources to be a compelling reason for determining significance.

b. Source Category Emissions with Global Context

Another important criterion that the EPA considers, as a secondary factor, is the relative contribution of GHG emissions from the U.S. in a specific source category compared to worldwide emissions of similar sources. As previously described, Section 111(b)(1)(A) of the CAA states that the Administrator shall include source categories that contribute significantly to endangerment of health and welfare. When evaluating a global pollutant such as GHGs, the EPA views the impact of domestic emissions from domestic sources as a more germane consideration when determining whether a pollutant contributes significantly to endangerment of health or welfare. Because every ton of GHG contributes to the global problem, a domestic ton will still have some impact in the U.S. Accordingly, it is reasonable for the EPA to evaluate whether a source category is well-regulated internationally and whether the U.S. emissions from that sector make up a relatively large share of GHG emissions on a worldwide scale, as such evaluation in turn would inform whether U.S. emissions are significantly contributing to domestic impacts. If the emissions from the U.S. are comparatively a large contribution to source category/sector emissions worldwide, it may lend towards a finding of significance for the source category based on the U.S.'s substantial global contribution to the source category. If, however they are relatively small, it would suggest less benefit from the EPA regulation of that source category.

The EPA also considers, as one of the secondary criteria, an evaluation of whether a source category is vulnerable to being trade exposed (*i.e.* whether the source category is constrained in the sources' ability to pass through carbon costs due to actual or potential international competition). The EPA evaluates whether regulation of the source category would create a financial incentive for that source category/industry to move into, or increase production in, another country. This could be manifested as either a shift in production to facilities internationally or a complete closure of existing designated facilities in the U.S. It is not the EPA's intention in regulating source categories to drive production from the U.S. to other countries, and there is an environmental concern in pushing industries to other international locations. This concern is based on the potential for these new international emissions to increase compared to the corresponding displaced U.S. emissions.[15] While this is always a concern for the EPA in the regulation of industry within the U.S., it even more pronounced with the consideration of GHG emissions. As discussed, previously, the U.S. GHG emissions are a global pollutant that also have domestic impacts. As such, if a smaller quantity of domestic GHG emissions would be displaced, due to a regulation, by a greater quantity of international GHG emissions it may support a finding of insignificance for a given source category. This would occur if the U.S. sources are already significantly lower emitting in GHG emissions than sources in other countries. It should also be noted that source categories whose sources in the U.S. make up a relatively smaller proportion of the world's emissions from corresponding international

[15] If U.S. production shifted overseas to a jurisdiction that has laxer environmental regulations, for a global pollutant such as mercury or GHGs, there could be both increased local environmental and health impacts at the new overseas location and domestic impacts to the U.S. resulting from the increased U.S. GHG emissions.

sectors may be particularly vulnerable to being trade exposed as there is likely a greater international capacity to absorb the displaced U.S. production.

Given the global nature of GHG emissions, assessing and understanding the estimated potential net emissions impact of GHG control technologies provides useful context in which to consider the significance of a given set of GHG emissions In addition, there may also be value in evaluating and considering the technology with the associated source category (*i.e.,* intrinsic to the process of the source category) - a prime example of reductions associated with this evaluation might be assessing the likely impacts of efficiency improvements. From a public welfare and human health perspective, targeting source categories that provide the largest overall possible scope for emissions reductions could be an intrinsic part of determining the significance of a given magnitude of emissions. Thus, the EPA is determining that it is appropriate in a given instance to consider feasible technologies (including efficiency improvements) for further context in the Agency's determination of significance of a source category's overall emissions. Here, the magnitude of GHG emissions from EGUs coupled with the reductions available through efficiency improvements supports the EPA's determination of significance.

d. Temporal Evaluation of Criteria

As introduced in this framework, the evaluation of the secondary criteria is not intended to be performed in isolation. Rather, the EPA considers the weight of evidence of all the factors (both primary and secondary) to make an informed and comprehensive decision as to whether a source category that exceeds the 3-percent threshold contributes significantly to the U.S. GHG emissions. The consideration of criteria also has a temporal consideration to a significance determination. A source category's determination can be reevaluated in the future as the status and criteria described here may have changed for that source category. For example, the

technology to adequately regulate GHGs from a source category may not be readily available at this time, but in the future that technology may become more broadly available causing the EPA to then make a SCF.

E. Significant Contribution Finding for EGUs

As noted above, the Agency is finalizing a determination that GHG emissions from EGUs[16] contribute significantly to dangerous air pollution. The primary criterion in determining whether to make a SCF is the magnitude of GHG emissions from a given source category. It is readily apparent that EGUs emit a uniquely large amount of GHGs compared to all other categories of stationary sources. The EPA made this clear in the 2015 Rule, quoted above, and reiterated it in the 2020 Oil & Gas Rule: "the unique CO_2 emissions profile of fossil fuel-fired EGUs should be noted: the volume of emissions from EGUs dwarfs the amount of GHG emissions from every other source category." 85 FR 57039, n.49.

Although GHG emissions from EGUs have fallen since the EPA promulgated the 2015 Rule, they still remain uniquely large among stationary source categories. The EPA's Inventory of U.S. Greenhouse Gas Emissions[17] indicates that, as of 2018, the Electric Power sector directly emitted 1,778.5 MMT of GHGs.[18] This amount was more than twice the amount of GHGs emitted by all other industrial sources combined and more than all other industrial, commercial,

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[16] For this purpose, EGUs include the affected sources in the combined source category for boilers and turbines. In the 2015 Rule, the EPA "combine[d] the two categories of EGUs—steam generators and combustion turbines—into a single category of fossil fuel-fired EGUs for purposes of promulgating standards of performance for CO_2 emissions." 80 FR 64529 (2015 Rule).

[17] *See* Table 3-9, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2018, Report 430-R-20-002, April 13, 2020, *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2018*.

[18] The global warming potential (GWP) of a greenhouse gas is defined as the ratio of the accumulated radiative forcing within a specific time horizon relative to that of the reference gas CO_2. Total GHG emissions are the GWP-weighted emissions of all GHG emissions and reported in million metric tons of CO_2 equivalent (MMT CO_2e.).

and residential stationary combustion sources combined.[19] In addition, direct GHG emissions from EGUs account for approximately 27 percent of total U.S. GHG emissions and 43 percent of U.S. stationary source emissions. The direct GHG emissions from EGUs account for approximately 4 percent of total worldwide GHG emissions and are greater than the emissions of all but four countries.[20] These facts confirm that at current emission levels, EGUs have measurable impacts on both the U.S. contribution to GHG emissions and the worldwide total GHG emissions and continue to be uniquely large stationary source emitters of GHGs. It should be noted that if domestic EGUs no longer emitted any GHG emissions, there would be a measurable impact on worldwide GHG emissions and between 2020 and 2100, there would be a reduction in the projected increase in global temperatures by 0.049 degrees Celsius (^{o} C).

Because EGUs represent by far the largest stationary source of GHGs from combustion of fossil fuels, the EPA believes that this is the most appropriate place for the EPA, states, and sources to devote resources to reducing GHGs from stationary sources. Indeed, this uniquely large magnitude of emissions is the reason over the last 8 years, the Agency has devoted significant effort to determine how to best reduce GHGs from EGUs. Because EGUs are a relatively large U.S. source of emissions in an overall large pool of international EGU sources, regulation over time could help produce practices and technologies that have application to EGUs worldwide.

It is noteworthy that GHG emissions from EGUs are approximately an order of magnitude greater than the estimated emissions of the second largest stationary source category

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[19] See Table 3-9, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2018, Report 430-R-20-002, April 13, 2020, *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2018*.

[20] In 2016, worldwide GHG emissions were estimated to have been 49.4 gigaton (Gt) CO_2e. The GHG emissions of China, India, Russia, and Indonesia are 11,577, 3,235, 2,391, and 2,229 MMT CO_2e respectively. *https://www.wri.org/blog/2020/02/greenhouse-gas-emissions-by-country-sector.*

of GHGs attributed to combustion, industrial boilers. Because the magnitude of GHG emissions from EGUs is large compared to other stationary sources, this makes them clearly significant even without detailed consideration of other factors. As mentioned earlier, the EPA is also introducing a framework under which a source category that emits above a threshold of 3 percent of U.S. stationary source GHG emissions may contribute significantly to dangerous GHG air pollution. For those source categories above that threshold, the EPA is also determining that consideration of certain secondary criteria may, collectively, also inform the evaluation of whether a source category should be considered to significantly contribute. However, within this framework, that analysis of secondary criteria is not necessary in the case of EGUs, due to the overwhelmingly large emissions of the source category; it is clear that controlling GHG emissions from the EGU source category will be necessary to appropriately address dangerous air pollution. This conclusion is consistent with the EPA's 2018 Proposal where the Agency explained that if the EPA was required to evaluate significance, EGUs would be considered significant.

1. Secondary Criteria

The EPA is determining that the uniquely large GHG emissions from EGUs makes a finding of significant contribution and regulation appropriate by itself. Under the introduced framework, while the EPA does not think it is necessary to consider secondary criteria because of the uniquely large emissions from the EGU source category, as explained below, the EPA would make the same determination even if it did consider those criteria.

a. Source Category Trends

As mentioned earlier, an important criterion is the evaluation of the trends in emissions and number of designated facilities within a source category, such that the EPA can evaluate whether a source category is on a trajectory of U.S. GHG emission decline.

While electricity demand is projected to increase the U.S., due to the increased use of less carbon intensive generation technologies and more efficient generation, GHG emissions from the power sector are projected to remain relatively steady for the foreseeable future. However, EGUs are projected to remain the single largest stationary source of GHG emissions, and while the Agency expects few, if any, new coal-fired EGUs will be built to meet the demand for electricity, coal-fired EGUs are expected to continue to supply electricity and emit significant GHG emissions for the foreseeable future.[21] The EGU source category also includes stationary combustion turbines. The EPA expects new simple cycle and combined cycle combustion turbine EGUs will be built in the future and that the existing fleet of combustion turbines will continue to operate.[22] Therefore, efficient generation technology could eventually become standard for all new and existing EGUs. Consequently, the EPA would consider the source category trends as supporting the regulation of GHG emissions from EGUs.

b. Source Category Emissions with Global Context

The EPA is also determining that it can consider, as a secondary criterion, the relative contribution of GHG emissions from the U.S. in the specific source category compared to worldwide emissions of similar sources. Accordingly, the EPA evaluates whether a source category is well-regulated internationally and whether the U.S. emissions from that sector make

[21] According to Table 8 of the Annual Energy Outlook (AEO) 2020, while coal fired generation will decline between 2019 and 2025 from 959 billion kWh to 709 billion kWh, generation from coal-fired EGUs is projected to subsequently remain relatively steady through 2050.

[22] According to Table 8 of the AEO 2020, natural gas fired generation is projected to increase from 1,322 billion kWh to 1,629 billion kWh.

up a relatively large share of global GHG emissions, as such evaluation in turn would inform whether U.S. emissions are significantly contributing to domestic impacts. In this instance, this criteria points towards a finding of significance given that U.S. EGUs make up a sizeable portion (13 percent of the emissions) from EGUs worldwide.[23]

As mentioned earlier in this notice, the EPA is also introducing that one of the secondary criteria is an evaluation of whether a source category is vulnerable to being trade exposed (*i.e.*, whether the source category is constrained in its ability to absorb regulatory costs due to actual or potential international competition). Concerns about international competition would not impact the Agency's decision to regulate EGUs because electricity must be transported over power lines and it is not as easy to relocate or shift production locations as it is for other source categories. The ability to locate generation in Mexico and Canada and transmit the power to the U.S. is limited because of constraints on existing transmission lines and the expense to build additional transmission capacity. The only additional transmission capacity currently being considered is for electricity generated from hydroelectric power in Canada to supply power to New England. Since this electricity has a low carbon intensity, it would not contribute to an overall increase in GHG emissions. Furthermore, the emission standards in this rule will not increase the costs of electricity from a new coal-fired EGU such that it might be financially advantageous to locate new production internationally to countries with less stringent regulations. If international competition were a concern, the Agency would compare the forecast GHG emissions from international sources (in this case, EGUs in Canada and Mexico) against the forecast GHG emissions from domestic sources (in this case domestic EGUs) in both the

[23] U.S. EGU emissions from the Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2018, Report 430-R-20-002, April 13, 2020, *https://www.epa.gov/ghgemissions/inventory-us-greenhouse-gas-emissions-and-sinks-1990-2018*. Worldwide EGU emissions from the International Energy Agency estimates IEA (2020), CO_2 Emissions from Fuel Combustion, *https://www.iea.org/subscribe-to-data-services/co2-emissions-statistics*.

absence of and implementation of the NSPS. In addition, since few, if any, new coal-fired EGUs are forecast to be built in the U.S., the standards in this final rule will not impact electricity prices to end users to an extent that other industries would be incentivized to relocate internationally due to increased electricity costs. Therefore, domestic reductions in GHG emissions from regulating EGUs will not be offset by increased international GHG emissions. In contrast, for source categories that supply raw materials to other domestic source categories, the impact of international competition on those source categories and the resultant GHG impacts could be considered when determining an appropriate NSPS. It is conceivable that an overly stringent NSPS could result in an increase in global GHG emissions, if the increase in international emissions is greater than the reduction in domestic emissions.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected facilities?

This rule takes final action affecting fossil fuel-fired EGUs. These EGUs take two forms that are relevant for present purposes: steam generating units (utility boilers and gasification units) and stationary combustion turbines. Fossil fuel-fired steam generating units can burn natural gas, oil, or coal. However, coal is the dominant fuel for electric utility steam generating units. Coal-fired steam generating units are primarily either PC or fluidized bed (FB) steam generating units.[24] At a PC steam generating unit, the coal is crushed (pulverized) into a powder to increase its surface area. The coal powder is then blown into a steam generating unit and burned. In a fossil fuel-fired steam generating unit using FB combustion, the solid fuel is burned in a layer of heated particles suspended in flowing air. Power can also be generated from coal or

[24] Fossil fuel-fired utility steam generating units (*i.e.*, boilers) are most often operated using coal as the primary fuel. However, some utility boilers use natural gas and/or fuel oil as the primary fuel.

other fuels using gasification technology. An Integrated Gasification Combined Cycle (IGCC) unit gasifies coal or petroleum coke to form a synthetic gas (or syngas) composed of carbon monoxide (CO) and hydrogen (H_2), which can be combusted in a combined cycle system to generate power. Stationary combustion turbines include both fossil fuel-fired simple cycle and combined cycle combustion turbine EGUs.

B. What are the air quality impacts?

The EPA does not anticipate that this final rule for fossil-fuel-fired EGUs will result in significant CO_2 emission changes.

C. What are the energy impacts?

This final rule for fossil-fuel-fired EGUs is not anticipated to have an effect on the supply, distribution, or use of energy.

D. What are the cost impacts?

The EPA does not believe that this final rule for fossil-fuel-fired EGUs will have compliance costs associated with it.

E. What are the economic impacts?

The EPA does not anticipate that this final rule for fossil-fuel-fired EGUs will result in economic or employment impacts. Likewise, the EPA believes this rule will not have any impacts on the price of electricity, employment or labor markets, or the U.S. economy.

F. What are the benefits?

The EPA does not anticipate emission changes resulting from the final rule for fossil-fuel-fired EGUs.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action. There are no quantified cost estimates for this final rule because the EPA does not anticipate this action to result in costs or cost savings.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing parts 75 and 98 regulations and has assigned OMB control numbers 2060-0626 and 2060-0629, respectively.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. The EPA expects there to be few, if any, new, modified, or

reconstructed coal-fired EGUs. As such, this final rule would not impose significant requirements on those sources, including any that are owned by small entities. The EPA has, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. It would neither impose substantial direct compliance costs on tribal governments, nor preempt Tribal law. The EPA is aware of three coal-fired EGUs located in Indian Country but is not aware of any EGUs owned or operated by tribal entities. The EPA notes that this action would affect only existing sources such as the three coal-fired EGUs located in Indian Country if those EGUs were to take actions constituting modifications or reconstructions as defined under the EPA's NSPS regulations. However, as previously stated, the EPA expects there to be few, if any, new, reconstructed, or modified EGUs. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA offered consultation with tribal officials during the development of this action; however, the Agency did not receive a request for consultation. The EPA held meetings with tribal environmental staff during the public comment period to inform them of the content of the proposed rule and to encourage them to submit comments on the proposed rule.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs (OIRA). This final action is not anticipated to have impacts on emissions, costs, or energy supply decisions for the affected electric utility industry.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specific in Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not affect the level of protection provided to human health or the environment. As previously stated, the EPA expects that few, if any, coal-fired EGUs would be affected by this action.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Andrew Wheeler,
Administrator

Message

From: Mugdan, Walter [Mugdan.Walter@epa.gov]
Sent: 1/6/2021 5:46:12 PM
To: Benevento, Douglas [benevento.douglas@epa.gov]; Coxen, Carrie [coxen.carrie@epa.gov]; Landeene, Sarah [Landeene.Sarah@epa.gov]; Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Wright, Peter [wright.peter@epa.gov]; Cook, Steven [cook.steven@epa.gov]; Breen, Barry [Breen.Barry@epa.gov]; Voyles, Travis [Voyles.Travis@epa.gov]; Brazauskas, Joseph [brazauskas.joseph@epa.gov]; Richardson, RobinH [Richardson.RobinH@epa.gov]; Bloom, David [Bloom.David@epa.gov]; Terris, Carol [Terris.Carol@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]
CC: Lopez, Peter [lopez.peter@epa.gov]; McKeown, Paula [McKeown.Paula@epa.gov]; Pace, Donald [Pace.Donald@epa.gov]; Chin, Arlene [Chin.Arlene@epa.gov]; Evangelista, Pat [Evangelista.Pat@epa.gov]; Guerrero, Carmen [guerrero.carmen@epa.gov]
Subject: OIG Report: "Region 2's Hurricanes Irma and Maria Response Efforts in Puerto Rico and U.S. Virgin Islands Show the Need for Improved Planning, Communications, and Assistance for Small Drinking Water Systems"
Attachments: _epaoig_20201202-21-P-0032_cert.pdf

Dear Colleagues,

I'm sending this note on behalf of RA Pete Lopez. We are working to schedule an exit conference with OIG on the subject engagement. I've attached OIG's Final Report to this note. All of the Agency's corrective actions and timelines were accepted by OIG.

Set out below is the region's proposed, brief comment on the report that we are sharing for your review and consideration in advance of the exit conference.

If you have any questions or concerns on these comments, we would be grateful if you could please let us know by next Monday, January 11.

Regards,

Walter

Walter Mugdan
Deputy Regional Administrator
U.S. EPA Region 2
212-637-4390 (office)
646-369-0058 (mobile)

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Region 2 proposed response:

Ex. 5 Deliberative Process (DP)

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From: OIG News <OIG.News@epa.gov>
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Subject: OIG Report: "Region 2's Hurricanes Irma and Maria Response Efforts in Puerto Rico and U.S. Virgin Islands Show the Need for Improved Planning, Communications, and Assistance for Small Drinking Water Systems"

Attached is the EPA Office of Inspector General report, *Region 2's Hurricanes Irma and Maria Response Efforts in Puerto Rico and U.S. Virgin Islands Show the Need for Improved Planning, Communications, and Assistance for Small Drinking Water Systems* (Report No. 21-P-0032). This report will be available to the public on the OIG's website at www.epa.gov/oig.

U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Ensuring clean and safe water

Region 2's Hurricanes Irma and Maria Response Efforts in Puerto Rico and U.S. Virgin Islands Show the Need for Improved Planning, Communications, and Assistance for Small Drinking Water Systems

Report No. 21-P-0032 **December 3, 2020**

Report Contributors:

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Abbreviations

EPA	U.S. Environmental Protection Agency
FEMA	Federal Emergency Management Agency
OIG	Office of Inspector General
PRASA	Puerto Rico Aqueduct and Sewer Authority
USVI	U.S. Virgin Islands

Cover Photos: *Left to right:* Hurricane Maria, a rural water system in Puerto Rico, and clean drinking water. (Photos from the National Oceanic and Atmospheric Administration, EPA OIG, and Centers for Disease Control and Prevention)

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U.S. Environmental Protection Agency
Office of Inspector General

21-P-0032
December 3, 2020

At a Glance

Why We Did This Audit

We conducted this audit to determine how the U.S. Environmental Protection Agency's preparedness and response efforts for the three major hurricanes of 2017—specifically, hurricanes Harvey, Irma, and Maria—protected human health and water resources from storm-related drinking water and surface water contamination. This report addresses the response to drinking water and wastewater systems impacted by hurricanes Irma and Maria in Puerto Rico and the U.S. Virgin Islands.

The OIG issued two previous reports assessing EPA Region 6's preparedness and response efforts pertaining to water issues associated with Hurricane Harvey in Texas, and EPA Region 4's preparedness and response efforts pertaining to water issues associated with Hurricane Irma in Florida.

This audit addresses the following:

- *Ensuring clean and safe water.*
- *Partnering with states and other stakeholders.*
- *Operating efficiently and effectively.*

This audit addresses two top EPA management challenges:

- *Overseeing states and territories implementing EPA programs.*
- *Communicating risks.*

Address inquiries to our public affairs office at (202) 566-2391 or OIG_WEBCOMMENTS@epa.gov.

List of OIG reports.

Region 2's Hurricanes Irma and Maria Response Efforts in Puerto Rico and U.S. Virgin Islands Show the Need for Improved Planning, Communications, and Assistance for Small Drinking Water Systems

What We Found

Before hurricanes Irma and Maria made landfall, Region 2 established an incident command structure and staffing plan to direct and manage its emergency response efforts. The region also contacted agencies in Puerto Rico and the USVI to determine the ability of the islands' drinking water and wastewater systems to weather the storms.

Enhancements to water system capacity and emergency preparation for island response could better protect the health of communities impacted by hurricanes and other disasters.

Hurricane Irma approached Puerto Rico and the USVI on September 5, 2017, as a Category 5 storm. Beginning on September 20, 2017, Hurricane Maria struck the USVI as a Category 5 storm and Puerto Rico as a Category 4 storm. After the hurricanes, regional emergency response staff performed operational assessments of drinking water and wastewater systems; conducted water sampling and analyses; and helped small, rural drinking water systems obtain generators. Despite these regional efforts and the federal government's largest-ever hurricane response, some small, rural drinking water systems in Puerto Rico and the USVI still had not returned to normal operations more than nine months after the storms made landfall. The damage caused by the hurricanes and the pre-storm conditions of those systems complicated the response.

The EPA's internal review processes delayed distribution of public health announcements, such as instructions on how to treat drinking water to reduce risk of illness. In addition, Region 2 did not fully engage its local staff in Puerto Rico and the USVI during hurricane preparations. By adjusting its review-and-approval process for public outreach information; strengthening the capacities of small, rural drinking water systems; and involving local EPA staff in the planning stages, Region 2 can improve the effectiveness of its emergency response efforts.

Recommendations and Planned Agency Corrective Actions

We made three recommendations to Region 2: first, develop and train staff on a procedure to locally disseminate public health information after emergencies; second, develop a supplemental emergency response plan that includes roles for local staff and addresses specific geographic, logistical, and cultural challenges; third, help improve the capacity and resilience of small, rural drinking water systems.

The region agreed with the recommendations and provided estimated milestone dates for its planned corrective actions. All recommendations are resolved.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

December 3, 2020

MEMORANDUM

SUBJECT: Region 2's Hurricanes Irma and Maria Response Efforts in Puerto Rico and U.S. Virgin Islands Show the Need for Improved Planning, Communications, and Assistance for Small Drinking Water Systems
Report No. 21-P-0032

FROM: Sean W. O'Donnell

TO: Peter Lopez, Regional Administrator
Region 2

This is our report on the subject audit conducted by the Office of Inspector General of the U.S. Environmental Protection Agency. The project number for this audit is OPE-FY18-0005. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The Region 2 regional administrator is responsible for the findings outlined in this report.

In accordance with EPA Manual 2750, your office provided acceptable planned corrective actions and estimated milestone dates in response to OIG recommendations. All recommendations are resolved, and no final response to this report is required. However, if you submit a response, it will be posted on the OIG's website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public. If your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

We will post this report to our website at www.epa.gov/oig.

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Chapter 1
Introduction

Purpose

The U.S. Environmental Protection Agency's Office of Inspector General conducted an audit to determine how the EPA's preparedness and response efforts for the three major hurricanes of 2017—specifically, hurricanes Harvey, Irma, and Maria—protected human health and water resources from storm-related drinking water and surface water contamination.

Top Management Challenges

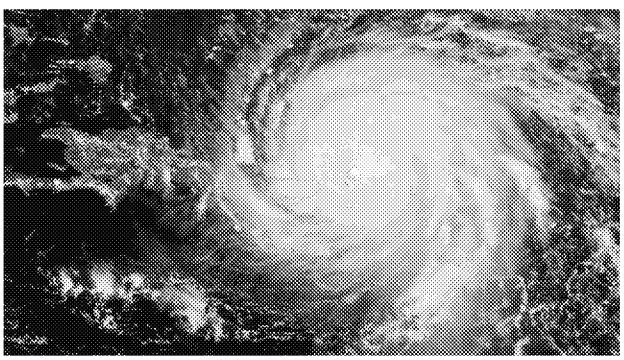
This audit addresses the following top management challenges for the Agency, as identified in OIG Report No. 20-N-0231, *EPA's FYs 2020–2021 Top Management Challenges*, issued July 21, 2020:

- Overseeing states and territories implementing EPA programs.
- Communicating risks.

This report contains our findings and recommendations related to EPA Region 2's response efforts in Puerto Rico and the U.S. Virgin Islands after hurricanes Irma and Maria. On July 16, 2019, the OIG issued Report No. 19-P-0236 assessing EPA Region 6's preparedness and response efforts pertaining to water issues associated with Hurricane Harvey in Texas. On October 7, 2019, the OIG issued Report No. 20-P-0001 assessing EPA Region 4's preparedness and response efforts pertaining to water issues associated with Hurricane Irma in Florida.

Background

Hurricane Irma began to impact Puerto Rico and the USVI on September 5, 2017, as the storm approached and passed over the islands. It was rated as high as a Category 5 storm with wind speeds up to 185 miles per hour. On September 20, 2017, Hurricane Maria struck the USVI as a Category 5 storm with wind speeds of up to 175 mph. Later that day, Hurricane Maria struck Puerto Rico as a Category 4 storm with wind speeds up to 155 mph.



Hurricane Irma over Puerto Rico and the USVI. (National Oceanic and Atmospheric Administration photo)

The resulting hurricane damage led the Federal Emergency Management Agency to initiate an emergency response that became the longest sustained air mission of food and water delivery in its history. Many lives were lost in the wake of these hurricanes. According to various news outlets, the government of Puerto Rico initially reported the official death toll as 64, but researchers at the George Washington University's Milken Institute School of Public Health estimated that 2,975 people in Puerto Rico died after Hurricane Maria. The official USVI toll of those who died as a direct result of the hurricanes

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was five, but the American Journal of Public Health reported that 49 others died after being medically evacuated from the USVI. In addition, the storms severely damaged drinking water and wastewater infrastructure. The U.S. Government Accountability Office reported the overall repair costs to be $132 billion for Puerto Rico and total damages of $10.7 billion for the USVI.

Drinking Water and Wastewater Systems

Water systems are considered one of the nation's critical infrastructures. They provide water for drinking and other household and commercial uses, as well as a means for treating our wastewater. Drinking water and wastewater systems are vulnerable to service interruption during and following extreme weather events, such as hurricanes.

A public ***drinking water system*** provides water for human consumption through a distribution system to at least 15 service connections or to an average of at least 25 people for at least 60 days a year. Distribution systems consist of an interconnected series of components, including pipes, storage facilities, and other components, that convey drinking water. A public drinking water system may be publicly or privately owned.

The EPA classifies public drinking water systems according to the number of people they serve and whether they serve the same customers year-round or on an occasional basis. Typically, very small systems serve 25 to 500 people and small systems serve 501 to 3,300 people. Throughout this report, we refer to both small and very small systems as "small" systems. A public water system that supplies water to the same population year-round is referred to as a "community water system."

A public ***wastewater system*** treats water that has been used for various purposes by residences, businesses, and industry. Sewers collect wastewater and deliver that water to a treatment plant for processing, so that it can be safely be reused or returned to lakes, rivers, and streams. Some wastewater systems have sewers that collect both stormwater and wastewater. These are known as "combined sewer systems."

Technical, Managerial, and Financial Capacities of Water Systems

Improving the technical, managerial, and financial capacities of water systems contributes to their resilience. ***Resilience*** is the ability of a water system to withstand and recover from disasters, such as hurricanes. In general, water systems in rural locations face longstanding capacity issues, thus hindering resilience.

Technical, managerial, and financial capacity issues can cause noncompliance with and violations of drinking water regulations. Some of the limitations are:

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- *Technical capacity limitations*, wherein systems lack the proper equipment or personnel to operate and maintain the equipment.

- *Managerial capacity limitations,* wherein systems lack accountable owners or adequate staffing and organization.

- *Financial capacity limitations,* wherein systems lack proper fiscal management and controls, such as the ability to collect payments from customers or apply for financial assistance.

Water systems are subject to laws and regulations governing safety and resilience. In 1972, the Clean Water Act was enacted to protect the waters of the United States. The EPA implements the Clean Water Act by establishing wastewater standards and water quality criteria, as well as by regulating discharges of pollutants. In addition, Congress passed the Safe Drinking Water Act in 1974 to ensure that public drinking water systems deliver safe water to their consumers. Under the Safe Drinking Water Act and its amendments, the EPA established protective drinking water standards for more than 90 contaminants.

America's Water Infrastructure Act of 2018, which amended the Safe Drinking Water Act, outlines strategies to address drinking water system resilience in the face of disasters and provides tools for improving resilience, including at small, rural drinking water systems. The 2018 Act requires the EPA administrator to:

> [P]rovide guidance and technical assistance to community water systems serving a population of less than 3,300 persons on how to conduct resilience assessments, prepare emergency response plans, and address threats from malevolent acts and natural hazards that threaten to disrupt the provision of safe drinking water or significantly affect the public health or significantly affect the safety or supply of drinking water provided to communities and individuals.

Water and Wastewater Services in Puerto Rico and USVI

The Puerto Rico Aqueduct and Sewer Authority provides most of Puerto Rico's 3.19 million residents with drinking water and wastewater services.[1] PRASA manages 114 community water systems, which at the time of hurricanes Irma and Maria served 97 percent of the island's residents (Figure 1). Drinking water for the remaining 3 percent of the population, about 76,000 people when the hurricanes made landfall, was provided by 237 small community water systems, which are commonly referred to as "non-PRASA" systems. In addition, as shown in Figure 1, PRASA operates 51 wastewater systems serving 60 percent of Puerto

[1] July 2019 U.S. Census data.

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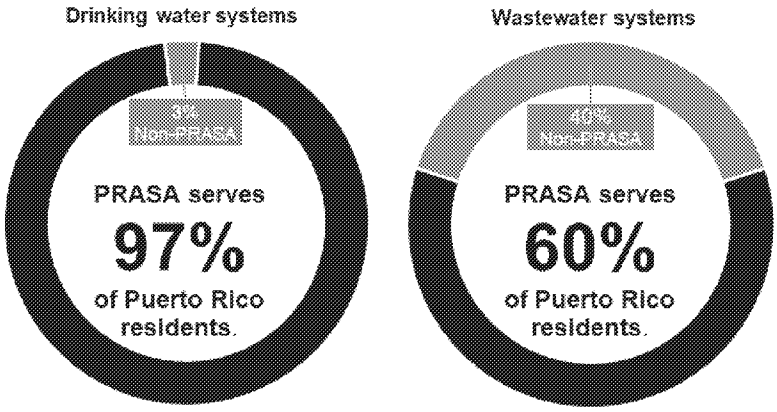
Rico's population. The remaining 40 percent of the island's population uses private septic systems for wastewater services.

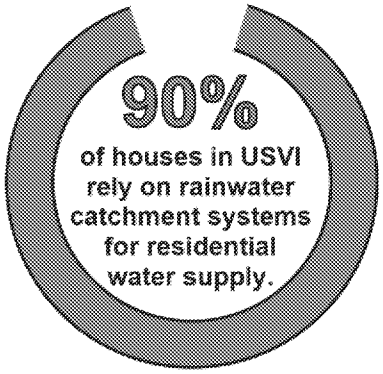
Figure 1: Puerto Rico population served by PRASA systems



Source: OIG analysis based on a 2018 EPA Caribbean Environmental Protection Division presentation. (EPA OIG image)

The USVI has nearly 106,000 residents, with 77 community water systems serving drinking water to approximately 81,000 people. Two large water systems serve the majority of residents (69,000). The remaining 75 are small systems that supply drinking water to a total of approximately 12,000 people. Despite the availability of these water systems, 90 percent of houses in the USVI rely on rainwater catchment systems, such as cisterns, as their main residential water supply (Figure 2). A ***cistern*** is an underground or aboveground vessel attached to a home or business that stores rainwater collected from a rooftop drainage system. Cisterns are not regulated under the Safe Drinking Water Act unless these sources regularly serve at least 25 individuals. The USVI Waste Management Authority provides wastewater services to 60 percent of the residents through eight municipal wastewater treatment plants.

Figure 2: USVI dependency on rainwater catchment systems



Source: OIG analysis based on 2019 USVI Department of Health Cistern Study. (EPA OIG image)

EPA Responds to Hurricane Disasters Under FEMA Direction and at Request of States or Territories

The EPA responds to disasters under the direction of FEMA and at the request of the states or U.S. territories experiencing the disaster. To facilitate a consistent federal approach to emergency response, all federal agencies adhere to the National Response Framework. The framework includes 15 emergency support functions under which federal agencies coordinate the resources and capabilities most needed in a national response (Table 1).

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Table 1: National Response Framework emergency support functions

#	Resource/capability	#	Resource/capability
1	Transportation	9	Search and Rescue
2	Communications	10	**Oil and Hazardous Materials***
3	Public Works and Engineering	11	Agriculture and Natural Resources
4	Firefighting	12	Energy
5	Information and Planning	13	Public Safety and Security
6	Mass Care, Emergency Assistance, Temporary Housing and Human Services	14	Superseded by the National Disaster Recovery Framework
7	Logistics	15	External Affairs/Standard Operating Procedures
8	Public Health and Medical Services		

Source: OIG analysis of U.S. Department of Homeland Security data. (EPA OIG table)

** EPA-led emergency support function in response to hurricanes Irma and Maria.*

Under each emergency support function, FEMA issues mission assignments to federal agencies for specific tasks, such as the cleanup of hazardous waste or the inspection of water systems. For hurricanes Irma and Maria, FEMA activated Region 2 with mission assignments under Emergency Support Function #10, *Oil and Hazardous Materials Response*, from October 30, 2017, through September 15, 2018. ESF #10 activities can expand beyond oil and hazardous materials to include monitoring more broadly for environmental contamination. For Region 2, this FEMA assignment included the sampling and monitoring of drinking water and wastewater systems in Puerto Rico and the U.S. Virgin Islands. At its peak, approximately 450 EPA staff participated in the emergency response.

Responsible Offices

The Region 2 Superfund and Emergency Management Division, which has staff in New York, New York, and Edison, New Jersey, implements the National Response Framework and provides emergency response services during environmental incidents, including hurricanes. The division is also responsible for emergency response planning, preparedness, and prevention activities.

The Region 2 Water Division, based in New York, New York, implements environmental statutes that protect water, such as the Clean Water and Safe Drinking Water acts. The Division also supports cross-cutting, water-related programs and provides financial and technical assistance to states and localities. The EPA Office of Water headquarters, based in Washington, D.C., is also responsible for implementing the Clean Water and Safe Drinking Water acts and works with the EPA's ten regional offices.

The Region 2 Caribbean Environmental Protection Division implements a variety of environmental programs from its main office in Guaynabo, Puerto Rico, and a field office in St. Thomas, USVI. The Division implements water protection

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programs in Puerto Rico and the USVI through permitting, grant administration, compliance assistance, and enforcement.

Scope and Methodology

We conducted this performance audit from July 2018 to August 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

We reviewed the EPA's management and situation reports about hurricanes Irma and Maria, as well as documents about federal emergency response. We interviewed Region 2 staff who participated in the response for hurricanes Irma and Maria; staff from Puerto Rico's and the USVI's environmental agencies; staff of a nongovernmental organization that provides support for public, environmental, and economic health in Puerto Rico and the USVI; and drinking water and wastewater system operators. The scope of our audit did not include examining Region 2's emergency response related to the monitoring of air quality, the remediation of household hazardous waste, or the assessment of oil and hazardous materials releases.

Prior Reports

The OIG published reports about other EPA hurricane response activities related to hurricanes Katrina, Harvey, and Irma. After Hurricane Katrina in 2006, we reported that the EPA could improve its coordination with state and local officials.[2] In the aftermath of the 2017 hurricane season, when hurricanes Harvey and Irma made landfall in the United States, we reported that Regions 4 and 6 had forged close working relationships with state emergency response partners.[3] This preparation enabled these regions to protect human health and water sector resources. We recommended that both regions improve their emergency response training and planning and that Region 6 improve its communications with non-English-speaking communities. According to the Agency's audit tracking system, as of November 2020, Region 4 had completed all corrective actions, while Region 6 had completed two recommendations and had corrective actions pending for two recommendations.

In the aftermath of Hurricane Harvey, we reported that we did not identify significant issues in the EPA's contracting, logistics, or resource acquisition

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[2] OIG, *Lessons Learned: EPA's Response to Hurricane Katrina*, Report No. 2006-P-00033, September 14, 2006.
[3] OIG, *Region 6 Quickly Assessed Water Infrastructure after Hurricane Harvey but Can Improve Emergency Outreach to Disadvantaged Communities*, Report No. 19-P-0236, July 16, 2019; *Region 4 Quickly Assessed Water Systems After Hurricane Irma but Can Improve Emergency Preparedness,* Report No. 20-P-0001, October 7, 2019.

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processes, and we did not make any recommendations in that report.[4] In a subsequent report, we did find that state, local, and EPA mobile air monitoring activities were not initiated in time to assess the impact of toxic air emission incidents occurring within a five-day period of the hurricane's landfall.[5] Additionally, once started, monitoring efforts did not always generate data considered suitable for making health-based assessments, in part because there was no guidance outlining how to monitor air quality following an emergency. We recommended that the EPA develop guidance for emergency air monitoring and provide public access to those data. As of November 2020, two of the six recommendations were resolved with corrective actions completed. Resolution efforts are underway for the remaining four recommendations.

[4] OIG, *EPA Adequately Managed Hurricane Harvey Funding Received from FEMA*, Report No. 20-P-0010, October 23, 2019.
[5] OIG, *EPA Needs to Improve Its Emergency Planning to Better Address Air Quality Concerns During Future Disasters,* Report No. 20-P-0062, December 16, 2019.

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Chapter 2
EPA Needs to Improve Its Emergency Response Planning, Communications, and Assistance to Small Water Systems

Hurricanes Irma and Maria severely damaged the water, electricity, communication, and transportation infrastructures in Puerto Rico and the USVI. This damage affected the EPA's ability to carry out FEMA mission assignments by hindering and delaying the deployment of response personnel and the Agency's access to communications and other equipment. Some drinking water systems in Puerto Rico and the USVI still had not returned to normal operations more than nine months after the storms made landfall. Despite these challenges, EPA staff prepared for and fulfilled their response roles performing operational assessments; conducting water sampling and analyses; and helping small, rural drinking water systems become operational after the storms. EPA Region 2 did not, however, optimally use the technical expertise and cultural awareness of its local employees when preparing for and responding to the hurricanes. In addition, pre-storm conditions rendered many small drinking water systems vulnerable to storm damage. Additional attention to advance planning can correct issues with small drinking water system resilience, public information dissemination, engagement of local EPA personnel, and awareness of cultural norms.

Conditions in Puerto Rico and USVI Slowed Response to Hurricanes Irma and Maria

We found the reasons for the EPA's delay in responding to the hurricanes' aftermath in Puerto Rico and the USVI were not fully within the control of the Agency's emergency response personnel. For example:

- Most Puerto Rico and USVI residents did not have electricity after Hurricane Irma made landfall on September 5, 2017. In the USVI, 98 percent of electrical service was not restored until February 2018, five months after the two storms. Full electrical service was not restored for most Puerto Rico residents until August 2018, almost one year after the storms.

- Damage to transportation infrastructure lengthened travel time across Puerto Rico and the USVI and prevented access to many rural communities.

- In the aftermath of Hurricane Maria, approximately 95 percent of the cell towers in Puerto Rico were out of service, and approximately 77 percent of cell towers in the USVI were out of service (Figure 3). According to a 2018 Federal Communications Commission report, cell service on the

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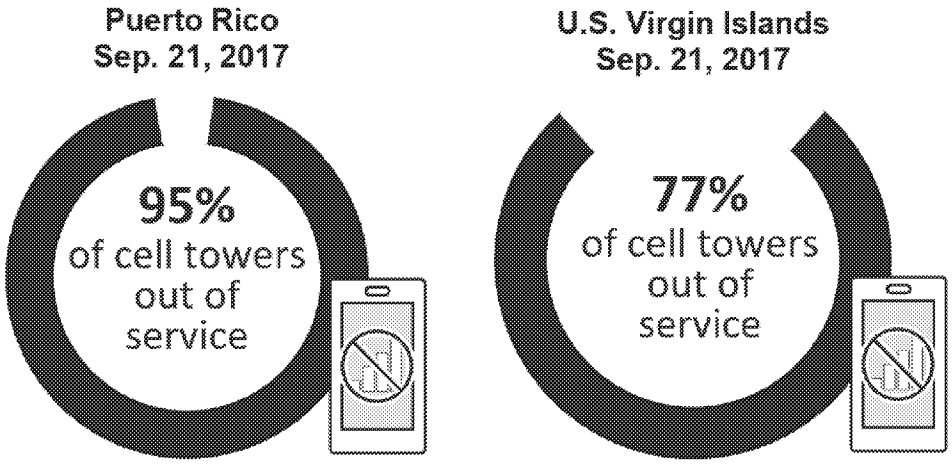
islands was restored gradually over a six-month period, considerably longer than for any other storm. This limited service hindered communication among emergency responders.

Figure 3: Cell service three weeks after Hurricane Maria



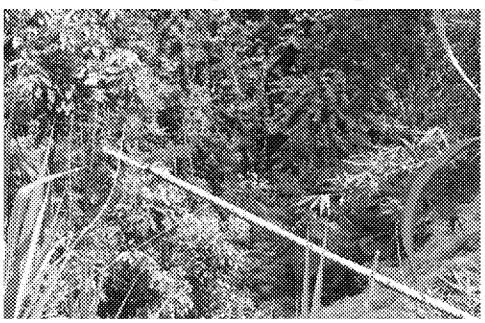
Source: OIG analysis of Federal Communications Commission data. (EPA OIG image)

- As Hurricane Maria approached the islands, the EPA evacuated its response personnel who had been deployed to the USVI after Hurricane Irma.

- There were not enough supplies available—such as water, meals, medical kits, and tarps—for distribution after Hurricane Maria made landfall because FEMA distributed the majority of its inventory from its Caribbean warehouse after Hurricane Irma struck.

- The EPA assisted the U.S. Coast Guard with over 700 sunken vessels, as well as with the resulting debris and oils spills.

In addition, the hurricanes exacerbated pre-storm conditions in Puerto Rico and the USVI. Technical, managerial, and financial capacity limitations preceding the storms not only left water systems vulnerable to storm damage but also placed residents' health at risk. Almost one year after the hurricanes made landfall in Puerto Rico, some non-PRASA drinking water systems were still dealing with hurricane damage, such as (1) power restoration taking months in some rural areas or (2) damage to the distribution system, such as broken aboveground plastic pipes, like the one pictured here.



Aboveground drinking water distribution pipe in rural Puerto Rico broken as a result of a hurricane. (EPA OIG photo)

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Small, rural drinking water system in Puerto Rico with treatment chemicals improperly stored outside and exposed. (EPA OIG photo)

Many of the water systems in isolated rural areas of Puerto Rico and the USVI—such as the small, rural drinking water system pictured here, with its treatment chemicals unsecured and exposed to the elements—generally lack full operational capacity even in nonemergency situations. The aftermath of hurricanes Irma and Maria demonstrated that small, rural drinking water systems lack the resilience to protect human health from drinking water contamination in the event of a disaster. This lack of resilience persists despite Region 2 working for years to address compliance and capacity problems at small drinking water systems in Puerto Rico.

In contrast, even though the 2017 hurricanes in Texas (Hurricane Harvey) and Florida (Hurricane Irma) were among the most powerful and damaging in U.S. history, the response on the mainland was quicker. In both Texas and Florida, EPA emergency response personnel immediately assessed the status of drinking water and wastewater systems by telephone and in person. As a result, the impacted residents of both states were served by operational drinking water and wastewater systems within days or weeks of the storms.

EPA Emergency Response Personnel Provided Critical Help

Prior to the hurricanes, Region 2 established an incident command structure and staffing plan to direct and manage its response to the storms. In response to the FEMA mission assignment, the EPA provided emergency response assessments of drinking water and wastewater systems, as well as assistance to non-PRASA drinking water systems. These efforts helped water and wastewater systems in Puerto Rico and the USVI return to operations in the aftermath of the back-to-back hurricanes.

EPA Made Emergency Response Preparations in Anticipation of Storms

Before the start of the 2017 hurricane season, the EPA's emergency response staff routinely participated in training sessions, preparation exercises, and other meetings. In anticipation of Hurricane Irma's arrival, Region 2 emergency response staff engaged in prelandfall and predeployment activities by establishing an incident command structure and a staffing plan to direct and manage response efforts. They also established data collection tools for the EPA's drinking water and wastewater assessment teams.

As part of those emergency response preparations, Region 2 developed a regional operations plan for the hurricane, which subsequently became the *Regional Operations Plan and Multiple Disaster Contingency Plan for the Hurricane Irma/Maria Response*. This emergency response plan supported the deployment

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of EPA staff and resources to FEMA's San Juan office, the Puerto Rico Environmental Quality Board office, and the USVI Department of Planning and Natural Resources office. The plan addressed preparations and administrative needs for response efforts involving public health and the environment.

Region 2's Emergency Response Personnel Evaluated Drinking Water and Wastewater Systems After Storms

As part of the FEMA mission assignments in Puerto Rico and the USVI, Region 2 evaluated the operational status of drinking water and wastewater systems and tracked the progress of systems returning to operational status. In Puerto Rico, EPA emergency response personnel and PRASA staff conducted 284 on-site assessments of drinking water systems and 233 on-site assessments of wastewater systems by the end of November 2017 to determine operational status.[6] Some systems were assessed multiple times. The EPA also helped 21 small, rural drinking water systems remain operational by fueling and maintaining their generators.

In the USVI, EPA response personnel conducted 1,282 on-site assessments of drinking water systems, the majority of which were cisterns, and 33 on-site assessments of wastewater systems, by the end of November 2017. Some of these systems were also assessed multiple times. In the USVI, more than 2,400 drinking water samples were collected for analysis.

Tables 2 and 3 detail the systems' progress in returning to operational status, as recorded in EPA management reports until June 2018. These reports did not contain information about the percentage of population with water services, only the percentage of drinking water and wastewater systems returning to pre-storm operational levels. From July 2018 until the conclusion of the Agency's mission assignment in September 2018, the EPA reported the remaining operational needs of individual drinking water systems, rather than reporting the overall number of operating drinking water and wastewater systems.

Table 2: Puerto Rico—operational status of drinking water and wastewater systems

	Number of systems assessed	Percentage of systems operational by:				
		10/20/17	11/20/17	12/20/17	1/22/18	6/6/18
PRASA drinking water systems	*114	60%	81%	93%	96%	99%
Non-PRASA drinking water systems	237	No data	81%	86%	87%	95%
Wastewater systems	51	80%	92%	100%	98%	100%

Source: OIG analysis of EPA management reports. (EPA OIG table)

* EPA reports varied in the number of PRASA drinking water systems assessed: 121 in October 2017, 115 in November and December 2017, and 114 thereafter. The percentage of systems operational is based upon the number of systems reported as assessed.

[6] Region 2's comments to the draft report noted that the Puerto Rice Department of Health also participated in on-site assessments of drinking water and wastewater facilities.

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Table 3: USVI—operational status of drinking water and wastewater systems

	Number of systems assessed	Percentage of systems operational by:				
		10/20/17	11/20/17	12/20/17	1/22/18	6/6/18
Public drinking water systems*	**344	No data	74%	74%	80%	85%
Private cisterns	***207	No data	95%	95%	84%	91%
Wastewater systems	8	No data	63%	100%	100%	100%

Source: OIG analysis of EPA management reports. (EPA OIG table)

* Management reports did not distinguish between community water systems and noncommunity water systems, such as hospitals, schools, and gas stations.

** The EPA reported 344 systems assessed until its June 2018 report, which reported 338. The percentage of systems operational is based upon the number of systems reported as assessed.

*** Management reports varied in the number of nonutility drinking water systems assessed: 207 in January 2017, 191 in November and December 2017, and 170 thereafter.

As shown in Table 2, when the EPA stopped tracking Puerto Rico's water and wastewater systems in June 2018, which was nine months after the first storm, nearly all systems had achieved pre-storm levels of operation. As shown in Table 3, 85 percent of public drinking water systems in the USVI had returned to pre-storm levels of operation by June 2018. Because at least 95 percent of the USVI's residents use private cisterns, many still had access to drinking water after the public water and power systems became inoperable; however, even in June 2018, 9 percent of private cisterns remained nonoperational.

EPA Provided Direct Assistance to Non-PRASA Drinking Water Systems

The EPA provided direct assistance to non-PRASA drinking water systems to fuel and maintain temporary generators. The widespread power outages in Puerto Rico after the hurricanes particularly affected non-PRASA drinking water systems. These remote systems were in areas where electricity was not restored for several months.

After the hurricanes, the owners or operators of drinking water systems could request generators through the FEMA Public Assistance grant program. FEMA Public Assistance provides federal funding to help communities respond to and recover from disasters, such as hurricanes. Not all Puerto Rican and USVI water systems were able to qualify for such assistance, however. As noted previously, non-PRASA systems face technical, managerial, and financial capacity limitations for both day-to-day operations and after weather emergencies, such as hurricanes. These capacity limitations contributed to the systems' inability to qualify for assistance from FEMA because water system operators could not provide the necessary documents to qualify for the Public Assistance grants. For example, before hurricanes Irma and Maria, many non-PRASA water systems were not incorporated, which is a requirement to obtain FEMA Public Assistance grants.

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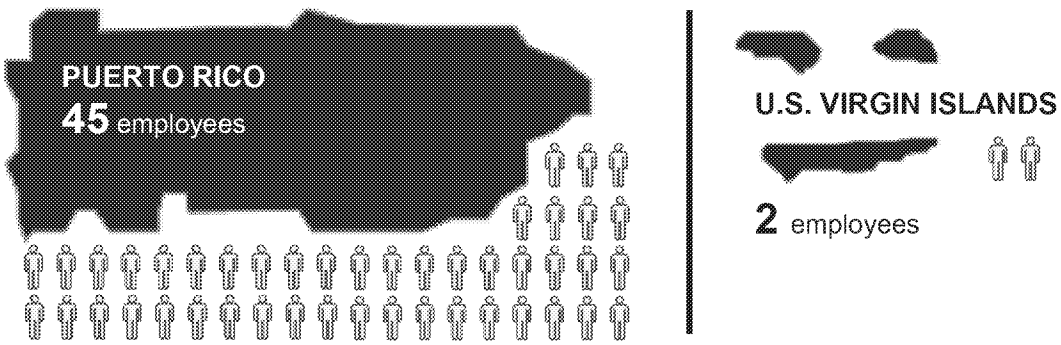
With EPA assistance, 68 percent (161) of the 237 non-PRASA water systems obtained certification during the EPA's emergency response period. Some of those systems then obtained temporary generators from FEMA to operate their water systems. In addition, as part of the Agency's mission assignments, EPA emergency response staff and contractors fueled and maintained 21 generators at non-PRASA systems until September 2018. The priority for generators was hospitals, PRASA systems, and power stations. As a result of prioritizing other facilities, not all non-PRASA systems needing generators received them due to a shortage of generators on the island.

Hurricane Preparation and Response Activities Should Include All Local EPA Staff and Follow Cultural Norms

While Region 2 devised an emergency response plan prior to the arrival of the storms to help guide its response efforts, it did not specify roles for the 45 local EPA staff in Puerto Rico and the two local EPA staff in the USVI (Figure 4). Staff we interviewed from the EPA's Puerto Rico office said that they participated in some preparations or emergency response activities. The two EPA staff stationed in the USVI said that they had limited or no involvement in preparation or response activities.

Figure 4: Local EPA staff



Source: Data from July 2018 meeting with Agency. (EPA OIG image)

Staff told us that some EPA emergency response personnel did not follow some cultural norms on the islands. For example, we were told that exchanging personal greetings regarding family or health before meetings begin is a cultural norm in the USVI but that EPA emergency response personnel did not always follow this etiquette. EPA response personnel also took photographs without the permission of local USVI residents, which was described to us as not in keeping with local cultural norms.

The local EPA staff were familiar with island geography and cultural norms, and they had logistical and technical expertise. Region 2 would have benefited from their knowledge and skills when preparing and, to the extent local EPA staff were safely available, in the immediate aftermath of the storms. Region 2 could

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strengthen cultural understanding by using local EPA staff expertise in disaster preparation activities and response efforts. These staff could help enhance understanding by mainland-based emergency response personnel about local cultural norms.

To address the lack of cultural awareness during the response effort, Region 2 staff created and distributed an etiquette document: *Things to Know Working in the Virgin Islands*. This document highlighted USVI cultural norms and suggested how to sensitively interact with residents.

The EPA's Office of Emergency Management reviewed the Agency's response activities for hurricanes Harvey, Irma, and Maria and the California wildfires. The resulting *2017 Hurricane and Wildfire Response After-Action Report*, dated September 2018, identified strengths, areas for improvement, and recommendations to improve the EPA's emergency response. The report identified local staff involvement in response operations as an area for improvement and recommended that the EPA delineate roles and responsibilities for local staff in future disasters. The report also suggested that "guidance on cultural attitudes in communication" be included in predeployment packages going forward.

EPA Could Better Inform the Public and Prepare Small Water Systems in Puerto Rico and USVI

Although Region 2 fulfilled its FEMA water sector mission assignment, we identified two additional areas for improvement that would further enhance the region's emergency response capabilities and would better prepare small, rural drinking water systems in Puerto Rico and the USVI to protect human health. Specifically, the EPA could improve its processes for informing the public about protecting health and for assisting small, rural drinking water systems with developing resilience.

Public Health Messages Delayed Because of EPA Procedures

In the USVI, most residents relied on cisterns as their drinking water source after hurricanes Maria and Irma caused power outages, which made public water systems nonoperational. In Puerto Rico, the damage to distribution systems and power outages after the hurricanes made small, rural drinking water systems inoperable, and residents either relied on alternative sources for water, such as artesian wells, or traveled several kilometers to obtain water. To reduce the risk of illness following disasters, residents need to know how to disinfect drinking water obtained from sources other than regulated public drinking water systems. According to EPA response staff, such public health information was delayed after hurricanes Maria and Irma because, in part, of the Agency's vetting process.

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As part of pre-storm preparations, Region 2 and headquarters implemented EPA Order 2010, *Crisis Communication Plan*. According to the *Crisis Communication Plan*, messages should be "conveyed to the public quickly, accurately, and consistently by working with the media and sharing information externally." The EPA had previously developed public health messages to distribute after disasters regarding how to disinfect drinking water. These messages, dated June 2015, were previously used in the Hurricane Harvey response efforts, which occurred less than two weeks before Hurricane Irma.

As specified in the EPA's *Crisis Communication Plan*, public health outreach messages are subject to review and approval by headquarters, even if they contain previously approved information, before they are distributed to the public. In response to hurricanes Irma and Maria, multiple headquarters offices were involved in the review-and-approval process for these messages: the Office of Public Affairs, which was identified as the lead reviewing office; the Office of General Counsel; and the Office of Water. According to Region 2, this required vetting process led to delays in the delivery of the public health messages in Puerto Rico and the USVI. The delayed dissemination of this information, however, was not in accordance with the *Crisis Communication Plan*'s directive to provide messages to the public quickly. In response to our draft report, Region 2 stated that in addition to internal vetting, it was necessary that messaging also be coordinated with other response partners, including the Puerto Rico Department of Health.

The EPA's *2017 Hurricane and Wildfire Response After-Action Report* also identified the distribution of public health messages as an area for improvement. Any delay in distributing public health information puts residents at risk if they do not know how to treat water that does not come from a regulated water system.

America's Water Infrastructure Act Could Help Vulnerable Systems

Region 2 has worked for years to address capacity problems at small, rural drinking water systems in Puerto Rico and the USVI. Despite this assistance, many small, rural drinking water systems lack the technical, managerial, and financial capacity to recover quickly from disasters, such as the two back-to-back hurricanes that devastated the islands in 2017.

In September 2018, Region 2 agreed to participate in a Memorandum of Understanding to enhance the resilience of non-PRASA systems in Puerto Rico. The memorandum establishes working relationships among Region 2, a university, and six nongovernmental organizations, with the intent to "build capacity, develop, and implement equitable, reliable, and resilient solutions" to non-PRASA and other unregulated drinking water systems in remote areas of Puerto Rico.

Implementation of the America's Water Infrastructure Act could further help vulnerable systems. The Act requires that the EPA provide guidance to small drinking water systems "on how to conduct resilience assessments, prepare

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emergency response plans, and address threats from [disasters] that threaten to disrupt the provision of safe drinking water." In response, the Office of Water:

- Issued instructions in July 2019 for water systems on how to develop emergency response plans.
- Issued guidance in May 2020 for small community water systems on how to conduct risk and resilience assessments.
- Developed risk assessment and emergency response plan training for systems that service over 3,300 people.
- Planned workshops for the fall of 2020 to help small water systems comply with the America's Water Infrastructure Act.

America's Water Infrastructure Act also established an annual grant program of up to $10 million to provide technical assistance grants to small drinking water systems to conduct resilience assessments, prepare emergency response plans, and address threats from malevolent acts and natural hazards. While Congress has, to date, not funded this grant program, Congress appropriated $3 million for fiscal year 2020 to fund a separate grant program for increasing drinking water resilience to natural hazards.[7] Small, rural drinking water systems in Puerto Rico and the USVI would benefit from this aid, which is consistent with the goals established in the 2018 Memorandum of Understanding.

Conclusion

The EPA's preparations for the 2017 hurricane season enabled EPA emergency response staff to complete their FEMA mission assignments in the aftermath of two back-to-back hurricanes. Specifically, the EPA assessed the status of drinking water and wastewater systems, collected and tested drinking water samples, and provided assistance to small drinking water systems in Puerto Rico and the USVI. However, the severity of the consecutive storms; the logistical difficulties the storms caused; the geographic isolation of the islands; the pre-storm operating challenges of some small, rural drinking water systems; and cultural differences complicated and prolonged the emergency response efforts, especially compared to the 2017 hurricane response efforts in Texas and Florida.

Region 2 can better protect human health after future disasters in Puerto Rico and the USVI by working with the Office of Water to improve the resilience of small, rural drinking water systems through implementing the America's Water Infrastructure Act. Additional improvements to the Region 2 emergency response planning processes can improve communications during the response, engage local EPA staff, and inform response personnel on local cultural norms.

[7] Appendix B contains Region 2's technical description of these two new grant programs that were created by the America's Water Infrastructure Act to support resiliency and federal appropriations for those activities.

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Recommendations

We recommend that the Region 2 regional administrator:

1. Develop and implement a written regional procedure for the timely approval and dissemination of predrafted public health messages in the aftermath of a disaster so that impacted communities receive critical information in a timely manner, in accordance with EPA Order 2010, *Crisis Communication Plan*. After this procedure is developed, also:

    a. Train regional emergency response personnel on the procedure.

    b. Include the procedure in disaster planning and response documents and exercises.

2. Develop and implement a supplement to Region 2's emergency response plan to describe and address the specific geographic, logistical, and cultural norms applicable to disaster response in Puerto Rico and the U.S. Virgin Islands. This supplement should include local EPA staff roles and responsibilities, as well as address the likely limitations to transportation, communications, and power in the aftermath of disasters.

3. In coordination with the Office of Water, implement America's Water Infrastructure Act in Puerto Rico and the U.S. Virgin Islands by:

    a. Developing and implementing a strategy to provide training, guidance, and assistance to small drinking water systems as they improve their resilience.

    b. Establishing a process for small drinking water systems to apply for America's Water Infrastructure Act grants. This process should include (1) implementing the EPA's May 2020 guidance provided to small drinking water systems regarding resilience assessments and (2) establishing a public information campaign to inform small drinking water systems of the America's Water Infrastructure Act grant opportunity, qualifying requirements, and application deadlines.

Agency Response and OIG Assessment

The Region 2 regional administrator provided an initial response (Appendix A) to our draft report on October 22, 2020, as well as a second response (Appendix B) on November 2, 2020, regarding Recommendation 3. Region 2 also provided technical comments, and we made changes to our report where appropriate. The region provided acceptable planned corrective actions and estimated milestone dates in response to our recommendations. All recommendations are resolved.

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Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	17	Develop and implement a written regional procedure for the timely approval and dissemination of predrafted public health messages in the aftermath of a disaster so that impacted communities receive critical information in a timely manner, in accordance with EPA Order 2010, *Crisis Communication Plan*. After this procedure is developed, also: a. Train regional emergency response personnel on the procedure. b. Include the procedure in disaster planning and response documents and exercises.	R	Region 2 Regional Administrator	9/30/21	
2	17	Develop and implement a supplement to Region 2's emergency response plan to describe and address the specific geographic, logistical, and cultural norms applicable to disaster response in Puerto Rico and the U.S. Virgin Islands. This supplement should include local EPA staff roles and responsibilities, as well as address the likely limitations to transportation, communications, and power in the aftermath of disasters.	R	Region 2 Regional Administrator	6/30/23	
3	17	In coordination with the Office of Water, implement America's Water Infrastructure Act in Puerto Rico and the U.S. Virgin Islands by: a. Developing and implementing a strategy to provide training, guidance, and assistance to small drinking water systems as they improve their resilience. b. Establishing a process for small drinking water systems to apply for America's Water Infrastructure Act grants. This process should include (1) implementing the EPA's May 2020 guidance provided to small drinking water systems regarding resilience assessments and (2) establishing a public information campaign to inform small drinking water systems of the America's Water Infrastructure Act grant opportunity, qualifying requirements, and application deadlines.	R	Region 2 Regional Administrator	12/31/22	

[1] C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress.

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Initial Agency Response to Draft Report

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 Broadway, New York, NY 10007-1866

MEMORANDUM

DATE: October 22, 2020

SUBJECT: Response to Office of Inspector General Draft Report for Project No. OPE-FY18-0005: "Region 2's Response Efforts in Puerto Rico and U.S. Virgin Islands Need Improved Planning, Communications, and Assistance for Small Drinking Water Systems," dated September 1, 2020

FROM: Walter Mugdan for: Peter D. Lopez
Regional Administrator

TO: Kathlene Butler
Director, Water Directorate
Office of Evaluation
Office of Inspector General

Thank you for the opportunity to respond to the issues and recommendations in the subject audit report. Following is a summary of our overall position. More detailed, specific comments and suggestions are included in a Technical Comments Attachment, below.

We agree with Recommendation 1 and 2, and we have provided an accounting of current management strategies/actions along with additional high-level intended corrective management initiatives. Please note that we have provided estimated completion dates to the maximum extent possible.

Recommendation 3 involves EPA's Office of Water (OW). In consultation with OW, we expect to provide additional comments about that recommendation (including factual corrections about AWIA and resilience grants) by October 30.

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AGENCY'S OVERALL POSITION

Region 2 appreciates the Office of Inspector General's initiative to undertake an assessment and reporting of the Region's hurricane response efforts in Puerto Rico (PR) and the U.S. Virgin Islands (USVI), and for acknowledging the severity of the consecutive storms and their disastrous impacts; the geographic isolation of the islands; the pre-storm operating and economic challenges of numerous small, rural drinking water systems; as well as cultural differences which complicated and prolonged the emergency response efforts.

EPA also thanks the OIG for its gracious acknowledgement of the additional and creative efforts made by EPA to respond to the urgent needs and unusual circumstances faced by the people of the Caribbean as we worked to stabilize and support both PR's and USVI's efforts to protect public health and the environment in the wake of the twin storms.

In response to the recommendations made by the OIG in this report, EPA respectfully offers the following:

> Region 2 agrees that additional attention should be given to expediting the approval and dissemination of public health messages.
>
> In this regard, however, EPA emphasizes that the pervasive and prolonged disruption of communications, power and transportation infrastructure systems provided serious challenges to advancing broad-based and rapid deployment of health information and services.
>
> While more effective protocols and systems can be established between EPA, the Commonwealth and local governments, it is imperative to recognize that local staffing and fiscal limitations present additional challenges to ensuring rapid, consistent response capabilities. As such, EPA intends to advance its capacity building efforts, even as it continues to coordinate closely and amplify the work of local health department systems.
>
> EPA concurs with the importance of ensuring rapid consensus on public health messages and the delivery of the same in coordination with other federal agencies such as the Federal Emergency Management Agency (FEMA) and Health and Human Services (HHS).
>
> EPA also agrees that the Region 2 emergency response plan could be enhanced by engaging its local staff and reducing the challenges to support disaster response typically caused by the specific geographic, logistical, cultural norms, and language barriers in PR and USVI. With that said, it is imperative to note that Region 2's plans must allow flexibility, allowing for the likelihood of limited availability of local staff from the Region's Caribbean Environmental Protection Division (CEPD) due to likelihood of staff being heavily impacted by

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a disaster, as they were in the 2017 hurricane season. It should also be noted that EPA's local staff in PR will invariably have responsibilities to continue to manage important ongoing environmental programs and, therefore, may not be able to assume disaster response functions.

Region 2 is proactively advancing actions to strengthen the capacity and resilience of small, rural drinking water systems in PR and USVI, and will continue to provide training and technical assistance for system operators, and financial assistance as available and authorized by law.

Our existing Memorandum of Understanding (MOU, see attachment 3), established a framework that supports collaborative working relationships between non-governmental organizations (NGOs), academia, and EPA that have joined efforts to build capacity, and develop and implement equitable, reliable and resilient solutions to help these remote drinking water systems continue achieving improved capacity and resilience. This MOU led to the creation of the Water Coalition, which further expands this collaboration with the PR Department of Health, the U.S. Department of Agriculture Rural Development, and other representatives from academia and the not-for-profit sector. Region 2 will continue to use its best efforts to ensure a reliable provision of safe drinking water to these communities.

Notably, this collaboration is furnishing additional support through USDA in the form of staff persons to serve as "circuit riders" responsible for providing a broad range of continuous, dedicated technical support to the small, non- PRASA community water systems. This initiative is being further augmented through the announcement of additional circuit rider contracting support funded through EPA's Office of Enforcement and Compliance Assurance (OECA) to provide compliance assistance to 45 non-PRASA systems in Puerto Rico.

AGENCY'S RESPONSE TO REPORT RECOMMENDATIONS

Agreements

No.	Recommendation	High-Level Intended Corrective Action(s)	Estimated Completion by Quarter and FY
1.	Develop and implement a written regional procedure for the timely approval and dissemination of pre-drafted public health messages in the aftermath of a disaster so that impacted communities receive critical information in a timely manner in accordance with EPA Order 2010, *Crisis Communication Plan*.	EPA is currently updating its Crisis Communications Plan to refine the plan and ensure that it clearly lays out the process for communicating during an emergency. Part of the challenge during the response to Maria and Irma was that some EPA responders were not familiar with the EPA Crisis Communications Plan. To rectify this, EPA Region 2 will ensure that the plan is provided as part of the mobilization/orientation package given to responders, particularly those who will serve as community liaisons in the field. Further, Region 2 will ensure that in the summary of preparations a responder should make before arriving on scene the crisis communications plan is noted, and responders are encouraged to familiarize themselves with the plan.	2nd Quarter FY 2021 3rd Quarter FY 2021 4th Quarter FY 2021, contingent upon HQ finalization and availability of

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		To address any delays in getting materials approved for public dissemination particularly on major incidents like Hurricanes Irma and Maria, Region 2 will embed an Assistant Public Information Officer (PIO) in the incident who will focus on the EPA approval process and will serve as a liaison to get materials approved as quickly as possible. This Assistant PIO would also help coordinate, through EPA' Office of Public Affairs, messaging with other federal agencies. In addition, Region 2 will provide the latest version of the EPA Crisis Communications Plan to relevant emergency response and response corps members and also ensure that it is discussed during training sessions or exercises so that all responders will better understand the expectations set forth in the plan.	the updated Crisis Management Plan in 2nd Quarter FY 2021
2.	Develop and implement a supplement to Region 2's emergency response plan to describe and address the specific geographic, logistical, and cultural norms to disaster response in Puerto Rico and the U.S. Virgin Islands. This supplement should include local EPA staff roles and responsibilities, as well as address the likely limitations to transportation, communications, and power in the aftermath of disasters.	Region 2 agrees with the recommendation. The Region 2 emergency response program has initiated the development/implementation of plans to respond to emergency and disaster responses in the Caribbean. Discussions include the development and scope of a training, workshop and exercise program to better coordinate and integrate local personnel into the region's response structure. This initiative would include training on EPA's various roles, responsibilities and procedures, as well as identification of ways to effectively utilize CEPD personnel capabilities and expertise, especially during the early stages of a response to address limitations to transportation, communications, and power in the aftermath of disasters. Further development of cultural awareness guidance developed during the response to Hurricanes Irma and Maria and strategies for addressing language barriers would also be addressed and included in deployment materials. Region 2's plans must allow flexibility since limited availability of local staff must also be considered, as the majority of CEPD staff will likely be heavily impacted by a disaster, as they were in the 2017 hurricane season. In addition, capabilities of the EPA local staff in PR and USVI may be limited due to existing responsibilities managing environmental programs.	3rd Quarter FY 2023 The implications of travel restrictions due to COVID, and also diversion of resources to disaster responses within the region or nationally, may delay this completion date.

Please refer to Attachment 2 for additional information that could provide context and background information for the above responses.

Recommendation 3 involves EPA's Office of Water (OW). In consultation with OW, we expect to provide additional comments about that recommendation (including factual corrections about AWIA and resilience grants) by October 30.

CONTACT INFORMATION

If you have any questions regarding this response, please contact let me know or have your staff contact Arlene Chin, Region 2's Audit Coordinator, at (212) 637-3408 or Chin.Arlene@epa.gov, or Rudnell (Rudy) O'Neal, Chief, Grants and Audit Management Branch, Mission Support Division, at (212) 637-3427 or Oneal.Rudnell@epa.gov.

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Attachments

cc: Doug Benevento, Associate Deputy
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Staff
David Ross, Assistant Administrator, Office of Water
Dennis Lee Forsgren, Jr., Deputy Assistant Administrator, Office of Water
Anna Wildeman, Principal Deputy Assistant Administrator, Office of Water
Susan Bodine, Assistant Administrator, Office of Enforcement & Compliance
Assurance
James Hewitt, Associate Administrator, Office of Public Affairs
Nancy Grantham, Principal Deputy Associate Administrator, Office of Public
Affairs

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Second Agency Response to Draft Report

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 Broadway, New York, NY 10007-1866

MEMORANDUM

DATE: **November 2, 2020**

SUBJECT: Supplemental Response to Office of Inspector General Draft Report for Project No. OPE-FY18-0005:
"Region 2's Response Efforts in Puerto Rico and U.S. Virgin Islands Need Improved Planning, Communications, and Assistance for Small Drinking Water Systems," dated September 1, 2020

FROM: Peter D. Lopez
Regional Administrator

TO: Kathlene Butler
Director, Water Directorate
Office of Evaluation
Office of Inspector General

Thank you for the opportunity to provide a supplement to our initial response provided on October 22, 2020. This supplemental response addresses Recommendation 3 in the subject audit report and has been developed in coordination with the Office of Water.

We agree with Recommendation 3, and consistent with our previous response we have provided an accounting of current management strategies/actions along with additional high-level intended corrective management initiatives. Please note that we have provided estimated completion dates to the maximum extent possible.

AGENCY'S POSITION (Related to Recommendation #3)

Region 2 is proactively advancing actions to strengthen the capacity and resilience of small, rural drinking water systems in PR and USVI, and will continue to provide training and technical assistance for system operators, and financial assistance as available and authorized by law. EPA will continue to promote America's Water Infrastructure Act (AWIA) section 2013 training. Small water systems and technical assistance providers in Puerto Rico and the U.S. Virgin Islands are welcome to attend these workshops to assist them in developing risk and resilience assessments and emergency response plans. Small drinking water systems in

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Puerto Rico and the U.S. Virgin Islands do not serve more than 3,300 people, so AWIA certification requirements do not apply to them. However, EPA encourages drinking water systems of all sizes to perform risk and resilience assessments and, in addition to the risk and resilience checklist specifically designed for use by small systems that serve 3,301-49,999 people, EPA plans to publish guidance for systems serving less than 3,300 people in 2021. EPA also plans to conduct outreach to primacy agencies, including Puerto Rico and U.S. Virgin Islands, and via press release or social media when the competitive announcement for the resilience grant program authorized under the Safe Drinking Water Act (SDWA) section 1459A(l) (AWIA Section 2005) opens.

TECHNICAL COMMENTS ON THE REPORT (Related to Recommendation #3)

The discussion in the report regarding resiliency grant programs authorized under AWIA is unclear. AWIA amended SDWA in a number of ways, including establishing two new paragraphs that authorized two separate grant programs to support resiliency:

- 1433(g) – Technical Assistance Grants to implement the Drinking Water Infrastructure Risk and Resiliency Program and
- 1459A(l) – Drinking Water Infrastructure Resilience and Sustainability Grant to assist small and disadvantaged in increasing resilience to natural hazards.

No funding has been appropriated for the grant program authorized under Section 1433(g) of SDWA. EPA recommends clarifying that the recommendations and report do not relate to this program. For fiscal year 2020, Congress appropriated $3 million to fund grants authorized under 1459A(l). This program was not established to implement the programs in Section 1433 of SDWA.

AGENCY'S RESPONSE TO REPORT RECOMMENDATION 3

Agreements

No.	Recommendation	High-Level Intended Corrective Action(s)	Estimated Completion by Quarter and FY
3.	In coordination with the Office of Water, implement America's Water Infrastructure Act in Puerto Rico and the U.S. Virgin Islands by: a. Developing and implementing a strategy to provide training, guidance, and assistance to small drinking water systems as they improve their resilience. b. Establishing a process for small drinking water systems to apply for	EPA Office of Water will be promoting and conducting a series of AWIA section 2013 virtual workshops during January through March 2021 aimed at systems serving 3,301- 49,999 people, including a workshop focused on Region 2 water systems, to include Puerto Rico and U.S. Virgin Islands. Small water systems and technical assistance providers in Puerto Rico and the U.S. Virgin Islands are welcome to attend these workshops to assist them in developing risk and resilience assessments and emergency response plans. Since small drinking water systems in	Conduct training by end of Quarter 2 of FY 2021. Publish guidance for systems serving 3,300 or fewer customers by end of Quarter 1 of FY 2022. Conduct outreach when Request for Applications is released for the AWIA Drinking Water Infrastructure Resilience and Sustainability Grant by end of Quarter 1 of FY

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	America's Water Infrastructure Act grants. This process should include (1) implementing the EPA's May 2020 guidance provided to small drinking water systems regarding resilience assessments and (2) establishing a public information campaign to inform small drinking water systems of the America's Water Infrastructure Act grant opportunity, qualifying requirements, and application deadlines.	Puerto Rico and the U.S. Virgin Islands do not serve more than 3,300 people, AWIA certification requirements do not apply to them. However, EPA encourages drinking water systems of all sizes to perform risk and resilience assessments and has developed a risk and resilience checklist specifically designed for use by systems that serve 3,301-49,999 people. While the May 2020 guidance was for water systems serving 3,301-49,999 people, EPA plans to publish guidance for systems serving less than 3,300 people in 2021. EPA also plans to publish a Spanish version of this guidance to make it more accessible to small systems and technical assistance providers in Puerto Rico. As stated in the report, AWIA authorizes two grant programs to support resiliency of public water systems, and Congress appropriated $3 million for the program authorized under SDWA Section 1459A(l) (AWIA Section 2005). In accordance with EPA's *Policy for Competition of Assistance Agreements*, OW is preparing a competitive announcement to award the grants under this program. EPA will conduct outreach to primacy agencies, including Puerto Rico and U.S. Virgin Islands, and via press release or social media when the competitive announcement opens.	2022.

CONTACT INFORMATION

If you have any questions regarding this response, please contact let me know or have your staff contact Arlene Chin, Region 2's Audit Coordinator, at (212) 637-3408 or Chin.Arlene@epa.gov, or Rudnell (Rudy) O'Neal, Chief, Grants and Audit Management Branch, Mission Support Division, at (212) 637-3427 or Oneal.Rudnell@epa.gov.

cc: Doug Benevento, Associate Deputy Administrator Mandy Gunasekara, Chief of Staff
David P. Ross, Assistant Administrator, Office of Water
Dennis Lee Forsgren, Jr., Deputy Assistant Administrator, Office of Water Anna Wildeman, Principal Deputy Assistant Administrator, Office of Water

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Susan Bodine, Assistant Administrator, Office of Enforcement & Compliance Assurance James Hewitt, Associate Administrator, Office of Public Affairs
Nancy Grantham, Principal Deputy Associate Administrator, Office of Public Affairs

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Appendix C

Distribution

The Administrator
Assistant Deputy Administrator
Associate Deputy Administrator
Chief of Staff
Deputy Chief of Staff/Operations
Agency Follow-Up Official (the CFO)
Agency Follow-Up Coordinator
Regional Administrator for Region 2
Assistant Administrator for Water
Regional Deputy Administrator for Region 2
Principal Deputy Assistant Administrator for Water
Deputy Assistant Administrators for Water
General Counsel
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Director, Office of Continuous Improvement, Office of the Administrator
Director, Office of Regional Operations
Audit Follow-Up Coordinator, Office of the Administrator
Audit Follow-Up Coordinator, Region 2
Audit Follow-Up Coordinator, Office of Water

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Message

From: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
Sent: 1/6/2021 9:42:49 PM
To: OCSPP_Job_Opportunity [OCSPP_Job_Opportunity@epa.gov]
CC: Wallace, Ryan [Wallace.Ryan@epa.gov]; Gillespie, Andrew [Gillespie.Andrew@epa.gov]
Subject: OCSPP Job Opportunity: Supervisory Biologist/Toxicologist/Environmental Engineer/Physical Scientist/Chemist; GS-0401/0415/0819/1301/1320-15; OCSPP/OPPT/ECRAD/RAB5

The vacancy announcement for this position is currently open and is scheduled to close on Thursday, January 15, 2021. If you are interested in applying for this position, please make sure to read the entire vacancy announcement and instructions for submitting all required/necessary documentation to ensure your application is complete and acceptable for review and consideration.

The following job opportunity is being announced within the Office of Chemical Safety and Pollution Prevention **(OCSPP)**, Office of Pollution Prevention and Toxics **(OPPT)**, Existing Chemicals Risk Assessment Division **(ECRAD)**, Risk Assessment Branch 5 **(RAB5)**.

To view the specifics of this announcement, please click the following link:
https://www.usajobs.gov/GetJob/ViewDetails/588696100

Announcement Number: R-OCSPP-MP-2021-0022

Title:	Supervisory Biologist/Toxicologist/Environmental Engineer/Physical Scientist/Chemist
Series and Grade Announced:	GS-0401/0415/0819/1301/1320-15
Location of Position:	Arlington, VA
Area of Consideration:	Current permanent EPA employees with competitive status or EPA Career Transition Assistance Program (CTAP) eligibles.
Position Type:	Full time, permanent
Opening Date:	January 6, 2021
Closing Date:	January 15, 2021
Number of Vacancies:	1
Position Risk Designation:	This position is designated as Moderate Risk and requires a background investigation.

To be considered for this position, applicants must apply on-line at the USAJOBS.gov website by the closing date of the announcement and follow the vacancy announcement instructions for providing any applicable supplemental information.

Please share this announcement with anyone that you feel may be interested and meets the eligibility requirements.

Please do not respond to this email. For questions regarding this job opportunity, please contact Gloria Ashley Gaines on 919-541-0990 or gaines.gloria@epa.gov

Message

From: Willis, Sharnett [Willis.Sharnett@epa.gov]
Sent: 1/6/2021 10:10:59 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: Schedule for Thursday, January 7th
Attachments: Calendar for Chief of Staff.docx

Chief of Staff Calendar for Thursday, January 7, 2021

8:30 AM – 9:30 AM
AA Meeting (Doug Benevento will lead)
Green Room / Conference Call: Ex. 6 dial-in: Ex. 6
Barker, Kendal

10:30 AM – 11:00 AM
Check-In with George & Brock
Gunasekara, Mandy

12:00 PM – 12:30 PM
Check-In with Taylor
WJCN 3402
Gunasekara, Mandy

2:00 PM – 3:00 PM
Offboarding Information for Political Appointees
Microsoft Teams Meeting
Smith, Kathryn

Final Outgoing Appointees Transition

3:00 PM – 3:45 PM
Exit Conversation
WJCN-3402
Gunasekara, Mandy

Chief of Staff Calendar for
Thursday, January 7, 2021

▩	8:30 AM – 9:30 AM	[HYPERLINK \l "apptBB83BF3B_0"] Green Room / Conference Call: Ex. 6 ; dial-in: Ex. 6 Barker, Kendal
▩	10:30 AM – 11:00 AM	[HYPERLINK \l "apptBB83BF3B_1"] Gunasekara, Mandy
▩	12:00 PM – 12:30 PM	[HYPERLINK \l "apptBB83BF3B_2"] WJCN 3402 Gunasekara, Mandy
▩	2:00 PM – 3:00 PM	[HYPERLINK \l "apptBB83BF3B_3"] Microsoft Teams Meeting Smith, Kathryn [EMBED Word.Document.12 \s]
▩	3:00 PM – 3:45 PM	[HYPERLINK \l "apptBB83BF3B_4"] WJCN-3402 Gunasekara, Mandy

EPA Outgoing Appointees Transition Book

DECEMBER 2020

US ENVIRONMENTAL PROTECTION AGENCY

1200 Pennsylvania Avenue NW, Washington, D.C 20460

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[HYPERLINK "https://intranet.epa.gov/records/tools/files/rm_for_senior_officials.pdf"]

[HYPERLINK "https://intranet.epa.gov/records/senior_officials/files/CIO_Policy_2101.pdf"]

[HYPERLINK "https://www.epa.gov/sites/production/files/2018-09/documents/interim-records-mgmt-policy-20180822.pdf"]

[HYPERLINK "https://usepa.sharepoint.com/sites/oei/ermd/ECMS/SitePages/Home.aspx"]

[HYPERLINK "https://usepa.sharepoint.com/sites/oei/ermd/ECMS/SitePages/Guides(1).aspx"]

EPA Records Liaison Officers (RLO) Contacts;

- [HYPERLINK "https://intranet.epa.gov/records/hq.html"]
- [HYPERLINK "https://intranet.epa.gov/records/regional.html"]

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EPA Records Management Checklist 3110-49

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WHO CAN YOU CALL?

GENERAL:

WHL Office:	Micah Meadowcroft, White House Liaison; 202-564-0015; [HYPERLINK "mailto:Meadowcroft.Micah@epa.gov"]
Employee Services, Benefits, Unemployment:	Cynthia Burt, Supervisor, Employee Services Section, Human Resources Division, OARM-RTP; 919-541-0309 [HYPERLINK "mailto:tillman.nigel@epa.gov"], Benefits and Retirement Specialist, ESS; 919-541-2070

FINANCIAL/TRAVEL:

Payroll Solutions:	Eva Ripollone, Deputy Director, Office of Technology Solutions, 202-564-6768
Government Issued Travel Cards:	Cincinnati Finance Center, EPA Travel (Concur) Help Desk; 513-487-2346

RECORDS MANAGEMENT:

Records: 202-566-1643	[HYPERLINK "mailto:Ellis.john@epa.gov"], Agency Records Officer;

ETHICS:

Ethics:	Justina Fugh, Alternate Designated Agency Ethics Official, 202-564-1786 or [HYPERLINK "mailto:ethics@epa.gov"]

SECURITY/FACILITIES/ ELECTRONIC EQUIPMENT:

IT Equipment/Services:	Custodial Officer or Premier Support at 202-250-8890 or [HYPERLINK "mailto:Internal_EISD_FedTri_PremSup@epa.gov"] AO/Immediate Office: Donna Jenkins 202-564-6959
National Security:	National Security Information Program Team; 202-564-1983, [HYPERLINK "mailto:NSI_ProgramTeam@epa.gov"]
Headquarters Facilities and Security:	[HYPERLINK "mailto:jackson.yvette@epa.gov"], Director, Office of Administration;

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Prior to last day at EPA

1. Read the contents of this book!
2. Turn in Letter of Resignation
3. Review the [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/pdf/3110-2-Employee%20Standard%20Work%205-19-20.pdf"] document and begin completing EPA Form [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/pdf/3110-2.pdf"], Form [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/index.html"] for instructions. [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/pdf/EPA-Records-Management-Checklist-3110-49.pdf"], and the [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/pdf/Employee%20MD%20Acknowledgement%20Form_Fillable%20Offboarding.pdf"]
4. Submit [HYPERLINK "https://usepa.sharepoint.com/sites/OGC_Work/ethics/Shared%20Documents/Negotiation%20Notification%20Form%20for%20digital%20signature.pdf"] to OGC/ Ethics within 3 business days of negotiating for employment
5. Attend OMS Outboarding Session
6. Start disposition of records process
7. Turn in computer, phone, office keys, building ID, and EPA parking permit or Transit benefits and complete the Departing IT Request Form
8. Submit electronic EPA separation checklist see [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/index.html"] for instructions.
9. Complete Disposition of records and Chain of Custody form
10. Ensure Human Resources information is reviewed for accuracy and new forwarding address is submitted
11. Submit info for contact directory
12. Have your post-employment briefing with OGC/Ethics
13. Complete and submit the Public Financial Disclosure Form in INTEGRITY (late fees or penalties may apply.)
14. Complete the EPA exit survey

ASSISTANCE TOOL

THIS TOOL IS TO ASSIST YOU IN ENSURING YOU MEET ALL OF YOUR CHECK-OUT REQUIREMENTS. THERE ARE FIVE SECTIONS TO THIS TOOL:

GENERAL

FINANCIAL/TRAVEL

RECORDS MANAGEMENT

ELECTRONIC EQUIPMENT

SECURITY/FACILITIES

GENERAL

IF YOU HAVE ANY QUESTIONS, PLEASE CALL OR EMAIL MICAH MEADOWCROFT, WHITE HOUSE LIAISON AT 202-564-0015 OR [HYPERLINK "mailto:MEADOWCROFT.MICAH@EPA.GOV"]

Complete	Activity	Detail
☐	Receipt of Agency Departure Letter and Separation Date Determined	Contact: [HYPERLINK "mailto:Meadowcroft.Micah@epa.gov"], Whi House Liaison; 202-564-0015
☐	Political Appointee holds meeting with his/her respective Administrative Officer at least one week before departure	Contact the Administrative Officer for your respec organization
☐	Electronic Employee Separation Certification Form (EPA Form 3110-2) instructions are given to outgoing political appointees by their Administrative Officer. Detailed instructions are available at: [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/index.html"]	Contact the Administrative Officer for your respec organization
☐	Complete termination OGE-278 no earlier than 15 days before departure and no later than 30 days after departure	Contact: [HYPERLINK "mailto:ethics@epa.g Justina Fugh, 202-564-1786
☐	Exit Interview with OGC/Ethics prior to departure	Contact: [HYPERLINK "mailto:ethics@epa.g Justina Fugh, 202-564-1786
☐	Schedule Personnel Security De-briefing if you have Secret or Top-Secret clearance	Contact: National Security Information Program T HYPERLINK "mailto:NSI_ProgramTeam@epa.gov"]
☐	Preserve all records, schedule a meeting with your RLO to sign your 3110-49, and then obtain a signature from a supervisory official on your completed 3110-49 form.	Contact: your local [HYPERLINK "http://intranet.epa.gov/records/agency.html"

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☐	Schedule exit briefing with Retirement and Benefits specialist in the Employee Services Section, to discuss benefits, including Retirement, Thrift Savings Plan (TSP), Health Insurance and Life Insurance. The separation package will be mailed to you.	Contact: Cynthia Burt; 919-541-0309 or [HYPERLINK "mailto:tillman.nigel@epa.gov 919-541-2070
☐	Return EPA-issued equipment, including laptop, badge, mobile device, keys and any other government equipment	**HQ Separating Employees & Employees not i Region/Lab:** Contact you Immediate Supervisor Working Capital Fund Manager to initiate equipm return process. For additional guidance, contact Premier Support at 202-250-8890 or [HYPERLI "mailto:Internal_EISD_FedTri_PremSup@ep] to arrange for the return of the device. **Regional & Laboratory Separating Employees** Contact your Immediate Supervisor, RHRO, and Manager to initiate the return of equipment, keys badge.
☐	Return your government passport to OITA	Contact: Dennis Cunningham 202-564-6622
☐	Final Stop: Provide your Administrative Officer the fully executed SF-52 and completed Employee Separation Certification Form (EPA Form 3110-2)	Contact the Administrative Officer for your respec organization
☐		

FINANCIAL/TRAVEL

IF YOU HAVE ANY QUESTIONS, PLEASE CALL OR EMAIL EPA TRAVEL CENTER HELP DESK AT 513-487-2346 OR [HYPERLINK "mailto:CINWD_TRAVEL@EPA.GOV."]

Complete	Activity	Detail
☐	Destroy Travel Card	There is no need for EPA officials to turn in their travel card(s). Please **ensure that there is a zero balance remaining on the account**. This can be done by calling Citi, at 1-800-790-7206, and then **simply destroy the card**. If the cardholder has a balance remaining on the account, a travel claim for reimbursement should be submitted as soon as possible to the Cincinnati Finance Office or payment should be sent to Citi if reimbursement has already been made and there is an outstanding balance payable by employee. Upon receipt of the notification of separated employee(s), the Cincinnati Finance Office will close the travel card account.
☐	Submit Outstanding Travel Claims	Please ensure that **travel authorizations and/or vouchers are submitted** for processing as early as possible prior to your exit.
☐	Update Address in Employee Express	Please **update address, if necessary,** in Employee Express at **https//www.employeeexpress.gov/** This is important because W2s will be sent no later than January 31st to the address on record in Employee Express. W-2s will be mailed to the address on record as of

		12/31/2020. Please note: If you need to change or update your address or obtain a copy of your W-2, you will need to contact our payroll office. The Interior Business Center (IBC) at 888-367-1622, Option 3.

RECORDS MANAGEMENT

Senior Agency Officials and all noncareer staff departing the Agency are responsible for identifying EPA records in their possession (paper and electronic). All record material (electronic and hard copy) must be incorporated into the Agency's official filing system (e.g. ECMS), including email and text messages that are records. Please ensure that these records are maintained in a recordkeeping system and that custody is transferred to your Supervisor, Records Custodian (RC) or Records Liaison Officer (RLO).

Many of the paper or electronic records Senior Agency Officials have received and created during their tenure are of permanent value because they document the EPA's important decisions and policies. Examples of some documents that may be permanent records are calendars, schedules, and logs; committee records; email messages (for Capstone Officials); program development files; reports to Congress or to the President; and speeches and testimony. Additionally, the records that you create or receive in the conduct of Agency business during your tenure belong exclusively to the EPA.

Important Reminders

When leaving Federal service, government employees need to take steps to ensure all Federal records are properly managed and preserved until their authorized disposition. The willful and or accidental destruction of Federal records is punishable by a fine or imprisonment of up to three years, or both (18 U.S.C. 2071).

Removal of Documents (paper or electronic)

The Federal Records Act prohibits the unauthorized removal or destruction of federal records.

- Under no circumstance can a departing employee take the original record copy.
- Under no circumstance can a departing employee take a copy of a document subject to a preservation requirement such as a legal hold.
- A departing employee cannot take information that is deliberative or otherwise privileged.
- A departing employee cannot take classified information or other information subject to disclosure restrictions.

With authorization and subject to the requirements above:

- A departing employee can take non-records (that are not subject to a preservation requirement) and personal papers.
- A departing employee can take extra copies (convenience copies) of information that is in the public domain.

For more information about protecting federal records from unauthorized removal, please see [HYPERLINK "https://www.archives.gov/records-mgmt/bulletins/2013/2013-03.html"]. In addition, for more information about extra copies of records that you can remove, please see https://www.archives.gov/records-mgmt/publications/documenting-your-public-service.html

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Records Forms

There are two important forms that relate to records management:

1. EPA 3110-49 Form: EPA RECORDS MANAGEMENT CHECKLIST FOR SEPARATING/TRANSFERRING OR SEPARATED PERSONNEL; and

2. The Mobile Device Acknowledgement Form (if you were issued an EPA mobile device)

ALL employees must complete the EPA [HYPERLINK "https://intranet.epa.gov/records/files/EPA-Records-Management-Checklist-3110-49.pdf"], *which verifies that you have appropriately identified and transferred custody of your records before you depart. EPA 3110-49 must be signed by your Records Liaison Officer and a supervisory official; you cannot self-certify that you have met your records management obligations.*
[HYPERLINK "https://intranet.epa.gov/records/index.html"][HYPERLINK "https://intranet.epa.gov/records/faqs/email.html"]
Please see links to additional Records Management Guidance:

- [HYPERLINK "https://intranet.epa.gov/records/index.html"]
- [HYPERLINK "https://intranet.epa.gov/records/faqs/email.html"]
- [HYPERLINK "https://gcc01.safelinks.protection.outlook.com/ap/w-59584e83/?url=https%3A%2F%2Fusepa-my.sharepoint.com%2Fpersonal%2Fmurray_paulette_epa_gov%2FDocuments%2FEZ%2520Records%2520-%2520Private%2FProgram%2520Reviews%25202020%2FWorking%2520Documents%2FezD3246863_Program%2520Reviews%2520Overview%25206_22_2020.docx%3Fweb%3D1&data=04%7C01%7CKelly.Lynn%40epa.gov%7C9ec82324fad843dc613808d8961d384a%7C88b378b367484867acf976aacbeca6a7%7C0%7C0%7C637424399520690868%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=heij2THQ6kGKAbbcOkbbYy07dJVuycFvBwOsRT6cYkk%3D&reserved=0"]
- [HYPERLINK "https://usepa.sharepoint.com/sites/oei/ermd/ECMS/SitePages/MS-Teams-Saving-Records.aspx"]
- [HYPERLINK "https://usepa.sharepoint.com/sites/oei/ermd/nrmp/SitePages/faqs/mobile.aspx"]
- [HYPERLINK "https://intranet.epa.gov/records/faqs/socialmedia.html"]

One critical aspect of Form 3110-49 concerns litigation holds. If you are a litigation hold custodian, you must identify and preserve all litigation hold materials in your possession, custody or control. Box 13 of Form 3110-49 requires litigation hold custodians to provide the following information: (a) the name of the litigation hold; (b) the name of the case attorney who issued the hold; (c) a description of the litigation hold materials in your possession, custody or control, and (d) a description of the location of those materials. The space in Box 13 is limited, so if you are the subject of multiple litigation holds, please prepare a separate document to append to Form 3110-49 providing the information required by Box 13 and add "see attached" in Box 13 on the form. If you are not certain if you are a litigation hold custodian and/or you do not recall the list of holds to which you are subject, you can access the litigation holds to which you are subject by following the instructions here: [HYPERLINK "https://usepa.sharepoint.com/sites/OGC_Work/GLO/eDiscovery_eDocument/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2FOGC%5FWork%2FGLO%2FeDiscovery%5FeDocument%2FShared%20Documents%2FA%2E%20Litigation%20Holds%20and%20Preservation%2FCustodian%5FHold%5FReport%5FInstructions%2Epdf&parent=%2Fsites%2FOGC%5FWork%2FGLO%2FeDiscovery%5FeDocument%2FShared%20Documents%2FA%2E%20Litigation%20Holds%20and%20Preservation"]. You can also request that your office's Records Liaison Officer (RLO) run a report of your current litigation holds for you.

Please Complete EPA Records Management Checklist Form 3110-49 in Appendix 1

http://intranet.epa.gov/records/files/EPA-Records-Management-Checklist-3110-49-final-DC20161012.docx

Mobile Devices

Text messages, photos, or other information stored only on your government-issued phone (or your personal phone if used to conduct agency business) may be federal records. Information on the requirements for managing records on either type of mobile device is located on pages 4-5 of the Agency's [HYPERLINK "https://www.epa.gov/sites/production/files/2018-09/documents/interim-records-mgmt-policy-20180822.pdf"]. For additional guidance on this, please review the [HYPERLINK "https://usepa.sharepoint.com/sites/oei/ermd/nrmp/SitePages/faqs/mobile.aspx"].

If you were issued an EPA mobile device (cell phone, iPad, hot spot etc.) you must also complete the Employee Mobile Device Form after you have managed the records stored on that device. A completed Employee Mobile Device Form must be returned with each device. If you do not complete an Employee Mobile Device Form for each of your devices, your supervisor will have to manage the records on your device(s) and complete the form in order to terminate the device in eBusiness.

Before completing the Mobile Device Acknowledgment form, we recommend that you consult the [HYPERLINK "https://intranet.epa.gov/mobiledevices/pdf/How-to-Save-Text-Messages-QRG1.pdf"] *and* [HYPERLINK "https://intranet.epa.gov/mobiledevices/pdf/How-to-Save-Photos-and-Videos.pdf"] *documents.*

Please Complete EPA Mobile Device Acknowledgment Form in Appendix 2 (if applicable)

CONTACT INFORMATION FOR HEADQUARTERS RECORDS CONTACTS

AO Lena Ferris Phone: 202-564-8831 Email: [HYPERLINK "mailto:ferris.lena@epa.gov" \h]	**OMS** Mitchell Hauser Phone: 202-564-7636 Email: [HYPERLINK "mailto:hauser.mitchell@epa.gov"]
OAR Shawn W. Stingel Phone: 202-564-1503 Email: [HYPERLINK "mailto:stingel.shawn@epa.gov" \h]	**OECA** Daniele Albergottie, Sr. (Acting) Phone: 202-566-1550 Email: [HYPERLINK "mailto:albergottie.daniele@epa.gov"]
OCFO Chandra Kennedy Phone: 202-564-8317 Email: [HYPERLINK "mailto:kennedy.chandra@epa.gov"]	**OGC** LaShawn Williams Phone: 202-564-3822 Email: [HYPERLINK "mailto:williams.lashawn@epa.gov"]
OIG Billy Eason Phone: 202-566-2703 Email: [HYPERLINK "mailto:eason.billy@epa.gov" \h]	**OITA** Inga Barnett-Owens Phone: 202-564-6439 Email: [HYPERLINK "mailto:barnett-owens.inga@epa.gov" \h]

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ORD Brian Devir Phone: 513-569-7809 Email: [HYPERLINK "mailto:devir.brian@epa.gov" \h]	**OCSPP** Denise A. Adams Phone: 202-564-0329 Email: [HYPERLINK "mailto:adams.denise@epa.gov" \h]
OW Miriam Wiggins-Lewis Phone: 202-564-9373 Email: [HYPERLINK "mailto:wigginslewis.miriam@epa.gov" \h]	**OLEM** Terrence Ferguson Phone: 202-566-0370 [HYPERLINK "mailto:ferguson.terrence@epa.gov" \h]

CONTACT INFORMATION FOR REGIONAL RECORDS LIAISON OFFICERS

Region 1 (CT, MA, ME, NH, RI, VT) Margo Palmer Phone: 617-918-1949 Email: [HYPERLINK "mailto:palmer.margo@epa.gov"]	**Region 2** (NJ, NY, PR, VI) Kate Russ Phone: 212-637-3391 Email: [HYPERLINK "mailto:russ.mary@epa.gov"]
Region 3 (DC, DE, MD, PA, VA, WV) Michael Klotz Phone: 215-814-5382 Email: [HYPERLINK "mailto:klotz.michaelk@epa.gov"]	**Region 4** (AL, FL, GA, KY, MS, NC, SC, TN) Shayla Patillo Phone: 404-562-8385 Email: [HYPERLINK "mailto:patillo.shayla@epa.gov"]
Region 5 (IL, IN, MI, MN, OH, WI) David Hoff Phone: 312-353-0623 Email: [HYPERLINK "mailto:hoff.david@epa.gov"]	**Region 6** (AR, LA, NM, OK, TX) Leticia Lane Phone: 214-665-7202 Email: [HYPERLINK "mailto:lane.leticia@epa.gov"]
Region 7 (IA, KS, MO, NE) Vern Hoobler Phone: 913-551-7638 Email: [HYPERLINK "mailto:hoobler.vernonn@epa.gov"]	**Region 8** (CO, MT, ND, SD, UT, WY) Gina Mays Phone: 303-312-6721 Email: [HYPERLINK "mailto:mays.gina@epa.gov"]
Region 9 (AZ, CA, HI, NV, PI) Bess Gordon Phone: 415-972-3330 Email: [HYPERLINK "mailto:gordon.bess@epa.gov"]	**Region 10** (AK, ID, OR, WA) Yvette M. Whitmire Phone: 206-553-8320 Email: [HYPERLINK "mailto:whitmire.yvette@epa.gov"]

ELECTRONIC EQUIPMENT

Before you return any device, you must review the information on the device, manage any records that are saved to the device, and complete the employee mobile device acknowledgment form for each mobile device.

For HQ employees, if devices are in your office, you should make arrangements with your organization for you or, your supervisor to obtain access to the device and manage the records on the device. If devices are at a remote location, provide your shipping address in the eBusiness cancellation request.

Regional appointees should coordinate mobile device return with their local md administrator and coordinate computer return with their local helpdesk.

Please complete Employee Mobile Device Acknowledgement

Form in Appendix 2

LINK: [HYPERLINK "https://intranet.epa.gov/mobiledevices/pdf/Employee-Mobile-Device-Acknowledgement-Form_Fillable.pdf"]

Please Complete the Political Appointee Equipment Return Checklist in Appendix 5

SECURITY/FACILITIES

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT YVETTE JACKSON AT 202-564-7231 OR [HYPERLINK "mailto:Jackson.Yvette@epa.gov"]

Complete	Activity	Detail
☐	Security	Secret/Top Secret/SCI Debriefing - If you have an active clearance, you must contact the NSI Program Team at 202-564-1983 to schedule a mandatory debriefing to include signing off on the non-disclosure agreement(s) prior to leaving EPA. EPASS Badge and ID Badges – Your EPASS badge (the one with the gold chip) and any facility access card you may have, must be returned before you leave the agency. You may turn in this property to your local badging office or your administrative staff. If you have any questions, you may contact [HYPERLINK "mailto:SmartCard@epa.gov"]. (NOTE: During COVID Phases 1, 2 and 3, you will need to make an appointment at the badging office.)
☐	Property	**Property Pass** – If you have been issued a permanent property pass, you must return it to your program Property Custodial Officer. If you are uncertain about the identity of your Custodial Officer, contact Dexter Johnson, HQ Property Utilization Officer, at 202-564-2030. **Government-owned Property** – All government-owned property, such as laptop computers, Blackberries, and mobile phones, must be returned to your program Property Custodial Officer. **Keys** – All keys supplied to you including those for your government-owned vehicles or file cabinets must be returned to your program office Administrative staff or your Custodial Officer. All keys issued for access into your office should be returned to the Security Badge Office in B-317, WJC East. (Note – During COVID Phases 1, 2 and 3, you will need to make an appointment at the badging office.)
☐	Transportation	**Parking Permit and Assess Card** – If you have been issued an executive parking permit, you must contact your HQ Transportation Manager (HQTM) with the date you will last use the space and return the electronic access card to the HQTM in room B200, WJC West. **Transit Subsidy Program (TSP)** - If you are a participant in the Transit Subsidy Program (Smart Benefits), you must complete the TSP Withdrawal Form and submit it to the Transit Office located in RRB M300, or send by Agency mail to 3204T. You may contact the HQs Transportation Manager, Scotty Hayes at [HYPERLINK "mailto:hayes.scotty@epa.gov"], 202-566-2535, to receive a copy of the Withdrawal Form.

EMPLOYEE SEPARARION CERTIFICATION FORM

PLEASE COMPLETE EMPLOYEE SEPARATION CERTIFICATION FORM 3110-2 IN APPENDIX 3

PROCEDURES FOR COMPLETING EPA FORM 3110 -2, EMPLOYEE SEPARATION CERTIFICATION FORM

EPA employees are required to account for all government property in their possession or custody, outstanding monetary or leave advances, financial indebtedness to the Agency and unexpired terms and conditions of outstanding employment and/or training agreements. Employees are responsible for arranging through appropriate administrative channels, settlement of outstanding debts and obligations, return of any government property issued, and clearance for proprietary or confidential information. [HYPERLINK "http://webdev2.rtpnc.epa.gov/intranet/oarmpage/web2/offboarding/pdf/3110-5.pdf"] is incorporated by reference.

Failure to complete this certification will result in the delay of final payment(s) or annuities.

The form 3110-2 supersedes all previously issued Agency separation forms. With this revision, all certifications will be conducted by email. The following Standard Work is designed to ensure the most efficient method for employees to exit the Agency, regardless of geographic location or organization assigned. It is important to remember that this is a certification, and the guidance developed is to ensure a consistent and standard process across the EPA.

Once the EPA Form 3110-2 is complete, the separating employee and Immediate Supervisor will digitally sign and certify the form. By signing the EPA Form 3110-2, you and your Immediate Supervisor certify that all U.S. Government property has been returned and that all documentary materials and records have been properly identified and transferred. The statements made on the form and all attachments are true, accurate and complete.

You acknowledge that any false or misleading statement may be punishable by fine, imprisonment or both under 18 U.S.C. § 1001 or other applicable law.

INSTRUCTIONS FOR SEPARATING EMPLOYEE

You and your Immediate Supervisor will review the EPA Form [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/pdf/3110-2.pdf"] and the requirements for completion. You are **REQUIRED** to follow the Standard Work provided below.

Note: Please refer to Employee Separation Certification Form 3110-2 in Appendices 3 for standard work for employee and supervisor.

DISPOSITION OF EPA FORM 3110-2

Once you have received all required certification emails (except badging), you and your Immediate Supervisor will conduct a review of the folder created on the One Drive prior to your departure to ensure all requirements have been met and that the EPA Form 3110-2 is accurate.

You will then apply your digital signature to the form 3110.2. You will then save the form in the

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folder on One Drive as 3110-2 empsig. It is very important that you save it with this naming convention.

Your Immediate Supervisor will print a hardcopy for you which you will retain for your personal records. You may provide a personal email to your supervisor to receive the final digitally signed copy. Once the Immediate Supervisor digitally signs the document, the document will lock, and no further changes can be made. The Immediate Supervisor will notify the person competing the SF-52, this person will upload the Form 3110-2 into FPPS or the current HR system for final review and submission the HRSSC. The HRSSC will verify the 3110-2 is complete and process the offboarding action. This concludes the EPA Employee Separation Process.

All guidance for the employee separation process, including standard work guidance for Immediate Supervisors or Certifying Official, can be found on the EPA Employee Offboarding intranet site: [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/index.html"].

EPA OFFBOARDING PROCESS FOR POLITICAL APPOINTEES AND ADS DURING COVID-19

Steps	Actions	Process
1	**A.** Immediate Supervisor notifies **PMO/RHRO** of employee(s) retiring, transferring, reassigning, or otherwise leaving the agency. **B. PMO/RHRO** notifies the Offboarding PM of the separation. **C.** Offboarding PM will schedule an orientation meeting with the Immediate Supervisor and **Separating Employee**. (Days 1-2)	The Offboarding PM will set up an orientation meeting with the Immediate Supervisor and **Separating Employee** to go over the EPA Offboarding process requirements. Offboarding PM will review EPA's offboarding process requirements using the Offboarding website at: [HYPERLINK "https://intranet.epa.gov/ohr/offboarding/index.html" \h] Offboarding PM will provide instructions on how to setup Separation designated OneDrive folder.
2	**PMO/RHRO** provides the Immediate Supervisor with the current list of organizational certifying officials list. (Day 2)	**PMO/RHRO** ensures the list of certifying officials is accurate and up to date. The certifying list of officials should be sent via email to the Immediate Supervisor as soon as the notification of separation has been made.
3	Immediate Supervisor provides **Separating Employee** with the separation designated OneDrive folder, certifying official list, required forms to be completed, email template, and EPA separation certification form, 3110-2. (Days 2-3)	The Immediate Supervisor creates a separation designated OneDrive folder for the **Separating Employee** to upload separating documents. The separation designated OneDrive folder serves as the repository for approved employee separation certification documents, required forms (records management and mobile device form, *if applicable)* and email clearances provided by certifying officials.

Steps	Actions	Process
4	**Separating Employee** creates (using the provided email template) and distributes emails to applicable certifying officials. The **Separating Employee** ensures the Separation Certification Form, 3110-2 is completed and signed once all email clearances have been received and the EPA- issued equipment has been mailed back to EPA (*see Step 5 below for further details*). The **Separating Employee** will upload all separating documents into the Separation designated OneDrive Folder for the Immediate Supervisor review and signature. (Days 3-5)	**Separating Employee** prepares their emails to the provided list of certifying officials for clearance approvals. An email is not required for Records Management. The **Separating Employee must** complete the Records Management Form 3110-49 in lieu of the email submission. If the **Separating Employee** has an EPA-issued mobile device, the employee must complete following sections of the [HYPERLINK "https://intranet.epa.gov/mobiledevices/pdf/mobiledevices-acknowledgement-form.pdf"], in lieu of an email submission: EPA PROPERTY DECAL #/IMEI # (EXCEPT NEW DEVICE ORDERS) 3. DEVICE RETURN (RETURN OF OLD DEVICE, NO NEW DEVICE ASIGNED) SECTION 2 – REQUIRED FOR EMPLOYEES RETURNING DEVICES **POC: Premier Support 202-250-8890 or** [HYPERLINK "mailto:Internal_EISD_FedTri_PremSup@epa.gov"] The **Separating Employee** is responsible for ensuring all approved clearances are received and uploaded into OneDrive. If for any reason, the **Separating Employee** cannot complete this process, the Immediate Supervisor is responsible for completing the offboarding process for the **Separating Employee**.
5	***NPM managed Offices*:** Immediate Supervisor notifies Working Capital Fund Manager to set up EPA issued equipment return process. ***Regional & Laboratory Offices:*** Immediate Supervisor contacts **RHRO & Facility Manager** to set up EPA issued equipment return process. (Days 2-4)	**HQ Separating Employees and Separating Employees outside the National Capital area who are not in a Regional Office or a Regional Laboratory:** Working with the Immediate Supervisor, the Working Capital Fund Manager will request CT cancelation for departing employee's laptop. Please include a remote mailing address for the prepaid shipping box in the comments section of the cancelation order. Also include personal email and cell phone number just in case the team needs to contact you post separation. • A prepaid shipment box will be mailed to the employee's home address (if applicable). • The following items should be returned: laptop, badge, mobile device, keys, and any other government equipment. **Separating Employee** should use the enclosed checklist form when returning items. Also include the Separation Certification form before sealing the box. • Affix the prepaid address label and mail to EPA. **POC: Premier Support 202-250-8890 or** [HYPERLINK "mailto:Internal_EISD_FedTri_PremSup@epa.gov"]

Steps	Actions	Process
		Regional and Laboratory Separating Employees should contact the Immediate Supervisor, **RHRO** and **Facility Manager** to initiate the return of EPA issued equipment, keys and badge.
6	**Separating Employee** completes Exit Survey. (Days 5-10)	**Separating Employees** are encouraged to complete the exit survey at: [HYPERLINK "https://www.surveymonkey.com/r/X5XVTKJ" \h]
7	Immediate Supervisor digitally signs Separating Employee Separation Certification Form 3110-2 and notifies **PMO/RHRO**. (Day 10*)	**The Immediate Supervisor must receive the UPS Tracking number and confirms package is in transit before signing the Separation Certification Form, 3110-2.* Immediate Supervisor notifies the **PMO/RHRO** (via email) that the separating documents have been loaded into Separation designated OneDrive Folder.
8	**PMO/RHRO** enters employee separation paperwork into the Federal Personnel Processing System and notifies the respective HR-SSC. HR-SSC processes employee separation and issues final check.	**PMO/RHRO** enters information into FPPS for HR-SSC processing. Upon receipt of the signed Separation Certification Form 3110-2, HR-SSC processes employee separation and issues final check.

RESIGNATION LETTERS

To ensure timely and accurate processing of separation paperwork, last paycheck, lump sum annual leave, etc., it is imperative that, prior to separation, you submit a letter of resignation with reason for separation and your exact last day on the payroll. Guidance for staff resigning by request due to a change in administration will be forthcoming. Do not write or submit a letter until it is requested of you. When prompted by OPM/the White House, the Office of the White House Liaison will communicate with you the correct steps for writing and submitting your letter of resignation.

Eligibility and Nature of Resignation: If you resign by request due to a change in Presidential administration or agency leadership, you may be eligible for unemployment benefits, provided you meet all other eligibility requirements. If you resign before being requested to do so, you may not be

eligible. Resigning before receiving a request to resign is generally considered an unprompted resignation and is not usually viewed as sufficient for unemployment compensation purposes.

REFERENCE GUIDE

DEPARTURE PROCEDURE:

WHAT DO I NEED TO DO BEFORE I DEPART THE ENVIRONMENTAL PROTECTION AGENCY?

All Non-Career SES and Schedule C Appointees must submit a resignation letter addressed to **Administrator Wheeler** with a copy to the White House Liaison (WHL), Micah Meadowcroft. The letter is given to the WHL and placed in your OneDrive folder. A copy of this letter will be sent by the WHL to White House Presidential Personnel and to the EPA Executive Resources Team. Presidential Appointed, Senate Confirmed (PAS) Appointees must submit a letter of resignation addressed to the President, cc: **Administrator Wheeler.** The letter is given to the WHL and submitted to White House Presidential Personnel and a copy is given to the EPA Executive Resources Team. In addition, you have certain ethics responsibilities that are described in more detail below.

YOUR LAST WEEK AT WORK

The effective date of your separation is no later than **January 20, 2021** at 12:00 pm, unless you choose to resign before that date. A Non-Career SES, Schedule C, or AD employee may only resign "involuntarily" for retirement purposes once the PAS Appointee, to whom they report, has resigned and that the resignation letter has been received and accepted by the President.

The employee needs to complete all employee separation requirements, including records management requirements, prior to departing the agency in order to receive your final pay. You should meet with your Administrative Officer at least 1-week prior to your separation to obtain the appropriate "Separation and Check- out" documents. You must report to:

- *Administrative Officer*: Receive "Separation and Check-out" form, return all government-issued equipment, e.g., cell phone, laptop, keys. If you are uncertain who your Administrative Officer is, please contact the WHL, Micah Meadowcroft.
- *Cincinnati Finance Center/EPA Travel Helpdesk (CONCUR)*: All vouchers should be submitted prior to departure. Destroy government-issued travel card.
- *Ethics*: You will be assigned a termination public financial disclosure report (OGE Form 278e) in INTEGRITY. You must submit this form no later than 30 calendar days after your departure from federal service and no earlier than 15 calendar days before your termination date. You can ask for an extension for good cause; but must do so in writing before your due date. A $200 late fee applies to reports that are filed 30 calendar days after the due date. Failure to file a termination report will lead to referral to the U.S. Attorney General for civil action and possible civil penalties. In addition, there are several ethics rules applicable to you while you are seeking non-federal employment and still employed at EPA, as well as post- employment rules. You must schedule an exit interview with the Office of General Counsel's Ethics Team prior to your departure. Please [HYPERLINK "mailto:ethics@epa.gov"] or Justina Fugh, Alternate Designated Agency Ethics Official, at 202-564-1786 or, fugh.justina@epa.gov.
- *Facilities*: Return your Metro SmarTrip card or parking permit, including hang tag, to the Transportation Team located in room B200, WJC West.
- *Security*: Return your Agency identification (EPASS) badge as well as any Facility Access Card (the one without your photo) to the Badging Office located in room

B317, WJC East.(Note – during COVID Phases 1, 2 and 3, you will need to make an appointment with the badging office.) It you have a Secret or Top Secret security clearance, and those with Sensitive Compartmented Information (SCI) access, please notify the National Security Information (NSI) Program Team to schedule the required debriefings. For an appointment, they can be reached at 202-564-1983. If you are physically located in a Regional office or lab, please return your badge(s) to your local Security Representative.

If you have a Secret or Top Secret security clearance and those with SCI access, please contact your local NSI Representative to schedule the required debriefings. If you are unsure who your NSI Representative is, please contact the NSI Program Team on 202-564-1983 for assistance.

ANNUAL AND SICK LEAVE BALANCES:

WHAT HAPPENS TO MY SICK AND ANNUAL LEAVE WHEN I SEPARATE FROM THE FEDERAL GOVERNMENT?

ADs, Schedule Cs and Non-Career SES will be eligible for a lump sum payment of annual leave at the hourly rate of their former position. Your hourly rate can be found on your Leave and Earnings Statement found on the Employee Express website. There are no lump sum payments for unused sick leave. It will be held in abeyance and would be reinstated if the employee returns to federal employment. To ensure that your sick leave will be reinstated at the proper level if you rejoin the Federal Government, please print and save a copy of your last Leave and Earnings Statement, you may need to show it to a federal employer in the future.

You can access the website at: https://[HYPERLINK "http://www.employeeexpress.gov/" \h]

HOW DO I ACCESS EMPLOYEE EXPRESS?

Using a secured internet browser, the proper URL for Employee Express is https://**[HYPERLINK "http://www.employeeexpress.gov/" \h]**. You have access to Employee Express for 56 calendar days after your separation. After 56 calendar days any payroll related documentation would have to be obtained by contacting our payroll office, IBC, at 888-367-1622 Option 3.

HOW CAN I GET MY EMPLOYEE EXPRESS PASSWORD RESET?

Go to [HYPERLINK "https://www.employeeexpress.gov/DefaultLogin.aspx" \h]and click on, "Forgot Login ID or
Password?". The link will guide you through the process of resetting your password.

WHAT HAPPENS TO MY BENEFITS?

HOW LONG WILL MY HEALTH INSURANCE LAST AFTER I LEAVE THE GOVERNMENT?

After separation, Federal Employees Health Benefits (FEHB) coverage continues at no cost for 31 calendar days from the end of the pay period of your separation date. It could be continued temporarily for an additional 18 months under the Temporary Continuation of Coverage (TCC) program, which is the Federal Government's COBRA coverage. To continue coverage, you must file an election with the Agency and pay both the employee and employer cost (plus 2 percent administrative cost.) A representative from the EPA Benefits Office will give you notice of your TCC rights within 61 calendar days after you separate from service. If you want TCC, you must elect it within 60 calendar days from the later of: 1) your separation; or 2) the date of the notice provided by the Benefits

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Office. If you elect to continue your insurance for 18- months or if you are eligible for retirement, please contact Nigel Tillman at 919-541-2070 or by email at [HYPERLINK "mailto:Tillman.Nigel@epa.gov"].

Please note: If you want TCC, Nigel Tillman at 919-541-2070 or [HYPERLINK "mailto:Tillman.Nigel@epa.gov"].

WHERE CAN I FIND ADDITIONAL INFORMATION REGARDING TCC?

[HYPERLINK "https://www.opm.gov/healthcare-insurance/healthcare/temporary-continuation-of-coverage/" \h] [HYPERLINK "https://www.opm.gov/healthcare-insurance/healthcare/temporary-continuation-of-coverage/" \h]

WHAT HAPPENS TO MY FLEXIBLE SPENDING ACCOUNT (FSA)?

Money in an FSAFEDS flexible spending account – either the health care flexible spending account or the dependent care flexible spending account – must be used by the date the employee separates from the Government, or he or she will lose the unused balance. However, the claims do not have to be submitted by the separation date. When an employee incurs eligible expenses before the separation date, he or she can submit bills for services up to April 30, 2021. Current PAS, Non-Career SES and Schedule C employees who are participating or plan to participate under the FSA program should be careful when designating their annual amounts as there is a greater potential of signing up for more than what could reasonably be used before leaving EPA.

WHERE CAN I FIND ADDITIONAL INFORMATION REGARDING MY FSA?

https:/[HYPERLINK "http://www.fsafeds.com/fsafeds/index.asp" \h]

WHAT HAPPENS IF I REGISTERED FOR THE FEDERAL EMPLOYEE VISION AND INSURANCE PROGRAM (FEDVIP)?

Coverage under the FEDVIP terminates at the end of the pay period of your separation from Federal Service, unless the employee is eligible for an immediate annuity. Please note, FEDVIP is an employee- pay-all program and is separate from the Federal Employees Health Benefit (FEHB) Program as well as any dental or vision coverage you may receive from your FEHB Plan.

WHERE CAN I FIND ADDITIONAL INFORMATION REGARDING MY FEDVIP?

https:/[HYPERLINK "http://www.benefeds.com/" \h]

WHAT HAPPENS TO MY FEDERAL LONG-TERM CARE INSURANCE PROGRAM?

Long term care insurance coverage is fully portable, which means it continues without change when employees leave the Federal Government—the same product and the same price—if they continue to pay premiums. The US Office of Personnel Management (OPM) is still the policyholder, and the coverage continues to be administered by Long Term Care Partners, LLC. Employees paying through payroll deduction should contact Long Term Care Partners directly so they can switch their payment methods to direct bill or automatic bank withdrawal.

ONCE I LEAVE THE ENVIRONMENTAL PROTECTION AGENCY, WHOM CAN I CONTACT WITH QUESTIONS?

Please contact Nigel Tillman from the RTP Human Resources Management Division, at 919-541-2070 or by email at tillman.nigel@epa.gov.

RETIREMENT:

CAN I RETIRE AT THE END OF THE ADMINISTRATION? IF SO, WHAT WOULD MY RETIREMENT LOOK LIKE?

If you have at least five years of civilian service under FERS and are age 62 or older, you now qualify for an immediate annuity under FERS. This annuity would be 1% of your high three average salary for each year of service.

If you have at least 10 years of total federal service (civilian and/or military) under FERS, including at least five years of civilian service under FERS, and are now the Minimum Retirement Age, (age 55-57 based on your year of birth), you now qualify for an immediate annuity. This is called an MRA + 10 annuity. This annuity would be 1.0% of high three average salary for each year of service, but it would be permanently reduced by 5% for each year under age 62. Alternatively, you can elect to postpone this annuity until age 62, in which case there would be no age reduction.

An employee under CSRS may retire voluntarily after reaching age 55 with 30 years of service, age 60 with 20 years, or age 62 with 5 years.

Under FERS, voluntary retirement is available at the minimum retirement age (MRA, 55 to 57, depending on year of birth) with 30 years of service, age 60 with 20 years, or age 62 with five years. Under FERS, one can also retire on a reduced annuity at MRA with as little as 10 years of service.

An employee may also be eligible for early retirement (discontinued service retirement (DSR)), based on an involuntary separation. This type of retirement also qualifies for an immediate annuity. Under both CSRS and FERS, one must be age 50 and have at least 20 years of service or have at least 25 years of service regardless of age, in order to be eligible for discontinued service retirement.

If you leave at the end of the Administration, this is considered an involuntary separation.

To determine your eligibility or if you believe you fit the criteria for retirement at the end of the Administration, please contact Nigel Tillman at 919-541-2070 or [HYPERLINK "mailto:Tillman.Nigel@epa.gov"].

WHAT IS THE BASIC DIFFERENCE BETWEEN FERS AND CSRS RETIREMENT SYSTEMS?

Retirement-eligible appointees who are new to Government service will be covered under the Federal Employees' Retirement System (FERS), a three-tiered system consisting of Social Security benefits, basic FERS (a defined benefits plan), and the Thrift Savings Plan (a defined contributions plan). Most political appointees are covered under FERS. If your service to the Federal Government first began after 1987, you should automatically be covered under FERS instead of Civil Service Retirement System (CSRS).

Appointees who have prior Government service starting before 1987 may be covered under one of several plans, depending upon individual circumstances. Those plans include FERS, CSRS without Social Security coverage, or a coordinated combination of CSRS with Social Security coverage, called CSRS Offset.

HOW DO I KNOW WHICH RETIREMENT SYSTEM I AM UNDER?

The fastest way is to look in the Deductions section of your Leave and Earnings Statement accessible on the Employee Express website at: https://[HYPERLINK "http://www.employeeexpress.gov/" \h]

WHEN DO I QUALIFY FOR A RETIREMENT BENEFIT?

If you have at least five years of civilian service, you qualify for retirement benefits. If you have not yet reached five years of civilian service, the money you put in your FERS retirement fund will stay in abeyance until you return to service (or until you take a refund of your contributions). Once you hit the 5-year mark, you are eligible for payment of a benefit when you turn 62.

IF I AM RETIREMENT ELIGIBLE, HOW DO I KNOW IF I GET CONTINUED HEALTH BENEFITS?

If you retire under a retirement system for Federal employees, you can continue your group health insurance into retirement, provided you qualify for an immediate annuity and you were enrolled for the 5 years of service immediately before retirement, or – if less than 5 years – for all service since your first opportunity to enroll. As a retiree, you would pay the same contribution for health insurance as active employees do.

IF I AM NOT 62 YEARS OF AGE OR THE MINIMUM RETIREMENT AGE AND COVERED UNDER FERS, WHAT HAPPENS TO MY RETIREMENT BENEFITS?

If you leave Federal service before you meet the age and service requirements for an immediate retirement benefit and you do not withdraw your FERS retirement contributions (which EPA suggests you do not, even if you do not have 5 years of service at the end of the Administration. because you never know when you might return to federal service), you may be eligible for deferred retirement benefits. To be eligible, you must have completed at least 5 years of creditable civilian service. You may receive benefits when you reach one of the following ages and service:

If you retire at the MRA with at least 10, but less than 30 years of service, your benefit will be reduced by 5 percent a year for each year you are under 62, unless you have 20 years of service and your benefit starts when you reach age 60 or later. This annuity would also be 1.0% of high three average salary for each year of service.

WILL I MAINTAIN ANY ADDITIONAL BENEFITS UNDER A DEFERRED ANNUITY?

Under a deferred annuity, health and life insurance benefits cannot be reinstated.

HOW DO I RECEIVE MY DEFERRED RETIREMENT ANNUITY WHEN I TURN 62?

If you wish to apply for deferred retirement under FERS, an application form (RI Form 92-19) should be requested from OPM at least three months in advance of the desired retirement date. The RI Form 92-19 is also available on the OPM website. Your completed application should be submitted to the following address:

Office of Personnel Management Civil Service
Retirement System Retirement Operations
Center Boyers, PA 16017

Please note: To receive your retirement benefit if/when you meet the criteria, you MUST contact the US Office of Personnel Management. OPM does not automatically send out the Application for Deferred Retirement or try to find you to pay you your money.

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SHOULD I TAKE THE FERS REFUND?

The decision is completely up to you. If you return to the Federal government, it is possible to make a redeposit for the refunded service. If you do not make a redeposit, the service will still be creditable for making you eligible for retirement but will not be used in the calculation of a retirement annuity.

IF I HAVE LESS THAN 5 YEARS OF SERVICE AND WITHDRAW MY FERS CONTRIBUTIONS, WILL I RECEIVE THE PORTION THAT THE GOVERNMENT PAID IN? OR DO I RECEIVE ONLY THE MONEY THAT I CONTRIBUTED?

You would only receive your contributions.

IF I HAVE LESS THAN 5 YEARS OF SERVICE, DO I GET A REFUND OF MY FERS CONTRIBUTIONS WHEN I REACH RETIREMENT AGE?

In order to receive a refund, you need to apply for it. OPM does not automatically send it out. A refund can be requested any time after 31 calendar days of separation. You don't have to wait until "retirement age" although EPA suggests you do not take the payout until you are 100% sure you will never return to federal service.

IF I LEAVE FEDERAL GOVERNMENT IN JANUARY 2021 WITH 3 YEARS OF SERVICE AND RETURN TO FEDERAL GOVERNMENT AT OR AROUND THE AGE OF 58, THEN WHAT ARE MY OPTIONS FOR RETIREMENT? WOULD I BE ELIGIBLE TO RETIRE AFTER 5 YEARS OF SERVICE OR WOULD I NEED TO WAIT UNTIL I REACHED MY MINIMUM RETIREMENT AGE?

In order to be eligible for a benefit in this example, you would need at least 5 years of service and be at least 62. If you have 3 years and come back at age 58, then you would reach 5 years at age 60. However, in order to meet both age and service requirements, you would need to work until age 62 so that you would then have 7 years of service at retirement.

HOW DO I GET A RECORD OF HOW MUCH TIME I HAVE IN FEDERAL SERVICE IF I HAVE WORKED FOR MANY FEDERAL AGENCIES? ON THE HILL? IN THE JUDICIAL BRANCH?

You should request a copy of your service history from Executive Resources. In addition, you should work with the human resources specialist to be sure all your service is reflected correctly in your OPF. For additional information, please contact Nigel Tillman at 919-541-2070.

DO I GET HEALTH BENEFITS IF I AM ELIGIBLE FOR DEFERRED RETIREMENT?

No, if you retire on a deferred retirement, you cannot keep your Health Benefits. Your health benefits will terminate on the last day of the pay period in which your resignation is effective, however, you will continue to be covered by your plan for 31 calendar days after your enrollment terminates (at no cost to you). This continuation of coverage gives you an opportunity to convert to a non-group plan with your current FEHB insurance company. You will not be required to provide evidence of insurability (good health) to convert to a non-group plan under FEHB during these 31 calendar days.

As an alternative to converting to a non-group contract, you may choose to continue your FEHB coverage under the Temporary Continuation of Coverage (TCC) program. This program allows for an additional eighteen (18) months of coverage under the FEHB after the date of your resignation. You have sixty (60) calendar days from your separation date or from the date you receive the notice of the opportunity to elect TCC (whichever is later). Coverage for the TCC plan is effective the day your 31-calendar

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day temporary extension ends.

WHERE CAN I GET ADDITIONAL INFORMATION REGARDING RETIREMENT?

https://[HYPERLINK "http://www.opm.gov/retire/index.asp" \h]

THRIFT SAVINGS PLAN (TSP):

WHEN AM I VESTED IN TSP?

Most FERS employees become vested in their Agency Automatic (1%) Contributions after completing 3 years of Federal (generally civilian) service. However, employees who are in one of the following positions at separation are vested after 2 years of civilian service.

- A Non-Career or Limited Term SES appointee.
- Executive Schedule positions listed in 5 U.S.C. 5312, 5313, 5314, 5315, or 5316 and a position placed in level IV or level V of the Executive Schedule, under 5U.S.C. 5317 (aka PAS and PA positions).
- A position in the executive branch that is exempted from the competitive service by the Office of Personnel Management because of the confidential and policy-determining character of the position (aka Schedule C positions).

WHAT DOES IT MEAN TO BE VESTED IN MY TSP CONTRIBUTIONS?

If you meet the SP vesting requirements when you leave Federal service, you are entitled to the Agency automatic (1%) contributions in your account and their earnings.

I HAVE CONTRIBUTED TO MY TSP – WHAT HAPPENS TO MY CONTRIBUTIONS WHEN I LEAVE FEDERAL SERVICE BUT WANT TO KEEP MY MONEY IN THE TSP ACCOUNT?

If your account balance is $200 or more when you separate from service and you do not want to withdraw your account, you can leave your entire account balance in the TSP. Your account will continue to accrue earnings, and you can continue to change the way your money is invested in the five TSP investment funds by making interfund transfers. Please note, however, that you cannot make additional contributions to your account after you separate (other than transfers from eligible employer plans, traditional IRAs or another TSP account), and you cannot borrow from your account or make an in-service withdrawal. You are required to either withdraw your account balance in a single payment, begin receiving monthly payments or begin receiving annuity payments by April 1 or *the latter* of: the year following the year you become age 72 *or* the year following the year you separate from Federal service.

I HAVE CONTRIBUTED TO MY TSP—ONCE I LEAVE FEDERAL SERVICE, CAN I ROLL MY MONEY INTO ANOTHER FUND OUTSIDE OF THE GOVERNMENT?

A TSP account is a portable retirement benefit. This means that when you leave service you can have the TSP transfer the account to a traditional IRA or eligible employer plan (for example, the 401(k) plan of a new employer). Check with your new employer to see if its plan can accept your transfer. Amounts transferred will continue to accrue tax- deferred earnings until you receive your money unless you have chosen the Roth option, which will not be subject to taxes.

If you choose to receive the account in a single payment, you can have the TSP transfer all or part of your account balance to a traditional IRA or eligible employer plan. However, you can direct the transfer to only one IRA or eligible employer plan. The amount not transferred will be paid directly to you.

To request a transfer, please complete Form TSP-70, Withdrawal Request. Also, you and

the financial institution or administrator of the IRA or plan that is to receive your money must complete Form TSP-70-T. Please note there are tax implications for all transfers except for ROTH designated TSP accounts. Please note there are tax implications for all transfers. Please make sure you read the notice, "Important Tax Information About Payments From Your TSP Account," found at [HYPERLINK "http://www.tsp.gov/" \h]

WHERE CAN I LOOK FOR FURTHER INFORMATION ABOUT MY TSP ACCOUNT IN GENERAL?

[HYPERLINK "http://www.tsp.gov/" \h]

WHOM DO I CONTACT ABOUT MY TSP ACCOUNT BEFORE I LEAVE FEDERAL SERVICE?

Please contact a representative in the RTP Human Resources Management Division, Employee Services Section. Nigel Tillman is the retirement and benefits counselor. He may be reached via email at Tillman.Nigel@epa.gov.

WHOM DO I CONTACT WITH QUESTIONS ABOUT MY TSP ACCOUNT AFTER I LEAVE FEDERAL SERVICE?

The TSP Service Office can answer questions about your account and can send you TSP withdrawal materials to supplement withdrawal package provided to you by EPA Human Resources Benefits Staff when you separate.

TSP Service Office National Finance Center
P.O. Box 61500
New Orleans, LA 70161
1-877-968-3778

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UNEMPLOYMENT COMPENSATION (UCFE):

CAN I FILE FOR UNEMPLOYMENT?

Presidential appointees, Non-Career and limited term SES appointees, and Schedule C employees who resign by request or are separated due to a change in agency leadership or as a result of the transition to a new Presidential Administration may be eligible for Unemployment Compensation for Federal Employees (UCFE). Unemployment compensation is typically provided through the state in which the individual's last official duty station is located (though it is determined by a three-factor equation, so this is not always 100% the case). For most agency appointees, this will be Washington, DC. Benefit levels and eligibility requirements vary from state to state. For further information about UCFE requirements and benefits and to ensure that you receive the correct benefit if you are eligible, contact the specific State Workforce Agency *in which you reside first*. To find your local State Workforce Agency, please visit the following website: [HYPERLINK "http://www.servicelocator.org/OWSLinks.asp" \h]

To ensure that unemployment offices are aware that the separation by request is due to a change in Presidential Administrations or agency leadership, it is important to have your human resources office indicate on your SF-50 and all UCFE claims inquiry forms "R19-Reason for resignation-Asked to resign due to change in administration."

Individuals are advised to provide a copy of the request for resignation to the State unemployment compensation office when filing.

WHAT FORMS TO I NEED?

a. "Notification of Personnel Action," SF-50, documenting your separation,
b. "Notice to Federal Employee about Unemployment Insurance," SF-8,
c. Copy of your last Statement of Earnings and Leave, and
d. Social Security Card

WHERE CAN I GET ADDITIONAL INFORMATION ABOUT UNEMPLOYMENT?

The Department of Labor established a website that includes applications for unemployment compensation and information on career resources at: [HYPERLINK "http://www.careeronestop.org/PeoplePlaces/PeoplePlaces.aspx" \h]

ONCE I LEAVE THE EPA, WHOM CAN I CONTACT WITH QUESTIONS?

Nigel Tillman is the retirement and benefits counselor. He may be reached via email[HYPERLINK "mailto:"] tillman.nigel@epa.gov.

LIFE INSURANCE:

WHAT HAPPENS TO MY LIFE INSURANCE COVERAGE WHEN I LEAVE?

If you registered for the Federal Employee Group Life Insurance (FEGLI) when you became a federal employee, your life insurance will continue for 31 calendar days after separation at no cost to you. The life insurance can be converted, without medical examination, to non-group coverage at that time, with rates based on age and class of risk.

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HOW DOES SOMEONE CONVERT THEIR LIFE INSURANCE TO AN INDIVIDUAL POLICY?

When your group life insurance (FEGLI) terminates, you are entitled to convert to an individual policy. If you have assigned your insurance (assignment is the transfer of ownership of life insurance to another individual, corporation, or trustee--you are still the insured person, but you no longer own the insurance), it is the assignee(s), rather than you, who is (are) entitled to convert your coverage.

Under the conversion privilege, you may convert all or any part of your Basic and Optional insurance to an individual policy. No medical examination is required.

The individual policy will be issued by any insurance company you (or your assignee(s), if applicable) select that has been accepted by OPM as eligible and that has agreed to issue such policies under the provisions of the FEGLI contract. When you are ready to convert your coverage, you may request a list of eligible insurance companies from the *Office of Federal Employees' Group Life Insurance at P. O. Box 2627, Jersey City, NJ 07303-2627 or 1-800-633- 4542.*

The individual policy may be for any type of life insurance customarily issued by the insurance company you select, except term insurance, universal life insurance or any other type of life insurance with an indeterminate premium. It cannot include disability or Accidental Death & Dismemberment benefits.

Any insurance policy purchased under the conversion privilege is a private business transaction between you and the insurance company. The cost of the individual policy is determined by the insurance company and is based on your age and class of risk.

WHERE DO I GO TO GET ADDITIONAL INFORMATION?

Additional information on how you can convert your insurance is found in your copy of the Notice of Conversion Privilege (SF-2819) mailed to you by a representative in the RTP Shared Service Center. You can contact them by calling 919-541-2201.

IS THERE A FORM TO FILL OUT TO CONVERT MY LIFE INSURANCE POLICY TO AN INDIVIDUAL POLICY?

Yes, complete the SF-2819, Notice of Conversion Privilege.

IS THERE TIME I MUST SEND IN THE CONVERSION FORM BY?

Your time to convert is limited. You must submit your SF-2819 within 31 calendar days after your FEGLI benefit expires, or said in another way, no later than 62 calendar days after you separate from Federal Service. If you fail to request conversion information within the 31-day calendar time limit due to a cause beyond your control, you may be allowed to convert your life insurance within six months after your FEGLI benefit expires, provided you attach a full explanation of what prevented you from making a timely request. If approved, the effective date of the conversion policy will be retroactive to the day following the day group coverage ended.

Please note: To be on the safe side, if you want to convert your life insurance, submit your SF-2819 to *Office of Federal Employees' Group Life Insurance (OFEGLI), 200 Park Avenue, New York, NY 10166-0188* as soon as possible after you separate from Federal Service.

ONCE I LEAVE THE ENVIRONMENTAL PROTECTION AGENCY, WHOM CAN I CONTACT WITH QUESTIONS ABOUT LIFE INSURANCE?

Please contact a representative in the RTP Human Resources Management Division, Employee Services Section. Nigel Tillman is the retirement and benefits counselor. He may be reached via email at tillman.nigel@epa.gov[HYPERLINK "mailto:mcallister.amy@epa.gov" \h]or by phone at 919-541-2070.

SECURITY CLEARANCES:

WHAT ARE MY RESPONSIBILITIES TO BE FULLY COMPLIANT WITH EPA'S OUT-PROCESSING PROCEDURES?

You must notify your Administrative Officer or the Executive Resources Team of your imminent departure so they may provide you the necessary information on what is required for you to properly out-process from the agency. Not doing so can prolong the process for you to transfer to another federal agency or private sector position. There are forms that will need to be completed, as well as debriefings based on your holding a security clearance and if applicable, access to SCI.

WHAT ARE MY OUT-PROCESSING RESPONSIBILITIES SPECIFICALLY REGARDING MY SECURITY CLEARANCE AND SCI ACCESS?

All personnel with a Top Secret or Secret security clearance and those who have SCI access will be required to receive a debriefing and execute the Non-Disclosure Agreement (NDA).

This is the same form that was signed when the person was indoctrinated. Please contact the National Security Information Program Team to schedule your debriefing.

It is recommended that you contact the National Security Information Program Team at 202-564-1983 to schedule a debriefing appointment 2-weeks prior to your planned departure.

WHEN DOES A SECURITY CLEARANCE EXPIRE?

A security clearance does not actually expire, but there is a reinvestigation requirement for maintaining one in good standing, as well as a requirement for there being a continued need for access. If the level of clearance you hold is a Top Secret, you are subject to periodic reinvestigations every five years. For a Secret clearance, the periodic reinvestigation requirement is every 10 years.

WHAT HAPPENS TO MY SECURITY CLEARANCE WHEN I LEAVE MY JOB?

Since your security clearance was granted based upon the requirements of your position, when you depart the agency, your clearance will be withdrawn. This is not an adverse action.

WHAT SHOULD I DO IF I PLAN TO TRANSFER TO ANOTHER JOB WITH A FEDERAL AGENCY THAT REQUIRES A SECURITY CLEARANCE?

If, after you leave the EPA, your new position requires a security clearance, then depending on the circumstances, you can be granted a clearance by that organization, as long as your background investigation is in scope (not more than 5 years old for Top Secret or 10 years old for Secret) and it meets the standard for the clearance level. If you have questions about your clearance level or the completion date of your last investigation, please call the Personnel Security Office at 202-564-7912.

WHAT SHOULD I DO IF I PLAN TO TRANSFER TO ANOTHER JOB, BUT I WILL BE A CONTRACTOR FOR A PRIVATE COMPANY AND THE POSITION REQUIRES A SECURITY CLEARANCE?

Inform the company during the hiring process that you held security clearance with the Environmental Protection Agency. The contractor or private company's security office will know the process to determine if a clearance can be reciprocally recognized for your new position.

TRANSFERRING TO ANOTHER FEDERAL AGENCY:

WHAT DO I NEED TO DO IF I AM TRANSFERRING TO ANOTHER OFFICE IN THE FEDERAL GOVERNMENT DIRECTLY FROM THE EPA?

First, notify [HYPERLINK "mailto:Meadowcroft.Micah@epa.gov"], EPA's White House Liaison, and then notify your Administrative Officer. They will inform the Executive Resources Team of your pending departure. The EPA HR specialist will ensure that your benefits and records transfer smoothly to your new federal agency (via Standard Form-75).

If you are transferring to another federal position that requires the filing of a public financial disclosure report and you will not have a break in service of more than 30 days, , you will not need to file a termination OGE 278e.. If your new federal position will require that you file an OGE- 278, then contact Justina Fugh, Alternate Designated Agency Ethics Official, or [HYPERLINK "mailto:ethics@epa.gov"] so that EPA can notify the ethics officials at your new agency to merge your accounts in INTEGRITY. If your new federal position does not require that you file an OGE278, then you must file a termination OGE278e in INTEGRITY no later than 30 days calendar after you leave EPA, absent an extension.

FEDERAL RECORDS AND PERSONAL PAPERS (FILES):

ARE THERE PENALTIES FOR NOT PROPERLY FOLLOWING THE FEDERAL RECORDS AND PERSONAL PAPER

Yes, there could be penalties. The willful and/or accidental destruction of records is punishable by a fine or imprisonment of up to three years, or both (18 U.S.C. 2071).

Therefore, if you have any questions, we urge you to contact your Program Office's records officer or your Administrative Officer first. If you are in doubt whether you can take something, please get authorization first.

OUTGOING FINANCIAL DISCLOSURE/TERMINATION OGE-278e:

WHO NEEDS TO FILE A TERMINATION OGE-278e?

All appointees (e.g., Schedule C, Non-Career SES, PAS and some ADs) who file a

public financial disclosure report (OGE278e) with the Office of General Counsel/Ethics must submit a termination OGE278e through INTEGRITY within 30 calendar days after leaving the EPA. You may file the report no earlier than 15 calendar days prior to your departure. Please provide OGC/Ethics with a personal email address to contact you after departure in case of any questions regarding this last report.

WHAT IF I DO NOT FILE A TERMINATION OGE 278e?

If you file your termination report more than 30 calendar days after the due date without receiving an extension, you will be assessed a $200 late fee. This late fee is subject to collection by EPA even after your departure. If you fail to file a termination OGE 278, you will be referred to the U.S. Attorney General for civil action and penalties. In the past, EPA once had to refer a former employee to the Department of Justice for failure to file a termination report. That individual did file a report and paid a civil penalty of $15,000.

HOW MANY DAYS DOES AN OUTGOING APPOINTEE HAVE TO FILE A TERMINATION OGE-278 AFTER LEAVING EPA BEFORE GETTING A FINE?

If you are leaving the Federal Government and not assuming another OGE-278 position, then you must submit your termination report within 30 calendar days after leaving the position. You may request an extension by contacting [HYPERLINK "mailto:ethics@epa.gov"] or Justina Fugh, Alternate Designated Agency Ethics Official, but your request must be submitted prior to the 30th calendar day. The maximum extension is 90 calendar days.

CAN AN OUTGOING APPOINTEE FILE THE TERMINATION OGE 278 BEFORE THEY LEAVE THEIR APPOINTMENT?

Yes, the termination report can be filed up to 15 calendar days before the last day of the appointment.

ONCE I LEAVE, WHOM MAY I CONTACT ABOUT QUESTIONS RELATING TO MY OGE 278e?

Please direct any ethics questions or questions relating to the public financial disclosure report to [HYPERLINK "mailto:ethics@epa.gov"] or to Justina Fugh, Alternate Designated Agency Ethics Official, at 202-564-1786. All appointees (PAS, non-career SES, Schedule C and Administratively Determined) are subject to the federal ethics laws and regulations regarding seeking and negotiating for employment and for post-employment. *See, e.g.,* 5 CFR Part 2635, Subpart F; 18 U.S.C. § 208; 5 C.F.R. Part 2641; and 18 U.S.C. § 207. But how the rules apply to your situation will depend on your EPA duties, whether you are a supervisor, your area of official responsibility, your annual salary and your prospective employer. In other words, the rules are not necessarily intuitive, so we urge you to reach out to an ethics official <u>before</u> you make an ethics error.

TOP SEVEN THINGS TO KNOW ABOUT SEEKING AND POST-EMPLOYMENT

1. **Contact OGC/Ethics early!** We can be reached easily at **[HYPERLINK "mailto:ethics@epa.gov"]** .

2. **Your ethics obligations begin as soon as you start to "seek employment"**

You are **SEEKING EMPLOYMENT** when you:

- directly or indirectly make an unsolicited communication regarding possible employment
- engage in discussions with a view toward reaching an agreement on possible employment
- receive a response to a job application or employment proposal indicating an interest in employment discussions
- make a response, other than rejection, to an unsolicited communication regarding possible employment with someone

3. **You must recuse while seeking employment**

Do not work on any matter at EPA that has a direct and predictable effect on the financial interest of a prospective employer.

TYPE AND STATUS OF JOB APPLICATION	MATTERS OF GENERAL APPLICABILITY*	SPECIFIC PARTY MATTERS**
Unsolicited application (but haven't heard anything in the first two months)	OKAY to participate	RECUSE from participation
Unsolicited application (but haven't heard anything after two months)	OKAY to participate	OKAY to participate
You receive a response other than an affirmative rejection.	RECUSE	RECUSE

* Official actions that affect the entire sector or discrete industry, such as legislative initiatives, rulemaking or policy determinations

** Official matters that affect the prospective employer as an identified party, such as a grant, contract, permit, license, enforcement action, lawsuit, or audit.

EXAMPLES

Talking to a headhunter but you have no idea about the identity of possible employer	No need to recuse until you know the name of the possible employer
Talking to friends for general networking ideas or contacts	No need to recuse until you submit a resume or application to a specific job or company
You post your resume on LinkedIn or another social media site	You are NOT seeking employment with the world
"Not interested now, but talk to me after January 2021"	You are NOT seeking employment
"I'll make a decision on your situation and then we can talk about a possible job"	You need to recuse before making the decision

4. **Once you begin negotiations, continue to recuse and submit the Notification of Negotiating or Agreement form to OGC/Ethics**

You are **NEGOTIATING FOR EMPLOYMENT** when you:

- enter two-way discussions or communications about a potential non-federal job that is mutually conducted with another person with a view toward reaching an agreement regarding possible employment or compensation.

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As soon as you take a meaningful step toward reaching an agreement (even if not quite at the point of discussion about actual terms of employment), you have *three* business days to submit the attached form to OGC/Ethics.

Please complete the Notification of Negotiation or Agreement Form in Appendix 4

[HYPERLINK "https://usepa.sharepoint.com/sites/OGC_Work/ethics/Shared%20Documents/Negotiation%20Notification%20Form%20for%20digital%20signature.pdf"]

5. **You must file a termination OGE 278e Financial Disclosure Form**

   You must submit a termination OGE 278e in INTEGRITY that is due no later than 30 calendar days after leaving EPA. We can accept your report *no earlier than* 15 calendar days before your departure. The reporting period for this last report will be January 1, 2020 through your last day at EPA. (NOTE: if you filed a new entrant report in 2020, then your reporting period is from your start date through your departure date).

   If you need more time for good cause, then submit an extension request, with a reason, to [HYPERLINK "mailto:ethics@epa.gov"] before the deadline expires. We cannot grant any extensions after the deadline.

   A $200 late filing fee is automatically imposed and due upon the filing of a late report, which is one that is filed more than 30 calendar days after the due date without an extension. If this fee is not paid in a timely manner, and no fee waiver was requested and granted for extraordinary circumstances, then this debt will be referred to the appropriate federal agency for collection.

   Please note that, in 2012, the Department of Justice settled a case with a former EPA employee who did not file her termination 278. She had to turn in her form and pay a fine of $15,000.

6. **After you leave, you are subject to federal post-employment restrictions and Trump Ethics Pledge restrictions**

   After you leave federal service, you will be subject to the criminal provisions of the post-employment statute, 18 U.S.C. § 207 and the implementing regulations at [HYPERLINK "http://www.ecfr.gov/cgi-bin/text-idx?SID=702bfcea659a6288d7ec575fc1291d06&mc=true&node=pt5.3.2641&rgn=div5" \h]. Some of the restrictions depend upon your current rate of pay and your type of your appointment. In addition, as a political appointee, you are subject to additional post-employment restrictions in the President's Ethics Pledge, such as not registering as a foreign agent. If you were a procurement official, then you are also subject to the Procurement Integrity Act restrictions at [HYPERLINK "https://www.gpo.gov/fdsys/pkg/USCODE-1998-title41/html/USCODE-1998-title41-chap7-sec423.htm" \h], [HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2016-07-26/pdf/2016-17553.pdf" \h] [HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2016-07-26/pdf/2016-17553.pdf" \h].

7. OGC/Ethics is still here to answer your post-employment questions

Even after you leave, remember that we are still here to answer questions and provide you with written opinions regarding the post-government employment rules. You may reach us at [HYPERLINK "mailto:ethics@epa.gov" \h].

WHOM DO I CONTACT WITH ANY QUESTIONS REGARDING ETHICS RULES?

Contact Justina Fugh, Alternate Designated Agency Ethics Official at 202-564-1786, or send an email to [HYPERLINK "mailto:ethics@epa.gov"].

FAQs FOR OUTGOING APPOINTEES

PAYROLL Q's & A's

Q. *When will I get my last paycheck?*

A. Separated employees will receive their last paycheck anywhere between 1-2 pay periods after separation.

Q. How can I get my Employee Express password reset?

A. Go to [HYPERLINK "https://www.employeeexpress.gov/Default.aspx" \h]and click on, "Forgot Login ID or Password?" The link will guide you through the process of resetting your password.

Q. *Where will W-2s be sent?*

A. Paper W-2s will be mailed to latest address indicated on the employee's most recent Leave and Earnings Statement. Any check payments that may be made will also be sent to this address.

Employees are urged to check their addresses and make any changes directly in Employee Express or with their servicing human resources office prior to separation.

Q. *Will I be paid for any unused leave?*

A. Separating employees will be paid for any unused annual leave. In most cases, payment will be made at the same time as the last paycheck.

Q. If I have advanced sick leave at the time of departure, will I be charged for it?

A. Yes. Often this is referred to as a negative leave balance, in which the monetary amount associated with that leave is deducted from the last check. If you have taken advanced sick leave or a different type negative balance exists, it will be taken from your last paycheck. If funds are unavailable, you will be responsible for paying the amount owed. This is referred to as an Out of Service Debt, and a letter will be sent to provide information on repayment.

Q. *Will I be paid for regular and travel compensatory time (comp time)?*

A. Separating employees will be paid for unused regular compensatory time. In most cases, payment will be made at the same time as the last paycheck.

Travel compensatory time will not be paid out and should be used prior to departure.

Q. *If I have any questions, regarding Employee Express who should I call?*

A For questions regarding Employee Express, please contact Patricia Freeman at 202-564-0590.

Q. *If I have questions regarding pay who should I call?*

A. For questions regarding pay, please contact Eva Ripollone at 202-564-6768.

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Q. *What should I do with my government travel card? What should I do with my government travel card?*

A. Make sure your travel account is closed. Destroy the travel card. For non-HQ employees, government travel cards should be hand-delivered by you or a member of your staff to your Agency Program Coordinator (APC).

Q. *How long do I have to submit my claim for reimbursement for my past trips?*

A. You should submit any claims for reimbursement (outstanding travel vouchers) as soon as possible. As a traveler, you are required to electronically sign your vouchers within 5 business days of your return to the office to facilitate payment. In the event you have departed the agency contact your SBO or regional Mission Support Office to coordinate the processing of any open travel vouchers.

Remember, if you **don't** submit a travel voucher before your exit, EPA will **not** reimburse you for your expenses, but you will still be **required** to promptly reimburse the travel charge card company.

Q. *Who should I call if I have any questions?*

A. If you have any travel related questions, you should contact the EPA Travel Center Help Desk at 513-487-2346.

RELOCATION – OUTGOING OFFICIALS

Q. Will the Agency cover my relocation costs after I leave EPA?

A. The Government is not authorized to pay relocation expenses for separating Presidential appointees, non-career SES appointees, or Schedule C appointees to return to private industry or to their place of residence. Please see the General Services Administration's website at [HYPERLINK "http://www.gsa.gov/portal/content/104790" \h]for additional information about travel and transportation allowances, in particular those for departing political appointees.

Q. Who should I call if I have any questions?

A. If you have any relocation travel related questions, you should contact the EPA Federal Employee Relocation Center at (513) 487-2346 or 1-800-887-2067

[SEQ CHAPTER \h \r 1]**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
Washington, D.C. 20460

OFFICE OF
GENERAL COUNSEL

UPDATED NOVEMBER 2020
FOR PAS AND NON-CAREER SES

Ethical Rules Relating to Your Departure from EPA

Thank you for your service to EPA and the Executive Branch. While you are planning to move to the next phase of your career or retirement, you have continuing ethics obligations because you are still an EPA employee. This document reviews the ethics rules regarding:

- seeking and post-employment criminal laws and regulations;
- termination financial disclosure reporting requirements;
- employment negotiation and procurement integrity notification requirements; and
- Trump Ethics Pledge post-employment requirements.

Your ethics officials are here for you during and after your departure from federal service to answer your questions and provide ethics opinions, so please use us as a resource! Contact us at [HYPERLINK "mailto:ethics@epa.gov"].

BEFORE YOU LEAVE GOVERNMENT SERVICE

1. <u>Seeking employment</u>: you may not participate in a "particular matter" having a direct and predictable effect on the financial interests of any person or entity with whom you are seeking or negotiating for employment or with whom you have an agreement for future employment. *See generally, 5 Code of Federal Regulations, Subpart F, 18 United States Code (U.S.C.) § 208.*

"Seeking employment" <u>begins</u> *when you:*

- directly or indirectly make an unsolicited communication regarding possible employment with any person or entity;
- engage in negotiations with a view toward reaching an agreement regarding possible employment;
- receive a response to a job application or employment proposal indicating an interest in employment discussions; or
- make a response, other than rejection, to an unsolicited communication from any person regarding possible employment with that person.

"Seeking employment" <u>ends</u> when:

- you or the prospective employer reject the possibility of employment and all discussions of possible employment have terminated; or

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- two months have elapsed since you sent an unsolicited resume or employment proposal, and you have not received an interest in employment discussions.

See generally, 5 C.F.R. Part 2635, Subpart F

Example 1: You are contacted by an official of a State Environmental Department in your home state. On the call, he asks if you are interested in a position with the State beginning in the next calendar year. You are currently working on an enforcement action involving the State but are interested in returning to the area at the beginning of the year. You agree to send him your resume for an open position.

Answer: Because you are open to the prospect of future employment and have sent your resume for an open position, *you are "seeking employment"* and must immediately disqualify yourself from participating in the pending enforcement action until either you or the State affirmatively rejects the possibility of employment or you leave the EPA to take the position, whichever is *later*.

Example 2: Deferring employment discussions. You give a speech to a trade association and afterwards, someone says, "hey, have you been thinking about what you're going to do when the Trump Administration is over? My company would be very interested in someone like you." You say that you aren't considering any future employment prospects until after you leave government."

Answer: This response will be considered a *rejection* of an offer of future employment and therefore you *are not "seeking employment."*

Another Example: But let's say instead that you know your region is working on a regulation affecting the financial interests of the company as a member of a discrete industry sector and you respond by saying you cannot discuss future employment while you are working on the regulation, but you would like to discuss employment with the company when the regulation is final.

Answer: Because you have merely deferred employment discussions until the foreseeable future, you have begun "seeking employment" under the ethics regulations and now may not work on the regulation that affect the company's financial interests. It's not enough that you said you won't talk to them until after the regulation is issued.

2. <u>Negotiating for future employment</u>: you have a financial interest in any entity in which you begin employment "negotiations"-- which means a two-way communication made either personally or through an intermediary such as a headhunter -- with a view towards reaching an agreement regarding future employment or compensation. The financial conflict of interest law requires you to recuse yourself from participating in a government matter affecting the entity's financial interests until either party affirmatively rejects the possibility of future employment or you leave the Agency. *See 18 U.S.C. § Section 208(a).*

<u>Notification requirement</u>: once you engage in an employment negotiation, you must complete, sign, date, and file a Negotiation Notification Form within *three business days* and send it to [HYPERLINK "mailto:ethics@epa.gov"].

3. <u>Procurement integrity requirements</u>: if you are participating in an ongoing procurement in excess of $150,000, procurement integrity regulations require that you notify your supervisor and the Ethics Office in writing if you make or receive a contact for future employment with a competing contractor. If you do not affirmatively reject the possibility of future employment, you

must disqualify yourself from further participation in the procurement until either party affirmatively rejects the possibility of future employment and the Contracting Officer approves your continued participation. *See* 41 U.S.C. § 2103.

4. Gifts relating to *bona fide* employment negotiations: you may accept gifts that are customarily provided by a prospective employer in connection with bona fide employment discussions (e.g., travel, lodging, and meals). You may accept these gifts even if the prospective employer is a federally registered lobbyist and you signed the Trump Ethics Pledge. If the prospective employer has matters that may be affected by your official duties, you must first disqualify yourself from EPA matters affecting the financial interests of the prospective employer. If the value of the benefits you accept meet the reporting thresholds, you must report these gifts on your termination financial disclosure report. *See* 5 C.F.R. § 2635.204(e)(3).

5. Post-employment training: make an appointment to talk to OGC/Ethics or your regional ethics counsel for live counseling. In addition, we highly recommend that you take the online post-employment course [HYPERLINK "https://intranet.epa.gov/ogc/LFS/10.html"].

6. Financial disclosure reporting requirements:

You must submit a ***termination Public Financial Disclosure Report (OGE 278e) in INTEGRITY (***[HYPERLINK "http://www.Integrity.gov"]***) within 15 days of departure or no more than 30 days after departure.*** Once you know your departure date, contact the Ethics Office at [HYPERLINK "mailto:ethics@epa.gov"] so that we can assign you a termination report in INTEGRITY. You may begin the report at that time after assignment*, but do not submit the report earlier than 15 days of your departure date.* We urge you to file the report before you depart so that you can access the electronic system using your EPA PIV card. If you do not complete the report prior to your departure date, you must notify OGC/Ethics of your forwarding email address so that we can make the necessary changes for your access from your personal computer. It is your responsibility to provide us with your forwarding information and submit a timely report.

Late filing fee: if you file the OGE 278e more than 30 days after the due date without requesting and receiving an extension from the Ethics Office *before the due date*, **you will be assessed a $200 late filing fee once you file the report.** We can grant up to a 90-day extension for good cause shown. **Failure to file a termination OGE-278e will result in a referral to the U.S. Attorney General for civil action which may result in civil penalties up to $50,000. Failure to pay late fees will result in referral for debt collection.**

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ETHICS RULES THAT APPLY *AFTER* YOU LEAVE GOVERNMENT SERVICE

1. Criminal post-employment restrictions - 18 U.S.C. § 207

a) Permanent Bar, 18 U.S.C. § 207(a)(1):

You may not, on behalf of a third party, appear before or communicate with an officer or employee of the United States with the intent to influence that person on a particular matter involving specific parties in which you participated personally and substantially while a government employee. This restriction does not prohibit providing "behind the scenes" assistance. (If you are an attorney, your state bar rules may prohibit this type of assistance, but we do not provide opinions on your bar obligations).

A *"particular matter involving specific parties"* include an investigation, application, request for a ruling or determination, contract, controversy, claim, charge, accusation, arrest, or judicial or other proceeding. The term *does not include* a rulemaking or other matter of general applicability. "Personal" participation means that you participated directly in the matter and includes the direction or control over a subordinate employee's participation. Your participation is "substantial" if, at the time of your involvement, it was of significance to the matter. This includes decision-making, reviewing, or recommending an action to be taken. It does not include ministerial acts relating to the matter.

b) One-Year Bar (Trade or Treaty Negotiations), 18 U.S.C. § 207(b):

For one year after leaving federal service, you may not knowingly represent, aid, or advise on the basis of covered information, any other person (except the United States) concerning any ongoing trade or treaty negotiation in which you participated personally and substantially as an employee during your last year of federal service.

c) Two-year restriction for former supervisors, 18 U.S.C. § 207(a)(2):

For two years after your departure, you may not appear before or represent others with the attempt to influence government action before the federal government on particular matters involving specific parties that were actually pending under your "official responsibility" in your last year of federal service. This restriction applies only to the supervisors (including the Administrator, Regional Administrators, Assistant Administrators, etc.) but not to team leaders. For the purposes of this restriction, personal and substantial participation is not required. Note that this restriction applies even if you did not participate in the matter personally or substantially because of a recusal.

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Example: Six months ago, a Regional Administrator recused herself from participating personally in a contract award to a company because she owns stock in that company. Upon leaving federal service, she takes a position with the winning contractor and now wants to make representations back to the federal government on behalf of her new employer on that contract. Even though she did not work personally and substantially on the contract because of her recusal, she may not, for two years after her departure, represent her new employer before the government on this contract because it was pending under her official responsibility during her last year of government service.

The definition of "official responsibility" is the "direct administrative or operating authority, whether intermediate or final, and whether exercisable alone or with another, and either personally or through subordinates, to approve, disapprove, or otherwise direct Government action." The scope of your "official responsibility" is determined by those areas assigned by statute, regulation, Executive Order, job description or delegation of authority. For the Agency head, all matters in the Agency are deemed to be within his or her "official responsibility." For a Regional Administrator, all pending matters in the Region are deemed to be within your "official responsibility." For the General Counsel and the Assistant Administrator for Enforcement and Compliance Assurance, their areas of "official responsibility" include their respective offices as well as the ten regional counsels because of the regional alignment with Headquarters.

d) Additional Post-Employment Restrictions for Former "Senior Employees:"

A ***"senior employee"*** includes members of the Senior Executive Service (SES) (either career and non-career), and individuals who are paid at a rate of basic pay that is equal to or greater than 86.5 percent of the rate for level II of the Executive Schedule (this figure changes every January). **As of January 2020, the figure is $170,665.** In addition, all Presidential Appointees with Senate Confirmation (PAS) appointees, irrespective of their salaries, are former "senior employees." *See* 5 C.F.R. 2641.104 and 5 U.S.C. §§ 5313-5315.[1]

1) One-Year Bar on communicating with or appearing before the EPA - 18 U.S.C. § 207(c):

For one year after serving as a "senior employee," you may not knowingly make any communication to or appearance before an officer or employee of EPA on behalf of another with the intent to influence government action on a matter pending at the Agency. Please note that the restriction will apply to *any matter* pending before the Agency, to include broad policies, regulations, legislation, as well as a "particular matter involving specific parties" or a "matter of general applicability" that is narrowly focused on a discreet industry sector.

NOTE: if you were detailed from EPA to another department, agency, or other entity, during the period of your detail, you are deemed to be an officer or employee of BOTH departments, agencies, or other entity.

Example: You leave EPA as a "senior employee" to work for a regulated entity. The next week, the Agency issues a new regulation affecting your new employer. Because you are a former senior employee, you may not submit comments on behalf of your new employer to the Agency objecting to the regulatory requirements because you are still within the one-year "cooling-off" period under 18 U.S.C. § 207(c). **Remember, this is a criminal statute.**

[1] The statute lists the following specific EPA positions: Administrator, Deputy Administrator, Assistant Administrator for Toxic Substances, Assistant Administrator for Solid Waste, Assistant Administrators, Chief Financial Officer, Chief Information Officer. For the purposes of this statute, OGC Ethics assumes that the General Counsel is included.

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2) One-Year Bar Relating to aiding, advising, or representing a foreign entity, 18 U.S.C. § 207(f):

For one year after serving as a "senior employee," you may not knowingly aid, advise, or represent a foreign entity before any employee of a federal department or agency with the intent to influence a decision of such employee in carrying out his or her official duties. This restriction extends to all federal agencies, U.S. courts or court martials, as well as the President, Vice President, and Members of Congress. A "foreign entity" is a foreign government or a foreign political party. *See* 18 U.S.C. § 207. Unlike the other criminal post-employment restrictions, this restriction applies to "behind-the-scenes" activities.

e) Exceptions to the criminal post-employment law:

1) Common exceptions to the permanent and two-year bars, 18 U.S.C. §§ 207(a)(1) and (2):

- Acting on behalf of the US government - if you are re-employed by the United States or called as a witness by Congress, the post-employment restrictions do not apply. However, working for a government contractor is not covered by this exception.
- Acting as an elected official - if you are carrying out your official duties as an *elected official* of a state or local government, the post-employment restrictions do not apply.
- Employee of a Tribe – if you are an employee or an elected or appointed official of a tribal organization or inter-tribal consortium, you may represent the tribe back to the United States provided that you submit adequate notice to the EPA Administrator and OGC/Ethics.
- Providing testimony - you may give testimony under oath or make statements required to be made under penalty of perjury. Unless expert opinion testimony is given pursuant to court order, or you are called as a witness by the United States, you may not provide such testimony on a matter on behalf of any other person except the United States or Congress if the activity is one covered by the permanent restrictions at 18 U.S.C. § 207(a)(1).

2) Additional exceptions for the one-year restriction for former "Senior Employees" before the EPA, 18 U.S.C. § 207(c):

- Acting as an employee of a state, local government or an instrumentality thereof, a hospital, or certain educational institutions
- Acting on behalf of an international organization in which the United States participates, if approved by the Secretary of State
- Imparting special knowledge not for compensation
- Making appearances made solely on behalf of a candidate, an authorized committee, a State committee, or a political party.

c) Compensation bar for matters affecting the government, 18 U.S.C. § 203:

After you depart, a new employer may not compensate you for any covered representational services that were provided at a time when you were a federal employee. *"Representational services"* means communications to or appearances before federal entities (not just EPA) with the intent to influence the government on behalf of a third party. Common examples are legal and consulting services where you may share in profits or fees related to those representations once you leave federal service.

Example: You are a former EPA attorney who is now an equity sharing partner at Dewey, Cheatham and Howe, a prominent law firm with an extensive federal practice. As a former federal employee, you may not share in any fees attributable to the firm's representational services before the government while you were still employed by the EPA. Therefore, your compensation plan, to include any bonus or partnership share, may not include any of the firm's profits that comes from its covered representational services before the federal government during your federal tenure.

7. Additional Post-Employment Restrictions for Procurement Officials

a) Procurement integrity provisions relating to contracts in excess of $10 million:

- Officials with a major role in a federal procurement in excess of $10 million may not accept compensation from the winning contractor as an employee, officer, director, or consultant within one year after serving as: the procurement contracting officer; the source selection authority; a member of the source selection board; or the chief of the financial or technical evaluation panel of a contract involving payment or claims of over $10 million.

- This restriction also applies to former officials who have personally made the federal agency decision to: award a contract, subcontract, modification of a contract or subcontract, or a task order or delivery order to that contractor; establish overhead or other rates applicable to one or more contracts for that contractor that are valued in excess of $10 million; approve issuance of one or more contract payments in excess of $10 million; or pay or settle a claim in excess of $10 million with that contractor. *See* 41 U.S.C. § 2104 and 48 C.F.R. § 3.104.

b) Non-disclosure of procurement-sensitive information: as a former employee, you may not knowingly disclose contractor bid or proposal information or source selection information before the award of a federal agency procurement contract. *See* 41 U.S.C. § 2102.

8. Additional Post-Employment Guidance for Officials Involved in Grants:

If you were involved in any grant competition activities while at EPA, then you should review the post-employment implications under EPA's Grants Competition Conflicts of Interest and Competitive Advantage policies. While not strictly statutory or regulatory prohibitions, these policies ensure that EPA can preserve the integrity of its competitions. Applicants competing for EPA awards cannot have an unfair competitive advantage or even the appearance of an unfair advantage. If you were involved in certain grant activities, including but not limited to the development, review and preparation of solicitations, then you, your family members, or your new employer may be constrained in competing for grants under the solicitations in which you participated. For more information about grants conflicts of interest and competitive advantage policies, contact Bruce S. Binder, Senior Associate Director for Grants Competition, at [HYPERLINK "mailto:binder.bruce@epa.gov"].

9. A Special Note for Attorneys:

Attorneys are reminded to consult their state bar rules or seek advice from state bar counsel even if you did not work as an attorney for EPA. These rules may differ from the federal criminal post-employment rules. For example, although the federal post-employment laws permit "behind the scenes" work for a new employer on matters you worked on or on which you supervised others, the American Bar Association (ABA) restricts such communications. ABA Model Rule 1.11(a) permits a

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former government employee to represent a client in connection with a matter in which the lawyer participated personally and substantially as a "public officer or employee" only if he first obtains consent from the appropriate government agency. The DC Bar is even more restrictive than the ABA. DC Bar rule 1.11(a) prohibits the former employee from accepting employment in connection with a matter which is the same as, or substantially related to, a matter in which the lawyer participated personally and substantially as a public officer or employee. Under this rule, there is no waiver possibility, and the former government lawyer is not permitted even to provide "behind the scenes" work. OGC/Ethics does not provide guidance on state bar rules.

10. <u>Additional restrictions imposed by the Trump Ethics Pledge, Executive Order 13770</u>:

The Trump Ethics Pledge you signed subjects you to additional restrictions under the Lobbying Disclosure Act (LDA) and the Foreign Agents Registration Act of 1938, as amended (FARA):

- Under Paragraph 1, you may not engage in "lobbying activities" with respect to EPA for **five years;**
- Under Paragraph 3, you may not engage in lobbying activities with respect to any covered executive branch official[2] or non-career SES appointee for the remainder of the Trump Administration; and
- Under Paragraph 4, after leaving federal service, you may never engage in any activity on behalf of any foreign government or foreign political party that, if it had been undertaken on January 20, 2017, would have required you to register under the FARA.

NOTE: The EPA Ethics Office does not provide guidance on the interpretation of either statute. We can, however, provide you with a summary of the restrictions.

As used in the Pledge paragraphs 1 and 3, the term *"lobbying activities"* has "the same meaning as in the LDA, except that *the term does not include* communicating or appearing with regard to:

- a judicial proceeding
- a criminal or civil law enforcement inquiry, investigation, or proceeding;
- any agency process for rulemaking, adjudication, or licensing, as defined in and governed by the Administrative Procedures Act, as amended, 5 U.S.C. § 551 *et seq*.

The term relies partly on the definition of "lobbying activities" found in the LDA, which includes both *"lobbying contacts"* and behind-the-scenes efforts in support of such contacts.[3] *"Lobbying contacts"* are limited to written or oral communications with covered officials that are made on behalf of a client.[4] The term *"client"* means any person or entity that employs or retains another

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[2] For the purposes of E.O. 13770, "<u>covered executive branch official</u>" means: the President; the Vice President; any official in the Executive Office of the President; any Executive Schedule official (EL I-V); any uniformed officer at pay grade 0- 7 or above; and any officer or employee serving in a position of a confidential, policy-determining, policy-making, or policy-advocating character….", including Schedule C employees. 2 U.S.C. § 1602(3). *See* E.O. 13770, sec. 2(c).

[3] The term "lobbying activities" means "lobbying contacts and efforts in support of such contacts, including preparation and planning activities, research and other background work that is intended, at the time, for use in contacts, and coordination with the lobbying activities of others." 2 U.S.C. § 1602(7).

[4] 2 U.S.C. § 1602(8)(A).

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person for financial or other compensation to conduct lobbying activities on behalf of that person or entity.[5]

For purposes of the Pledge paragraphs 1 and 3, "*lobbying activities*" includes the following:

- any oral or written communication to a covered executive branch official or non-career SES appointee; or
- efforts that are intended, at the time of performance, to support a covered lobbying contact to such person.

The LDA's definition of "*lobbying contacts*" is limited to certain types of communications but excludes 19 types of communications.[6] For example, the definition excludes "a request for a meeting, a request for the status of an action, or any other similar administrative request, if the request does not include an attempt to influence a covered executive branch official."[7]

For the purposes of Pledge paragraph 4, you cannot ever act as an "agent" of a "foreign principal," which includes any foreign governments and foreign political parties. Under the FARA, you are required to register before acting as an agent of a foreign principal in undertaking any of the following actions within the United States, either directly or through another person: (a) engaging in "political activities" on behalf of a foreign principal; (b) acting as a foreign principal's public relations counsel, publicity agent, information service employee, or political consultant; (c) soliciting, collecting, disbursing, or dispensing contributions, loans, money, or other things of value for or in the interest of a foreign principal; or (d) representing the interests of the foreign principal before any agency or official of the U.S. Government. Your Pledge restrictions do not prohibit any activities that the FARA exempts from its registration requirement, but if you have questions about the FARA, you will need to [HYPERLINK "https://www.justice.gov/nsd-fara"] directly. The EPA Ethics Office does not provide advice on the FARA.

ADDITIONAL PLEDGE RESTRICTIONS

ETHICS PLEDGE	**Paragraph 1**	**Paragraph 3**	**Paragraph 4**
Basic Prohibition	I will not, within 5 years after the termination of my employment as an appointee in any executive agency in which I am appointed to serve, engage in lobbying activities with respect to that agency.	In addition to abiding by the limitations of paragraphs 1 and 2, I also agree, upon leaving government service, not to engage in lobbying activities with respect to any covered executive branch official or non-career SES appointee for the remainder of the Trump Administration.	I will not, at any time after the termination of my employment in the United States Government, engage in any activity on behalf of any foreign government or foreign political party which, were it undertaken on January 20, 2017, would require me to register under the Foreign Agents Registration Act of 1938, as amended.
Length of Restriction	5 years	Remainder of the Trump Administration (January 20, 2021)	permanent
Commencement of Restriction	Termination of employment as an appointee	Termination of government service	Termination of government service

[5] 2 U.S.C. § 1602(2).

[6] *See* 2 U.S.C. § 1602(8)(B)(i)-(xix) for the 19 exemptions.

[7] 2 U.S.C. § 1602(8)(B)(v).

From Whom Appointees are Restricted	Covered executive branch officials at the former appointee's former agency ("with respect to that agency")	Covered executive branch officials throughout the executive branch; Non-career senior executive service appointees throughout the entire executive branch	Everyone in the United States. Unless a FARA exemption applies, can't ever engage in any in any of the activities listed above on behalf of any foreign government or foreign political party, if the activity occurs within the United States.

* * * * *

This document provides you with a summary of the major ethics rules that apply to you when you are seeking or negotiating for employment and for post-employment. *It is not a substitute for tailored ethics advice and is not an ethics opinion.* We strongly recommend that you schedule a meeting with the Ethics Office to receive an opinion on your specific facts and circumstances. Although the advice we provide you is not subject to privilege, we remind you that, when you seek advice from an ethics official, provide the relevant facts, and follow our guidance in good faith, then the ethics opinion may be a mitigating factor in any prosecution should you violate the criminal provisions. Please contact us at [HYPERLINK "mailto:ethics@epa.gov"]. Even after you leave EPA, we are here to answer your post-employment questions.

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[SEQ CHAPTER \h \r 1]**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

Washington, D.C. 20460

OFFICE OF
GENERAL COUNSEL

UPDATED NOVEMBER 2020
FOR SCHEDULE C APPOINTEES

Ethical Rules Relating to Your Transition Out of EPA

Thank you for your service to EPA and the Executive Branch. While you are planning your transition to the next phase of your career or retirement, you have continuing ethics obligations because you are still an EPA employee. This document reviews the ethics rules regarding:

- seeking and post-employment criminal laws and regulations;
- termination financial disclosure reporting requirements;
- employment negotiation and procurement integrity notification requirements; and
- Trump Ethics Pledge post-employment requirements.

Your ethics officials are here for you during and after your transition out of federal service to answer your questions and provide ethics opinions, so please use us as a resource! Contact us at [HYPERLINK "mailto:ethics@epa.gov"].

BEFORE YOU LEAVE GOVERNMENT SERVICE

1. Seeking employment: you may not participate in a "particular matter" having a direct and predictable effect on the financial interests of any person or entity with whom you are seeking or negotiating for employment or with whom you have an agreement for future employment. *See generally, 5 Code of Federal Regulations, Subpart F, 18 United States Code (U.S.C.) § 208.*

***"Seeking employment" begins** when you:*

- directly or indirectly make an unsolicited communication regarding possible employment with any person or entity;
- engage in negotiations with a view toward reaching an agreement regarding possible employment;
- receive a response to a job application or employment proposal indicating an interest in employment discussions; or
- make a response, other than rejection, to an unsolicited communication from any person regarding possible employment with that person.

***"Seeking employment" ends** when:*

- you or the prospective employer reject the possibility of employment and all discussions of possible employment have terminated; or

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- two months have elapsed since you sent an unsolicited resume or employment proposal, and you have not received an interest in employment discussions.

  See generally, 5 C.F.R. Part 2635, Subpart F

Example 1: You are contacted by an official of a State Environmental Department in your home state. On the call, he asks if you are interested in a position with the State beginning in the next calendar year. You are currently working on an enforcement action involving the State but are interested in returning to the area at the beginning of the year. You agree to send him your resume for an open position.

Answer: Because you are open to the prospect of future employment and have sent your resume for an open position, *you are "seeking employment"* and must immediately disqualify yourself from participating in the pending enforcement action until either you or the State affirmatively rejects the possibility of employment or you leave the EPA to take the position, whichever is *later*.

Example 2: Deferring employment discussions. You give a speech to a trade association and afterwards, someone says, "hey, have you been thinking about what you're going to do when the Trump Administration is over? My company would be very interested in someone like you." You say that you aren't considering any future employment prospects until after you leave government."

Answer: This response will be considered a *rejection* of an offer of future employment and therefore you *are not "seeking employment."*

Another Example: But let's say instead that you know your region is working on a regulation affecting the financial interests of the company as a member of a discrete industry sector and you respond by saying you cannot discuss future employment while you are working on the regulation, but you would like to discuss employment with the company when the regulation is final.

Answer: Because you have merely deferred employment discussions until the foreseeable future, you have begun "seeking employment" under the ethics regulations and now may not work on the regulation that affect the company's financial interests. It's not enough that you said you won't talk to them until after the regulation is issued.

2. <u>Negotiating for future employment</u>: you have a financial interest in any entity in which you begin employment "negotiations"-- which means a two-way communication made either personally or through an intermediary such as a headhunter -- with a view towards reaching an agreement regarding future employment or compensation. The financial conflict of interest law requires you to recuse yourself from participating in a government matter affecting the entity's financial interests until either party affirmatively rejects the possibility of future employment or you leave the Agency. *See 18 U.S.C. § Section 208(a).*

<u>Notification requirement</u>: once you engage in an employment negotiation, you must complete, sign, date, and file a Negotiation Notification Form within *three business days* and send it to [HYPERLINK "mailto:ethics@epa.gov"].

3. <u>Procurement integrity requirements</u>: if you are participating in an ongoing procurement in excess of $150,000, procurement integrity regulations require that you notify your supervisor and

the Ethics Office in writing if you make or receive a contact for future employment with a competing contractor. If you do not affirmatively reject the possibility of future employment, you must disqualify yourself from further participation in the procurement until either party affirmatively rejects the possibility of future employment and the Contracting Officer approves your continued participation. *See* 41 U.S.C. § 2103.

4. Gifts relating to *bona fide* employment negotiations - you may accept gifts that are customarily provided by a prospective employer in connection with bona fide employment discussions (e.g., travel, lodging, and meals). You may accept these gifts even if the prospective employer is a federally registered lobbyist and you signed the Trump Ethics Pledge. If the prospective employer has matters that may be affected by your official duties, you must first disqualify yourself from EPA matters affecting the financial interests of the prospective employer. If the value of the benefits you accept meet the reporting thresholds, you must report these gifts on your termination financial disclosure report. *See* 5 C.F.R. § 2635.204(e)(3).

5. Post-employment training

Make an appointment to talk to OGC/Ethics or your regional ethics counsel for live counseling. In addition, we highly recommend that you take the online post-employment course [HYPERLINK "https://intranet.epa.gov/ogc/LFS/10.html"].

6. Financial disclosure reporting requirements

You must submit a ***termination Public Financial Disclosure Report (OGE 278e) in INTEGRITY (***[HYPERLINK "http://www.Integrity.gov"]***) within 15 days of departure or no more than 30 days after departure.*** Once you know your departure date, contact the Ethics Office at [HYPERLINK "mailto:ethics@epa.gov"] so that we can assign you a termination report in INTEGRITY. You may begin the report at that time after assignment*, but do not submit the report earlier than 15 days of your departure date.* We urge you to file the report before you depart so that you can access the electronic system using your EPA PIV card. If you do not complete the report prior to your departure date, you must notify OGC/Ethics of your forwarding email address so that we can make the necessary changes for your access from your personal computer. It is your responsibility to provide us with your forwarding information and submit a timely report.

Late filing fee: if you file the OGE 278e more than 30 days after the due date without requesting and receiving an extension from the Ethics Office *before the due date*, **you will be assessed a $200 late filing fee once you file the report.** We can grant up to a 90-day extension for good cause shown. **Failure to file a termination OGE-278e will result in a referral to the U.S. Attorney General for civil action which may result in civil penalties up to $50,000. Failure to pay late fees will result in referral for debt collection.**

ETHICS RULES THAT APPLY *AFTER* YOU LEAVE GOVERNMENT SERVICE

1. Criminal post-employment restrictions – 18 U.S.C. § 207

a) Permanent Bar, 18 U.S.C. § 207(a)(1):

You may not, on behalf of a third party, appear before or communicate with an officer or employee of the United States with the intent to influence that person on a particular matter involving

specific parties in which you participated personally and substantially while a government employee. This restriction does not prohibit providing "behind the scenes" assistance. (If you are an attorney, your state bar rules may prohibit this type of assistance, but we do not provide opinions on your bar obligations).

A *"particular matter involving specific parties"* include an investigation, application, request for a ruling or determination, contract, controversy, claim, charge, accusation, arrest, or judicial or other proceeding. The term *does not include* a rulemaking or other matter of general applicability. "Personal" participation means that you participated directly in the matter and includes the direction or control over a subordinate employee's participation. Your participation is "substantial" if, at the time of your involvement, it was of significance to the matter. This includes decision-making, reviewing, or recommending an action to be taken. It does not include ministerial acts relating to the matter.

b) One-Year Bar (Trade or Treaty Negotiations) - 18 U.S.C. § 207(b)

For one year after leaving federal service, you may not knowingly represent, aid, or advise on the basis of covered information, any other person (except the United States) concerning any ongoing trade or treaty negotiation in which you participated personally and substantially as an employee during your last year of federal service.

c) Two-year restriction for former supervisors - 18 U.S.C. § 207(a)(2)

For two years after your departure, you may not appear before or represent others with the attempt to influence government action before the federal government on particular matters involving specific parties that were actually pending under your "official responsibility" in your last year of federal service. This restriction applies only to the supervisors (including the Administrator, Regional Administrators, Assistant Administrators, etc.) but not to team leaders. For the purposes of this restriction, personal and substantial participation is not required. Note that this restriction applies even if you did not participate in the matter personally or substantially because of a recusal.

> *Example*: Six months ago, a Regional Administrator recused herself from participating personally in a contract award to a company because she owns stock in that company. Upon leaving federal service, she takes a position with the winning contractor and now wants to make representations back to the federal government on behalf of her new employer on that contract. Even though she did not work personally and substantially on the contract because of her recusal, she may not, for two years after her departure, represent her new employer before the government on this contract because it was pending under her official responsibility during her last year of government service.

The definition of "official responsibility" is the "direct administrative or operating authority, whether intermediate or final, and whether exercisable alone or with another, and either personally or through subordinates, to approve, disapprove, or otherwise direct Government action." The scope of your "official responsibility" is determined by those areas assigned by statute, regulation, Executive Order, job description or delegation of authority. For the Agency head, all matters in the Agency are deemed to be within his or her "official responsibility." For a Regional Administrator, all pending matters in the Region are deemed to be within your "official responsibility." For the General Counsel and the Assistant Administrator for Enforcement and Compliance Assurance, their areas of "official responsibility" include their respective offices as well as the ten regional counsels because of the regional alignment with Headquarters.

d) Exceptions to the criminal post-employment law:

1) Common exceptions to the permanent and two-year bars - (18 U.S.C. §§ 207(a)(1) and

(2)):

- Acting on behalf of the US government - if you are re-employed by the United States or called as a witness by Congress, the post-employment restrictions do not apply. However, working for a government contractor is not covered by this exception.
- Acting as an elected official - if you are carrying out your official duties as an *elected official* of a state or local government, the post-employment restrictions do not apply.
- Employee of a Tribe – if you are an employee or an elected or appointed official of a tribal organization or inter-tribal consortium, you may represent the tribe back to the United States provided that you submit adequate notice to the EPA Administrator and OGC/Ethics.
- Providing testimony - you may give testimony under oath or make statements required to be made under penalty of perjury. Unless expert opinion testimony is given pursuant to court order, or you are called as a witness by the United States, you may not provide such testimony on a matter on behalf of any other person except the United States or Congress if the activity is one covered by the permanent restrictions at 18 U.S.C. § 207(a)(1).

e) Compensation bar for matters affecting the government, 18 U.S.C. § 203

After you depart, a new employer may not compensate you for any covered representational services that were provided at a time when you were a federal employee. *"Representational services"* means communications to or appearances before federal entities (not just EPA) with the intent to influence the government on behalf of a third party. Common examples are legal and consulting services where you may share in profits or fees related to those representations once you leave federal service.

Example: You are a former EPA attorney who is now an equity sharing partner at Dewey, Cheatham and Howe, a prominent law firm with an extensive federal practice. As a former federal employee, you may not share in any fees attributable to the firm's representational services before the government while you were still employed by the EPA. Therefore, your compensation plan, to include any bonus or partnership share, may not include any of the firm's profits that comes from its covered representational services before the federal government during your federal tenure.

2. Additional Post-Employment Restrictions for Procurement Officials

a) Procurement integrity provisions relating to contracts in excess of $10 million:

- Officials with a major role in a federal procurement in excess of $10 million may not accept compensation from the winning contractor as an employee, officer, director, or consultant within one year after serving as: the procurement contracting officer; the source selection authority; a member of the source selection board; or the chief of the financial or technical evaluation panel of a contract involving payment or claims of over $10 million.

- This restriction also applies to former officials who have personally made the federal agency decision to: award a contract, subcontract, modification of a contract or subcontract, or a task order or delivery order to that contractor; establish overhead or other rates applicable to one or more contracts for that contractor that are valued in excess of $10 million; approve issuance of one or more contract payments in excess of $10 million; or pay or settle a claim in excess of $10 million with that contractor. *See* 41 U.S.C. § 2104 and 48 C.F.R. § 3.104.

b) Non-disclosure of procurement-sensitive information: as a former employee, you may not knowingly disclose contractor bid or proposal information or source selection information before the award of a federal agency procurement contract. *See* 41 U.S.C. § 2102.

3. Additional Post-Employment Guidance for Officials Involved in Grants

If you were involved in any grant competition activities while at EPA, then you should review the post-employment implications under EPA's Grants Competition Conflicts of Interest and Competitive Advantage policies. While not strictly statutory or regulatory prohibitions, these policies ensure that EPA can preserve the integrity of its competitions. Applicants competing for EPA awards cannot have an unfair competitive advantage or even the appearance of an unfair advantage. If you were involved in certain grant activities, including but not limited to the development, review and preparation of solicitations, then you, your family members, or your new employer may be constrained in competing for grants under the solicitations in which you participated. For more information about grants conflicts of interest and competitive advantage policies, contact Bruce S. Binder, Senior Associate Director for Grants Competition, at [HYPERLINK "mailto:binder.bruce@epa.gov"].

4. A Special Note for Attorneys

Attorneys are reminded to consult their state bar rules or seek advice from state bar counsel even if you did not work as an attorney for EPA. These rules may differ from the federal criminal post-employment rules. For example, although the federal post-employment laws permit "behind the scenes" work for a new employer on matters you worked on or on which you supervised others, the American Bar Association (ABA) restricts such communications. ABA Model Rule 1.11(a) permits a former government employee to represent a client in connection with a matter in which the lawyer participated personally and substantially as a "public officer or employee" only if he first obtains consent from the appropriate government agency. The DC Bar is even more restrictive than the ABA. DC Bar rule 1.11(a) prohibits the former employee from accepting employment in connection with a matter which is the same as, or substantially related to, a matter in which the lawyer participated personally and substantially as a public officer or employee. Under this rule, there is no waiver possibility, and the former government lawyer is not permitted even to provide "behind the scenes" work. OGC/Ethics does not provide guidance on state bar rules.

5. Additional restrictions imposed by the Trump Ethics Pledge, Executive Order 13770

The Trump Ethics Pledge you signed subjects you to additional restrictions under the Lobbying Disclosure Act (LDA) and the Foreign Agents Registration Act of 1938, as amended (FARA):

- Under Paragraph 1, you may not engage in "lobbying activities" with respect to EPA for **five years;**
- Under Paragraph 3, you may not engage in lobbying activities with respect to any covered executive branch official[8] or non-career SES appointee for the remainder of the Trump

[8] For the purposes of E.O. 13770, "covered executive branch official" means: the President; the Vice President; any official in the Executive Office of the President; any Executive Schedule official (EL I-V); any uniformed officer at pay grade 0- 7 or above; and any officer or employee serving in a position of a confidential, policy-determining, policy-making, or policy-advocating character….", including Schedule C employees. 2 U.S.C. § 1602(3). *See* E.O. 13770, sec. 2(c).

Administration; and

- Under Paragraph 4, after leaving federal service, you may never engage in any activity on behalf of any foreign government or foreign political party that, if it had been undertaken on January 20, 2017, would have required you to register under FARA.

NOTE: The EPA Ethics Office does not provide guidance on the interpretation of either statute. We can, however, provide you with a summary of the restrictions.

As used in the Pledge paragraphs 1 and 3, the term "*lobbying activities*" has "the same meaning as in the LDA, except that *the term does not include* communicating or appearing with regard to:

- a judicial proceeding
- a criminal or civil law enforcement inquiry, investigation, or proceeding;
- any agency process for rulemaking, adjudication, or licensing, as defined in and governed by the Administrative Procedures Act, as amended, 5 U.S.C. § 551 *et seq*.

The term relies partly on the definition of "lobbying activities" found in the LDA, which includes both *"lobbying contacts"* and behind-the-scenes efforts in support of such contacts.[9] *"Lobbying contacts"* are limited to written or oral communications with covered officials that are made on behalf of a client.[10] The term *"client"* means any person or entity that employs or retains another person for financial or other compensation to conduct lobbying activities on behalf of that person or entity.[11]

For purposes of the Pledge paragraphs 1 and 3, "*lobbying activities*" includes the following:

- any oral or written communication to a covered executive branch official or non-career SES appointee; or
- efforts that are intended, at the time of performance, to support a covered lobbying contact to such person.

The LDA's definition of "*lobbying contacts*" is limited to certain types of communications but excludes 19 types of communications.[12] For example, the definition excludes "a request for a meeting, a request for the status of an action, or any other similar administrative request, if the request does not include an attempt to influence a covered executive branch official."[13]

For the purposes of Pledge paragraph 4, you cannot ever act as an "agent" of a "foreign principal," which includes any foreign governments and foreign political parties. Under the FARA, you are required to register before acting as an agent of a foreign principal in undertaking any of the following actions within the United States, either directly or through another person: (a) engaging in "political activities" on behalf of a foreign principal; (b) acting as a foreign principal's public

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[9] The term "lobbying activities" means "lobbying contacts and efforts in support of such contacts, including preparation and planning activities, research and other background work that is intended, at the time, for use in contacts, and coordination with the lobbying activities of others." 2 U.S.C. § 1602(7).

[10] 2 U.S.C. § 1602(8)(A).

[11] 2 U.S.C. § 1602(2).

[12] *See* 2 U.S.C. § 1602(8)(B)(i)-(xix) for the 19 exemptions.

[13] 2 U.S.C. § 1602(8)(B)(v).

relations counsel, publicity agent, information service employee, or political consultant; (c) soliciting, collecting, disbursing, or dispensing contributions, loans, money, or other things of value for or in the interest of a foreign principal; or (d) representing the interests of the foreign principal before any agency or official of the U.S. Government. Your pledge restrictions do not prohibit any activities that the FARA exempts from its registration requirement, but if you have questions about the FARA, you will need to [HYPERLINK "https://www.justice.gov/nsd-fara"] directly. The EPA Ethics Office does not provide advice on the FARA.

ADDITIONAL PLEDGE RESTRICTIONS

ETHICS PLEDGE	**Paragraph 1**	**Paragraph 3**	**Paragraph 4**
Basic Prohibition	I will not, within 5 years after the termination of my employment as an appointee in any executive agency in which I am appointed to serve, engage in lobbying activities with respect to that agency.	In addition to abiding by the limitations of paragraphs 1 and 2, I also agree, upon leaving government service, not to engage in lobbying activities with respect to any covered executive branch official or non-career SES appointee for the remainder of the Trump Administration.	I will not, at any time after the termination of my employment in the United States Government, engage in any activity on behalf of any foreign government or foreign political party which, were it undertaken on January 20, 2017, would require me to register under the Foreign Agents Registration Act of 1938, as amended.
Length of Restriction	5 years	Remainder of the Trump Administration (January 20, 2021)	Permanent
Commencement of Restriction	Termination of employment as an appointee	Termination of government service	Termination of government service
From Whom Appointees are Restricted	Covered executive branch officials at the former appointee's former agency ("with respect to that agency")	Covered executive branch officials throughout the executive branch; Non-career senior executive service appointees throughout the entire executive branch	Everyone in the United States. Unless a FARA exemption applies, can't ever engage in any in any of the activities listed above on behalf of any foreign government or foreign political party, if the activity occurs within the United States.

* * * * *

This document provides you with a summary of the major ethics rules that apply to you when you are seeking or negotiating for employment and for post-employment. *It is not a substitute for tailored ethics advice and is not an ethics opinion.* We strongly recommend that you schedule a meeting with the Ethics Office to receive an opinion on your specific facts and circumstances. Although the advice we provide you is not subject to privilege, we remind you that, when you seek advice from an ethics official, provide the relevant facts, and follow our guidance in good faith, then the ethics opinion may be a mitigating factor in any prosecution should you violate the criminal provisions. Please contact us at [HYPERLINK "mailto:Ethics@epa.gov"]. Even after you leave EPA, we are here to answer your post-employment questions.

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[SEQ CHAPTER \h \r 1]UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
GENERAL COUNSEL

UPDATED NOVEMBER 2020
FOR ADMINISTRATIVELY DETERMINED (AD) EMPLOYEES

Ethical Rules Relating to Your Departure from EPA

Thank you for your service to EPA and the Executive Branch. While you are planning your move to the next phase of your career or retirement, you have continuing ethics obligations because you are still an EPA employee. This document reviews the ethics rules regarding:

- seeking and post-employment criminal laws and regulations;
- termination financial disclosure reporting requirements;
- employment negotiation and procurement integrity notification requirements.

Your ethics officials are here for you during and after your departure from federal service to answer your questions and provide ethics opinions, so please use us as a resource! Contact us at [HYPERLINK "mailto:ethics@epa.gov"].

BEFORE YOU LEAVE GOVERNMENT SERVICE

1. Seeking employment: you may not participate in a "particular matter" having a direct and predictable effect on the financial interests of any person or entity with whom you are seeking or negotiating for employment or with whom you have an agreement for future employment. *See generally, 5 Code of Federal Regulations, Subpart F, 18 United States Code (U.S.C.) § 208.*

"Seeking employment" begins *when you:*

- directly or indirectly make an unsolicited communication regarding possible employment with any person or entity;
- engage in negotiations with a view toward reaching an agreement regarding possible employment;
- receive a response to a job application or employment proposal indicating an interest in employment discussions; or
- make a response, other than rejection, to an unsolicited communication from any person regarding possible employment with that person.

"Seeking employment" ends when:

- you or the prospective employer reject the possibility of employment and all discussions of possible employment have terminated; or

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- two months have elapsed since you sent an unsolicited resume or employment proposal, and you have not received an interest in employment discussions.

  See generally, 5 C.F.R. Part 2635, Subpart F

Example 1: You are contacted by an official of a State Environmental Department in your home state. On the call, he asks if you are interested in a position with the State beginning in the next calendar year. You are currently working on an enforcement action involving the State but are interested in returning to the area at the beginning of the year. You agree to send him your resume for an open position.

Answer: Because you are open to the prospect of future employment and have sent your resume for an open position, *you are "seeking employment"* and must immediately disqualify yourself from participating in the pending enforcement action until either you or the State affirmatively rejects the possibility of employment or you leave the EPA to take the position, whichever is *later*.

Example 2: Deferring employment discussions. You give a speech to a trade association and afterwards, someone says, "hey, have you been thinking about what you're going to do when you retire from the government? My company would be very interested in someone like you." You say that you aren't considering any future employment prospects until after you retire."

Answer: This response will be considered a *rejection* of an offer of future employment and therefore you *are not "seeking employment."*

Another Example: But, let's say instead that you know your region is working on a regulation affecting the financial interests of the company as a member of a discrete industry sector and you respond by saying you cannot discuss future employment while you are working on the regulation, but you would like to discuss employment with the company when the regulation is final.

Answer: Because you have merely deferred employment discussions until the foreseeable future, you have begun "seeking employment" under the ethics regulations and now may not work on the regulation that affect the company's financial interests. It's not enough that you said you won't talk to them until after the regulation is issued.

2. <u>Negotiating for future employment</u>: you have a financial interest in any entity in which you begin employment "negotiations"-- which means a two-way communication made either personally or through an intermediary such as a headhunter -- with a view towards reaching an agreement regarding future employment or compensation. The financial conflict of interest law requires you to recuse yourself from participating in a government matter affecting the entity's financial interests until either party affirmatively rejects the possibility of future employment or you leave the Agency. *See 18 U.S.C. § Section 208(a).*

<u>Notification requirement</u>: once you engage in an employment negotiation, you must complete, sign, date, and file a Negotiation Notification Form within *three business days* and send it to [HYPERLINK "mailto:ethics@epa.gov"].

3. <u>Procurement integrity requirements</u>: if you are participating in an ongoing procurement in excess of $150,000, procurement integrity regulations require that you notify your supervisor and

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the Ethics Office in writing if you make or receive a contact for future employment with a competing contractor. If you do not affirmatively reject the possibility of future employment, you must disqualify yourself from further participation in the procurement until either party affirmatively rejects the possibility of future employment and the Contracting Officer approves your continued participation. *See* 41 U.S.C. § 2103.

4. Gifts relating to *bona fide* employment negotiations: you may accept gifts that are customarily provided by a prospective employer in connection with *bona fide* employment discussions (e.g., travel, lodging, and meals). If the prospective employer has matters that may be affected by your official duties, you must first disqualify yourself from EPA matters affecting the financial interests of the prospective employer. If the value of the benefits you accept meet the reporting thresholds, you must report these gifts on your termination financial disclosure report. *See* 5 C.F.R. § 2635.204(e)(3).

5. Post-employment training: make an appointment to talk to OGC/Ethics or your regional ethics counsel for live counseling. In addition, we highly recommend that you take the online post-employment course [HYPERLINK "https://intranet.epa.gov/ogc/LFS/10.html"].

6. Financial disclosure reporting requirements:
If your current salary level is below a certain level, then you may have filed a confidential financial disclosure report. There is no requirement to file a final OGE 450 form. However, if your current salary level is above $131,239 *before locality pay,* then you were required to file a public financial disclosure report and are now required to file a termination report. You must submit a ***termination Public Financial Disclosure Report (OGE 278e) in INTEGRITY (***[HYPERLINK "http://www.Integrity.gov"]***) within 15 days of departure or no more than 30 days after departure.*** Once you know your departure date, contact the Ethics Office at [HYPERLINK "mailto:ethics@epa.gov"] so that we can assign you a termination report in INTEGRITY. You may begin the report at that time after assignment*, but do not submit the report earlier than 15 days of your departure date.* We urge you to file the report before you depart so that you can access the electronic system using your EPA PIV card. If you do not complete the report prior to your departure date, you must notify OGC/Ethics of your forwarding email address so that we can make the necessary changes for your access from your personal computer. It is your responsibility to provide us with your forwarding information and submit a timely report.

Late filing fee: if you file the OGE 278e more than 30 days after the due date without requesting and receiving an extension from the Ethics Office *before the due date*, **you will be assessed a $200 late filing fee once you file the report.** We can grant up to a 90-day extension for good cause shown. **Failure to file a termination OGE-278e will result in a referral to the U.S. Attorney General for civil action which may result in civil penalties up to $50,000. Failure to pay late fees will result in referral for debt collection.**

ETHICS RULES THAT APPLY *AFTER* YOU LEAVE GOVERNMENT SERVICE

1. Criminal post-employment restrictions – 18 U.S.C. § 207

a) Permanent Bar, 18 U.S.C. § 207(a)(1):

You may not, on behalf of a third party, appear before or communicate with an officer or employee of the United States with the intent to influence that person on a particular matter involving specific parties in which you participated personally and substantially while a government employee. This restriction does not prohibit providing "behind the scenes" assistance. (If you are an attorney, your state bar rules may prohibit this type of assistance, but we do not provide opinions on your bar obligations).

A *"particular matter involving specific parties"* include an investigation, application, request for a ruling or determination, contract, controversy, claim, charge, accusation, arrest, or judicial or other proceeding. The term *does not include* a rulemaking or other matter of general applicability. "Personal" participation means that you participated directly in the matter and includes the direction or control over a subordinate employee's participation. Your participation is "substantial" if, at the time of your involvement, it was of significance to the matter. This includes decision-making, reviewing, or recommending an action to be taken. It does not include ministerial acts relating to the matter.

b) One-Year Bar (Trade or Treaty Negotiations), 18 U.S.C. § 207(b):

For one year after leaving federal service, you may not knowingly represent, aid, or advise on the basis of covered information, any other person (except the United States) concerning any ongoing trade or treaty negotiation in which you participated personally and substantially as an employee during your last year of federal service.

c) Two-year restriction for former supervisors, 18 U.S.C. § 207(a)(2):

For two years after your departure, you may not appear before or represent others with the attempt to influence government action before the federal government on particular matters involving specific parties that were actually pending under your "official responsibility" in your last year of federal service. This restriction applies only to the supervisors (including the Administrator, Regional Administrators, Assistant Administrators, etc.) but not to team leaders. For the purposes of this restriction, personal and substantial participation is not required. Note that this restriction applies even if you did not participate in the matter personally or substantially because of a recusal.

> *Example*: Six months ago, a Regional Administrator recused herself from participating personally in a contract award to a company because she owns stock in that company. Upon leaving federal service, she takes a position with the winning contractor and now wants to make representations back to the federal government on behalf of her new employer on that contract. Even though she did not work personally and substantially on the contract because of her recusal, she may not, for two years after her departure, represent her new employer before the government on this contract because it was pending under her official responsibility during her last year of government service.

The definition of "official responsibility" is the "direct administrative or operating authority, whether intermediate or final, and whether exercisable alone or with another, and either personally or through subordinates, to approve, disapprove, or otherwise direct Government

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action." The scope of your "official responsibility" is determined by those areas assigned by statute, regulation, Executive Order, job description or delegation of authority. For the Agency head, all matters in the Agency are deemed to be within his or her "official responsibility." For a Regional Administrator, all pending matters in the Region are deemed to be within your "official responsibility." For the General Counsel and the Assistant Administrator for Enforcement and Compliance Assurance, their areas of "official responsibility" include their respective offices as well as the ten regional counsels because of the regional alignment with Headquarters.

d) Additional Post-Employment Restrictions for Former "Senior Employees:"

A "***senior employee***" includes members of the Senior Executive Service (SES) (either career and non-career), and individuals who are paid at a rate of basic pay that is equal to or greater than 86.5 percent of the rate for level II of the Executive Schedule (this figure changes every January). **As of January 2020, the figure is $170,665.**

1) One-Year Bar on communicating with or appearing before the EPA, 18 U.S.C. § 207(c):

For one year after serving as a "senior employee," you may not knowingly make any communication to or appearance before an officer or employee of EPA on behalf of another with the intent to influence government action on a matter pending at the Agency. Please note that the restriction will apply to *any matter* pending before the Agency, to include broad policies, regulations, legislation, as well as a "particular matter involving specific parties" or a "matter of general applicability" that is narrowly focused on a discreet industry sector.

NOTE: if you were detailed from EPA to another department, agency, or other entity, during the period of your detail, you are deemed to be an officer or employee of BOTH departments, agencies, or other entity.

> *Example:* You leave EPA as a "senior employee" to work for a regulated entity. The next week, the Agency issues a new regulation affecting your new employer. Because you are a former senior employee, you may not submit comments on behalf of your new employer to the Agency objecting to the regulatory requirements because you are still within the one-year "cooling-off" period under 18 U.S.C. § 207(c). **Remember, this is a criminal statute.**

2) One-Year Bar Relating to aiding, advising, or representing a foreign entity, 18 U.S.C. § 207(f):

For one year after serving as a "senior employee," you may not knowingly aid, advise, or represent a foreign entity before any employee of a federal department or agency with the intent to influence a decision of such employee in carrying out his or her official duties. This restriction extends to all federal agencies, U.S. courts or court martials, as well as the President, Vice President, and Members of Congress. A "foreign entity" is a foreign government or a foreign political party. *See* 18 U.S.C. § 207. Unlike the other criminal post-employment restrictions, this restriction applies to "behind-the-scenes" activities.

e) Exceptions to the criminal post-employment law:

1) Common exceptions to the permanent and two-year bars, 18 U.S.C. §§ 207(a)(1) and (2):

- Acting on behalf of the US government - if you are re-employed by the United States or called as a witness by Congress, the post-employment restrictions do not apply. However, working for a government contractor is not covered by this exception.

- Acting as an elected official - if you are carrying out your official duties as an *elected official* of a state or local government, the post-employment restrictions do not apply.
- Employee of a Tribe – if you are an employee or an elected or appointed official of a tribal organization or inter-tribal consortium, you may represent the tribe back to the United States provided that you submit adequate notice to the EPA Administrator and OGC/Ethics.
- Providing testimony - you may give testimony under oath or make statements required to be made under penalty of perjury. Unless expert opinion testimony is given pursuant to court order, or you are called as a witness by the United States, you may not provide such testimony on a matter on behalf of any other person except the United States or Congress if the activity is one covered by the permanent restrictions at 18 U.S.C. § 207(a)(1).

2) Additional exceptions for the one-year restriction for former "Senior Employees" before the EPA, 18 U.S.C. § 207(c):

- Acting as an employee of a state, local government or an instrumentality thereof, a hospital, or certain educational institutions
- Acting on behalf of an international organization in which the United States participates, if approved by the Secretary of State
- Imparting special knowledge not for compensation
- Making appearances made solely on behalf of a candidate, an authorized committee, a State committee, or a political party.

c) Compensation bar for matters affecting the government, 18 U.S.C. § 203:

After you depart, a new employer may not compensate you for any covered representational services that were provided at a time when you were a federal employee. *"Representational services"* means communications to or appearances before federal entities (not just EPA) with the intent to influence the government on behalf of a third party. Common examples are legal and consulting services where you may share in profits or fees related to those representations once you leave federal service.

Example: You are a former EPA attorney who is now an equity sharing partner at Dewey, Cheatham and Howe, a prominent law firm with an extensive federal practice. As a former federal employee, you may not share in any fees attributable to the firm's representational services before the government while you were still employed by the EPA. Therefore, your compensation plan, to include any bonus or partnership share, may not include any of the firm's profits that comes from its covered representational services before the federal government during your federal tenure.

7. Additional Post-Employment Restrictions for Procurement Officials

a) Procurement integrity provisions relating to contracts in excess of $10 million:

- Officials with a major role in a federal procurement in excess of $10 million may not accept compensation from the winning contractor as an employee, officer, director, or consultant within one year after serving as: the procurement contracting officer; the source selection authority; a member of the source selection board; or the chief of the financial or technical evaluation panel of a contract involving payment or claims of over $10 million.

- This restriction also applies to former officials who have personally made the federal agency decision to: award a contract, subcontract, modification of a contract or subcontract, or a

task order or delivery order to that contractor; establish overhead or other rates applicable to one or more contracts for that contractor that are valued in excess of $10 million; approve issuance of one or more contract payments in excess of $10 million; or pay or settle a claim in excess of $10 million with that contractor. *See* 41 U.S.C. § 2104 and 48 C.F.R. § 3.104.

b) Non-disclosure of procurement-sensitive information: as a former employee, you may not knowingly disclose contractor bid or proposal information or source selection information before the award of a federal agency procurement contract. *See* 41 U.S.C. § 2102.

8. Additional Post-Employment Guidance for Officials Involved in Grants

If you were involved in any grant competition activities while at EPA, then you should review the post-employment implications under EPA's Grants Competition Conflicts of Interest and Competitive Advantage policies. While not strictly statutory or regulatory prohibitions, these policies ensure that EPA can preserve the integrity of its competitions. Applicants competing for EPA awards cannot have an unfair competitive advantage or even the appearance of an unfair advantage. If you were involved in certain grant activities, including but not limited to the development, review and preparation of solicitations, then you, your family members, or your new employer may be constrained in competing for grants under the solicitations in which you participated. For more information about grants conflicts of interest and competitive advantage policies, contact Bruce S. Binder, Senior Associate Director for Grants Competition, at [HYPERLINK "mailto:binder.bruce@epa.gov"].

9. A Special Note for Attorneys

Attorneys are reminded to consult their state bar rules or seek advice from state bar counsel even if you did not work as an attorney for EPA. These rules may differ from the federal criminal post-employment rules. For example, although the federal post-employment laws permit "behind the scenes" work for a new employer on matters you worked on or on which you supervised others, the American Bar Association (ABA) restricts such communications. ABA Model Rule 1.11(a) permits a former government employee to represent a client in connection with a matter in which the lawyer participated personally and substantially as a "public officer or employee" only if he first obtains consent from the appropriate government agency. The DC Bar is even more restrictive than the ABA. DC Bar rule 1.11(a) prohibits the former employee from accepting employment in connection with a matter which is the same as, or substantially related to, a matter in which the lawyer participated personally and substantially as a public officer or employee. Under this rule, there is no waiver possibility, and the former government lawyer is not permitted even to provide "behind the scenes" work. OGC/Ethics does not provide guidance on state bar rules.

* * * * *

This document provides you with a summary of the major ethics rules that apply to you when you are seeking or negotiating for employment and for post-employment. *It is not a substitute for tailored ethics advice and is not an ethics opinion.* We strongly recommend that you schedule a meeting with the Ethics Office to receive an opinion on your specific facts and circumstances. Although the advice we provide you is not subject to privilege, we remind you that, when you seek advice from an ethics official, provide the relevant facts, and follow our guidance in good faith, then the ethics opinion may be a mitigating factor in any prosecution should you violate the criminal provisions. Please contact us at [HYPERLINK "mailto:ethics@epa.gov"]. Even after you leave EPA, we are here to answer your post-employment questions.

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NSI SECURITY REMINDER

SUBJECT: NSI SECURITY REMINDER – CHANGING DUTIES, JOB POSITIONS OR DEPARTING THE AGENCY

As a clearance holder, you are responsible for promptly notifying the NSI Program Team if you will be occupying an EPA position that does not require a clearance or if you will be leaving the agency. Security clearances are not permanent. Your clearance may be administratively withdrawn for a variety of reasons, including a change in your job duties, a long-term detail, a new position at EPA or at another agency, or retirement.

Should you find yourself changing positions or duties or leaving the agency, you must schedule a mandatory debriefing, after which your clearance will be administratively withdrawn. **Please Note**: If your new EPA position or duties do require a clearance, your manager must submit a clearance justification to the Personnel Security Branch.

When you contact the NSI Program Team or your local NSI Representative to schedule a debriefing, you may be asked several questions, such as:

- Do you have access to Sensitive Compartmented Information?
- Do you have a Courier Card?
- Do you have a "Q" Clearance?

On the day of your debriefing, bring your courier card if you were issued one. Courier cards cannot be retained after you have been debriefed. As part of the debriefing, you will be required to sign one or more Nondisclosure Agreement Forms acknowledging your continuing responsibility to protect the classified information that you accessed or possessed.

Having your security clearance administratively withdrawn means you cannot access classified materials or attend classified meetings. If you accept a position with another agency that requires a security clearance, the new agency will be able to view the clearance through the Office of Personnel Management's database and can choose to accept your clearance as part of the reciprocity process. More information on this is available during the termination briefing.

If you have questions, please contact the NSI Program Team or your NSI Representative.

Points of Contact:
NSI Program Team: 202-564-1983
After-hours Reporting: 202-564-3850 (EOC)
Website: [HYPERLINK "http://intranet.epa.gov/oa/smd/nationalsec.htm" \h]
Email: [HYPERLINK "mailto:NSI_ProgramTeam@epa.gov" \h]

UNEMPLOYMENT INFORMATION BY STATE

Alabama	Alabama Department of Labor	334-242-8025	[HYPERLINK "https://labor.alabama.gov/uc/ICCS/"]
Alaska	Alaska Department of Labor and Workforce Development	907-269-4700	[HYPERLINK "https://my.alaska.gov/"]
Arizona	Arizona Department of Economic Security	1-877-600-2722	[HYPERLINK "https://des.az.gov/services/employment/unemployment-individual/apply-ui-benefits"]
Arkansas	Arkansas Department of Workforce Services	501-682-2121	[HYPERLINK "https://www.ezarc.adws.arkansas.gov/"]
California	California Employment Development Department	1-800-300-5616	[HYPERLINK "https://edd.ca.gov/Unemployment/Filing_a_Claim.htm"]
Colorado	Colorado Department of Labor and Employment	303-318-9000	[HYPERLINK "https://www.colorado.gov/cdle/unemployment"]
Connecticut	Connecticut Department of Labor	1-800-956-3294	[HYPERLINK "http://www.ctdol.state.ct.us/UI-OnLine/"]
Delaware	Delaware Department of Labor	New Castle County: 302-761-6576 Other Areas: 1-800-794-3032	[HYPERLINK "https://uics.delawareworks.com/Forms/Form_WL1"]

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District of Columbia	District of Columbia Department of Employment Services	202-724-7000	[HYPERLINK "https://does.dcnetworks.org/InitialClaims/"]
Florida	Florida Department of Economic Opportunity	1-800-204-2418	[HYPERLINK "http://www.floridajobs.org/Reemployment-Assistance-Service-Center/reemployment-assistance/claimants/apply-for-benefits"]
Georgia	Georgia Department of Labor	1-877-709-8185	[HYPERLINK "https://dol.georgia.gov/"]
Hawaii	Hawaii Department of Labor and Industrial Relations	Oahu: 808-586-8970 Hilo: 808-974-4086 Kona: 808-322-4822 Maui: 808-984-8400 Kauai: 808-274-3043	[HYPERLINK "https://huiclaims.hawaii.gov/"]
Idaho	Idaho Department of Labor	208-332-8942	[HYPERLINK "https://www2.labor.idaho.gov/ClaimantPortal/Login"]
Illinois	Illinois Department of Employment Security	1-800-244-5631	[HYPERLINK "https://www2.illinois.gov/ides/individuals/UnemploymentInsurance/"]
Indiana	Indiana Department of Workforce Development	1-800-891-6499	[HYPERLINK "https://www.in.gov/dwd/2362.htm"]
Iowa	Iowa Workforce Development	1-866-239-0843	[HYPERLINK "https://uiclaims.iwd.iowa.gov/UIInitialClaim/"]

Kansas	Kansas Department of Labor	1-800-292-6333	[HYPERLINK "https://www.getkansasbenefits.gov/"]
Kentucky	Kentucky Career Center Office of Unemployment Insurance	502-564-2900	[HYPERLINK "https://kcc.ky.gov/Pages/default.aspx"]
Louisiana	Louisiana Workforce Commission	1-866-783-5567	[HYPERLINK "https://www.louisianaworks.net/hire/vosnet/"]
Maine	Maine Department of Labor	1-800-593-7660	[HYPERLINK "https://reemployme.maine.gov/accessme/faces/login/login.xhtml"]
Maryland	Maryland Department of Labor	410-949-0022	[HYPERLINK "http://www.dllr.state.md.us/employment/unemployment.shtml"]
Massachusetts	Massachusetts Department of Unemployment Assistance	617-626-6338	[HYPERLINK "https://www.mass.gov/unemployment-insurance-ui-online"]
Michigan	Michigan Department of Labor and Economic Opportunity	1-866-500-0017	[HYPERLINK "https://www.michigan.gov/leo/0,5863,7-336-78421_97241---,00.html"]
Minnesota	Minnesota Department of Employment and Economic Development	Twin Cities Area: 651-296-3644 Greater Minnesota: 1-877-898-9090	[HYPERLINK "https://uimn.org/applicants/"]
Mississippi	Mississippi Department of Employment Security	1-888-844-3577	[HYPERLINK "https://www.mdes.ms.gov/unemployment-claims/claims-information/"]

Missouri	Missouri Department of Labor and Industrial Relations	1-800-320-2519	[HYPERLINK "https://uinteract.labor.mo.gov/benefits/home.do"]
Montana	Montana Department of Labor and Industry	406-444-2545	[HYPERLINK "https://montanaworks.gov/Job-Seeker-UI-Claimant"]
Nebraska	Nebraska Department of Labor	1-855-995-8863	[HYPERLINK "https://neworks.nebraska.gov/vosnet/"]
Nevada	Nevada Department of Employment Training and Rehabilitation	Northern Nevada: 775-684-0350 Southern Nevada: 702-486-0350 Rural Areas and Out of State Callers: 1-888-890-8211	[HYPERLINK "http://ui.nv.gov/css.html"]
New Hampshire	New Hampshire Department of Employment Security	1-800-852-3400	[HYPERLINK "https://nhuis.nh.gov/claimant/"]
New Jersey	New Jersey Department of Labor and Workforce Development	North New Jersey: 201-601-4100 Central New Jersey: 732-761-2020 South New Jersey: 856-507-2340 Out-of-state claims: 1-888-795-6672	[HYPERLINK "https://myunemployment.nj.gov/labor/myunemployment/before/about/howtoapply/"]
New Mexico	New Mexico Department of Workforce Solutions	1-877-664-6984	[HYPERLINK "https://www.jobs.state.nm.us/vosnet/Default.aspx"]

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New York	New York Department of Labor	1-888-209-8124	[HYPERLINK "https://applications.labor.ny.gov/IndividualReg/"]
North Carolina	North Carolina Department of Commerce	1-888-737-0259	[HYPERLINK "https://des.nc.gov/"]
North Dakota	North Dakota Job Service	701-328-4995	[HYPERLINK "https://www.jobsnd.com/unemployment-individuals/resources-unemployment-individuals"]
Ohio	Ohio Department of Job and Family Services	1-877-644-6562	[HYPERLINK "http://jfs.ohio.gov/ouio/index.stm"]
Oklahoma	Oklahoma Employment Security Commission	1-800-555-1554	[HYPERLINK "https://oesc.ok.gov/"]
Oregon	Oregon Employment Department	1-877-345-3484	[HYPERLINK "https://secure.emp.state.or.us/ocs4/"]
Pennsylvania	Pennsylvania Department of Labor and Industry	1-888-313-7284	[HYPERLINK "https://www.uc.pa.gov/unemployment-benefits/file/Pages/File%20an%20Initial%20Claim.aspx"]
Puerto Rico	Puerto Rico Department of Labor and Human Resources	787-625-7900	[HYPERLINK "https://www.trabajo.pr.gov/desempleo_en_linea.asp"]
Rhode Island	Rhode Island Department of Labor and Training	401-243-9100	[HYPERLINK "http://www.dlt.ri.gov/ui/"]
South Carolina	South Carolina Department of Employment and Workforce	1-866-831-1724	[HYPERLINK "https://dew.sc.gov/individuals/apply-for-benefits/claims-process"]

South Dakota	South Dakota Department of Labor and Regulation	605-626-3179	[HYPERLINK "https://dlr.sd.gov/ra/individuals/file_claim.aspx"]
Tennessee	Tennessee Department of Labor and Workforce Development	1-877-813-0950	[HYPERLINK "https://www.tn.gov/workforce/unemployment.html"]
Texas	Texas Workforce Commission	1-800-939-6631	[HYPERLINK "https://www.twc.texas.gov/jobseekers/unemployment-benefits-services"]
U.S. Virgin Islands	U.S. Virgin Islands Department of Labor	340-773-1994	[HYPERLINK "https://www.vidol.gov/how-and-where-to-apply/"]
Utah	Utah Department of Workforce Services	Salt Lake and South Davis Counties: 801-526-4400 Weber and North Davis Counties: 801-612-0877 Utah County: 801-375-4067 Other Counties and Out of State: 1-888-848-0688	[HYPERLINK "https://jobs.utah.gov/ui/home/initialclaims"]
Vermont	Vermont Department of Labor	1-888-807-7072	[HYPERLINK "https://labor.vermont.gov/unemployment-insurance/ui-claimants/establishing-unemployment-claim"]
Virginia	Virginia Employment Commission	1-866-832-2363	[HYPERLINK "http://www.vec.virginia.gov/unemployed/online-services/apply-for-unemployment-benefits"]

Washington	Washington Employment Security Department	1-800-318-6022	[HYPERLINK "https://secure.esd.wa.gov/home/"]
West Virginia	Workforce West Virginia	1-800-379-1032	[HYPERLINK "https://uc.workforcewv.org/consumer/"]
Wisconsin	Wisconsin Department of Workforce Development	1-844-910-3661	[HYPERLINK "https://dwd.wisconsin.gov/uiben/"]
Wyoming	Wyoming Department of Workforce Services	307-473-3789	[HYPERLINK "https://wyui.wyo.gov/benefits/home.do"]

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APPENDICES

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APPENDIX 1

EPA RECORDS MANAGEMENT CHECKLIST FORM 3110-49

[EMBED AcroExch.Document.DC]

APPENDIX 2

EMPLOYEE MOBILE DEVICE ACKNOWLEDGEMENT FORM

[EMBED AcroExch.Document.DC]

APPENDIX 3

EMPLOYEE SEPARATION CERTIFICATION FORM 3110-2

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Appendix 4

Notification of Negotiation or Agreement Form

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Appendix 5

Political Appointee Equipment Return Checklist

1. Please insert all EPA equipment in the shipping box, including this checklist sheet.

2. Check which items are being returned:

☐ LAPTOP(s)

☐ MOBILE DEVICE

☐ BADGE(s)

☐ KEY(s)

☐ OTHER

***NOTE: IF ANY ITEMS ARE NOT RETURNED, PLEASE EXPLAIN WHY? ***

_____

_____

_____

_____

_____

It is required that all packages be return within 5 days of receiving the return box.

Please contact the Asset Manager if you have any questions and to schedule UPS pick-up.

Christina Brown

[HYPERLINK "mailto:Brown.Christina@epa.gov"]

(202) 564 - 1829 Office

(202) 394 - 8203 Mobile

REQUIREMENT: Notify OGC/Ethics within 3 business days of commencing the negotiation or agreement for post-government employment or compensation

NOTIFICATION OF NEGOTIATION OR AGREEMENT

Your full name	Your telephone number*	Date negotiation or agreement began
Your Title / Office / AAship or Region	Your email address*	Name of non-federal entity that you are negotiating with or have an agreement for employment or compensation

* *Provide information for OGC/Ethics to use to contact you as part of our official duty. For this purpose, you may provide a personal email address or cell number.*

RECUSAL STATEMENT

To assist in identifying your recusal obligations, check the appropriate boxes below:

	Yes	No	
1.	☐	☐	EPA's programs, policies, or operations affect the non-federal entity with which I am seeking employment.
2.	☐	☐	My office in EPA does work that affects the non-federal entity with which I am seeking employment.
3.	☐	☐	The work I participate in affects or will affect the non-federal entity with which I am seeking employment.

Need help answering these statements? See page 2.

For as long as I am negotiating for, or have an agreement of, employment or compensation with the entity listed above, I will not participate personally and substantially in any particular matter that has a direct and predictable effect on the financial interests of this entity, unless I first obtain from OGC/Ethics a written authorization or waiver consistent with 5 C.F.R. § 2635.605 or 18 U.S.C. § 208(b)(1). I understand that it is my responsibility to consult with OGC/Ethics if I have questions regarding my recusal obligations.

Sign and submit to ethics@epa.gov:

Your signature

OGC/Ethics Use Only:

Last Updated: November 2020

Statement 1: EPA's programs, policies, or operations affect the non-federal entity with which I am seeking employment.

If your answer is "yes" to any of the following questions, then you must answer "yes" to statement 1.

- Is the non-federal entity seeking official action from EPA (even if not your own office)?
- Does the non-federal entity do business or seek to do business with the EPA (even if not your own office)?
- Does the non-federal entity conduct activities that EPA regulates (even if not in your own office)?
- Does the non-federal entity have interests that may be substantially affected by the performance or non-performance of your official duties?
- Is the non-federal entity a membership organization in which the majority of the members are described in the preceding questions?

Statement 2: My office in EPA does work that affects the non-federal entity with which I am seeking employment.

To answer this question, think about the nexus between the work of your office and the non-federal entity. The closer the nexus, the more likely you will have to check "yes" to statement 2.

- Consider the particular matters your office works on and whether there is any connection to the work of this entity. Does your office work on permits, investigations, litigation, grants, licenses, contracts, applications, enforcement cases, or other similar types of matters where there is an identified non-federal entity (i.e., particular matters involving specific parties)?
- Also consider whether your office is involved in scientific programs, media programs, or other types of policies, procedures, guidance documents, regulations, etc., that would affect this particular industry or sector (i.e., particular matters of general applicability).

Statement 3: The work I participate in affects or will affect the non-federal entity with which I am seeking employment.

Think about the nexus between your work and the non-federal entity as well as its respective class, industry or sector. The closer the nexus between your work and the sector the non-federal entity belongs to, the more likely you will check have to check "yes" to statement 3.

- Will the work you do affect the sector? Don't concentrate on whether your personal contributions will be determinative but rather, overall, how the outcome of the work itself will affect the sector and the non-federal entity with which you are negotiating.
- Do you advise on or consult with your colleagues' projects and work? Does their work affect this sector or the non-federal entity?
- Do you actively supervise or assign work to subordinates? Do those assignments affect the sector or the non-federal entity?

Need help answering these statements? Contact ethics@epa.gov to discuss.

Last Updated: November 2020

United States Environmental Protection Agency

EPA RECORDS MANAGEMENT CHECKLIST FOR SEPARATING/TRANSFERRING OR SEPARATED PERSONNEL

ALL PERSONNEL ARE REQUIRED TO COMPLETE THIS CHECKLIST AND EPA FORM 3110-1 BEFORE SEPARATING FROM EPA OR TRANSFERRING TO ANOTHER PROGRAM OFFICE OR REGION WITHIN EPA. ALL PERSONNEL ARE REMINDED THERE ARE ADDITIONAL RESPONSIBILITIES TO MAINTAIN ANY INFORMATION THAT MAY BE SUBJECT TO A LITIGATION HOLD. EMPLOYEES AND SUPERVISORS MUST FOLLOW SEPARATE CLEARANCE PROCEDURES FOR LITIGATION HOLDS. SEE THE BACK OF THIS PAGE FOR ADDITIONAL INFORMATION.

PERSONNEL BACKGROUND INFORMATION

Name: _____ Job Title: _____ Date: _____

Employment Status: EPA Employee ____ Other ____ (Specify: _____) Location: _____

____ Already Separated ____ Will be Separating Approximate date of Separation: _____

____ Already Transferred ____ Will be Transferring Approximate date of Transfer: _____

Supervisor: _____ Office: _____ Records Liaison Officer: _____

Brief description of job duties: _____

Describe major records that you maintain: _____

POTENTIAL RECORD SOURCES TO BE REVIEWED

Each box below must be initialed by the employee, supervisor, and Records Liaison Officer (RLO) or designee after records in each location have been identified and appropriately managed. If not applicable, boxes should be marked as N/A.

Documents & Records in all media, personal or government owned (including email, hard drives, portable electronic storage devices, LAN, servers, collaboration tools, etc.), including working documents of completed, ongoing and pending activities (e.g., special projects and workgroups) should be transferred to an EPA recordkeeping system, when possible, or transferred to your supervisor or successor.

		Initial When Completed					Initial When Completed		
		Emp	Supv* IMO	RLO			Emp	Supv* IMO	RLO
1.	Email records including accounts such as private/personal or secondary (group and/or special purpose) email accounts *Indicate new custodian in comments section, if applicable				8.	Program File Rooms (RCRA, Air, Water, etc.) and Federal Records Center (FRC) *Initialed by Records Contact /Designee.* • Returned all files checked out • Submitted new records to be filed			
2.	Portable electronic storage devices (CDs, DVDs, USBs, floppies, etc.) *(List in comments)*				9.	Superfund Records Center *initialed by Superfund Records Contact/Designee* • Returned all files checked out • Submitted new records to be filed			
3.	PDAs (BlackBerry, Windows Phone, iPhone, cell phone, text messages, IM, etc.)				10.	Employee's Workspace Checked for Records • If not transferred, who will transfer? (List name in comments.)			
4.	Local Area Network Drive Files and Shared drive(s), transfer electronic files to OneDrive *(List the drives in comments.)*				11.	Confidential Business Information *initialed by Document Control Officer (DCO)* • Returned all files checked out • Request submitted to DCO to terminate CBI Authorized Access			
5.	Local hard drive and records on personal computer				12.	Identify any known open FOIA requests assigned to you for which the collection has not been completed by name/number; list in comments.			
6.	Lotus Notes and Microsoft Office Collaboration Tools (SharePoint, OneDrive, etc.) *(List the tools in comments.)*				13.	Identify and preserve current or potential litigation hold materials by name/number for which you have been or may be identified as a custodian. Review litigation hold portal at http://litholdandcollect.epa.gov/portal. List name/number in comments			
7.	Desktop GIS, local GIS servers, and GeoPlatform				14.	Identify and preserve existing audit or Congressional inquiry materials for which you have been identified as a custodian by name/number in comments.			

COMMENTS: For any items requiring additional notation or if any box above is left blank, you must provide explanation. If there are any other areas where you have stored records, please describe them and their disposition here. If the list of litigation holds is too lengthy to fit in the comments box, please attach the list to the 3110-49.

CERTIFICATIONS

To the best of my knowledge, I certify that all U.S. Government documentary materials (preservation of litigation holds, audits, and congressional inquiry materials), in any format, have been identified and transferred to the appropriate recordkeeping system or designee and that the statements made on this Checklist are true, accurate, and complete.

1. Employee (signature) (print/type name)

2. Supervisor/designee (signature) (print/type name)

OR for Senior Officials

IMO/designee (signature) (print/type name)

3. RLO/designee (signature) (print/type name)

INSTRUCTIONS

This Checklist is to be utilized as detailed in EPA Information Procedures on Preservation of Separating, Transferring or Separated Personnel's Records in Accordance with the Federal Records Act. The purpose of the Checklist is to help EPA personnel identify all potential locations of records in their custodianship. For personnel who have separated, the supervisor/manager should review the person's records first, when at all possible and ensure actions taken on records are documented on EPA Form 3110-49. See Preservation of Separating, Transferring or Separated Personnel's Records in Accordance with the Federal Records Act, Section III A and B, Separated Personnel, http://intranet.epa.gov/oei/imitpolicy/qic/ciopolicy/CIO-2155-P-04.0.pdf; 44 U.S.C. § 3106; Unlawful removal, destruction of records https://www.law.cornell.edu/uscode/text/44/3106; 36 CFR § 1230 Unlawful or Accidental Removal, Defacing, Alteration or Destruction of Records http://www.ecfr.gov/cgi-bin/text-idx?SID=8ca786c32479fb9fba535f5d1c3c61d9&mc=true&tpl=/ecfrbrowse/Title36/36cfr1230_main_02.tpl

PERSONNEL BACKGROUND INFORMATION SECTION to be completed by Employee or Supervisor.

For the statement "**Describe major records that you maintain,"** if the individual does not have specific records management responsibilities, "routine recordkeeping responsibilities" may be entered.

POTENTIAL RECORD SOURCES TO BE REVIEWED SECTION

Personnel, Supervisor/Designee, Records Liaison Officer (RLO)/Designee must *all* initial the Checklist for each numbered item. * For Senior Officials, the IMO or designee should initial in the Supv box in lieu of a supervisor.

1. Initial in the "completed" box next to each description to note that records have been identified, captured in an approved recordkeeping system or transferred to another employee, or enter "N/A" if that item is not applicable for that individual. (Not every description will be applicable to all personnel, i.e., not all personnel have an EPA provided Blackberry, iPhone, etc.)
2. If any box is left blank, provide explanation in the Comment field.
3. For items requiring additional notations, use the Comment field, noting the item number being clarified.
4. Supervisor and RLO/designee is responsible to resolve any item which has not been initialed. Final resolution should be noted on the Checklist when completed.

CERTIFICATIONS SECTION

If the individual has already separated from EPA, insert "N/A-already separated" on the Employee signature line. The supervisor or designee and the RLO will be responsible for completing this checklist and certifying, to the best of their knowledge, that all records were properly identified and saved to a recordkeeping system. This completed, certified original Checklist should be maintained by the local Records Liaison Officer/designee in accordance with Schedule 0568 or appropriate subsequent schedule.

Employee Mobile Device Acknowledgement Form (Page 1 of 5)

EPA PROPERTY DECAL #/ IMEI # (EXCEPT NEW DEVICE ORDERS): _____

This form is being completed to authorize a (check one only):

1. DEVICE UPGRADE/REPLACEMENT (RETURN OF OLD DEVICE AND ASSIGNMENT OF NEW DEVICE) ___
2. NEW DEVICE (NO OLD DEVICE, ASSIGNMENT OF NEW DEVICE) ___
3. DEVICE RETURN (RETURN OF OLD DEVICE, NO NEW DEVICE ASSIGNED) ___
4. DEVICE WITH NO CONTENT CAPACITY (E.G. AIR CARDS, ACCESSORIES) ___
   - SIGNATURE OF ORDERING OFFICIAL FOR DEVICE WITH NO CONTENT CAPACITY – NO FURTHER ACTION REQUIRED:

     _____

The signed copy of this notice is to be stored in the EPA's eBusiness system with the record for the associated device. In cases where the device is being replaced with a new device, the new device cannot be issued until the MD Acknowledgement form for the previous device is received.

INSTRUCTIONS (TO BE COMPLETED FOR ACTION 1-3 ABOVE):

1. EMPLOYEE MUST READ ALL INFORMATION IN BOX 1 BELOW
2. EMPLOYEE MUST SIGN ATTESTATION IN BOX 2 BELOW
3. UPLOAD COMPLETED FORM TO EBUSINESS
4. PROVIDE DEVICE TO EMPLOYEE/ACCEPT DEVICE FROM EMPLOYEE WITH A SIGNED COPY OF THE MD ACKNOWLEDGMENT FORM

BOX 1

Employee Mobile Device Notice

You Have No Expectation of Privacy for Any Activity on this Device

You are accessing a U.S. Government information system, which includes: (1) this mobile device, (2) any U.S. Government network you connect to with this device, and (3) all devices and storage media attached to this network or to a computer or mobile device on this network. This information system is provided for U.S. government-authorized use only. Unauthorized or improper use of this system or your EPA email address may result in disciplinary action, as well as civil and criminal penalties. By using this information system you understand and consent to the following: You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. You are not to backup records to personal email accounts, devices, or personal files. At any time, the government may for any lawful governmental purpose monitor, intercept, wipe or reset, search and seize any communication or data transiting or stored on this information system. Any communications or data transiting or stored on this information system may be disclosed or used for any lawful government purpose.

EPA reserves the right to install or update a mobile device management software to secure, monitor, manage and support mobile devices deployed across the Agency.

You Have a Duty to Retain Records

This device is subject to EPA's Records Management Policy, CIO 2155.3 (approved February 10, 2015). You have an obligation to preserve agency records transmitted or stored on this device in the course of official agency business that may be subject to preservation or production requirements under the Federal Records Act, the Privacy Act, the Freedom of Information Act, litigation holds, or court preservation orders. Such records may include, but are not limited to, text messages, email messages, voicemail messages, photographs, call logs and calendar entries. Before returning this device, you must ensure that you have met your duties to preserve such information.

Employee Mobile Device Acknowledgement Form (Page 2 of 5)

Box 1 Cont.

Notice to Users who are returning mobile devices: You have an obligation to preserve all records for the purposes listed or described in the above paragraph that are located on your current mobile device(s). By accepting this new device and by signing this notice, you hereby attest that you have met your obligation to preserve all such records before such devices are returned to the Agency. Knowing or willful misrepresentation with respect to these matters may subject you to administrative, civil, or criminal penalties.

(**Note**: Records may be preserved by forwarding them to your EPA email account and filing them using EZ Records, or copying, saving, downloading or otherwise transferring and reproducing them to an EPA system.)

Quick Reference Guide, How to Save Text Messages:
http://intranet.epa.gov/mobiledevices/pdf/Instructions-Saving-Text-Messages.pdf

Mobile and Portable Devices, and Records:
http://intranet.epa.gov/records/faqs/pda.html

Limited Personal Use of Government Equipment

Use of this device is subject to EPA's Limited Personal Use of Government Equipment Policy, CIO 2101.0. You cannot use this device for any unlawful purpose or for any purpose prohibited by EPA policy. Prohibited activities include but are not limited to pornography, gambling, political activity, charitable fundraising, or compensated outside activity.

Specific Rules Regarding Mobile Devices and Mobile Device Software

As a user of a government-issued mobile device, YOU ARE PROHIBITED from modifying the operating system and default storage or security settings and from downloading any software (also known as applications or "Apps") solely for personal use or entertainment on this device. Do not modify the default setting for retention of text messages on this device.

You are prohibited from expending any non-appropriated funds (e.g., your personal money or the funds of a third party) to acquire or download any software, tools, data, applications, or other goods or services onto this device, for governmental purposes.

You are prohibited from downloading any Apps that are not included in the EPA App Catalog on your mobile device. Apps listed in the App Catalog have been approved for Agency authorized use.

Additional policies and procedures, particularly regarding the use of social media, may be found in EPA's Web Guide, http://www2.epa.gov/webguide/policies-and-procedures#governance and the Managing Social Media Records Procedure, http://intranet.epa.gov/oei/imitpolicy/qic/ciopolicy/2155-P-06.pdf.

Personal Property Policy

This device is subject to EPA's Personal Property Policy and Procedures Manual, No. 4832. EPA may hold its employees liable for the loss, damage, or destruction of government personal property or for the unauthorized use of equipment. 5 U.S.C. § 301.

Employee Mobile Device Acknowledgement Form (Page 3 of 5)

Security Notifications **Box 1 Cont.**

As covered in EPA's information security policy, you are responsible for:

- Knowing information security requirements associated with the use of mobile devices.
- Ensuring the physical security of mobile devices (e.g., do not check with luggage or leave unattended).
- Promptly contacting your Information Security Officer (ISO) and the EPA Call Center in the event a mobile device is lost or stolen.
- Promptly contacting your ISO and the EPA Call Center in the event of a suspected or actual information breach.

International Travel

In order to safeguard EPA's information and systems, all employees, contractors, and other users are required to follow the Agency's International Travel Procedure for Mobile Devices while on international travel, including the specific requirements for high risk locations.
(http://intranet.epa.gov/oeiintra/imitpolicy/qic/ciopolicy/CIO-2150.3-P-18.1.pdf)

BOX 2

Your obligations and attestation

Required for all new devices and transfers:
By using this device, you acknowledge that you understand and will comply with the terms set forth above.

_____
Print Name

_____ _____
Employee Signature Date

Required for employees returning devices:
I hereby attest that I have met my obligation to preserve agency records transmitted or stored on this device in the course of official agency business that may be subject to preservation or production requirements under the Federal Records Act, the Privacy Act, the Freedom of Information Act, litigation holds, or court preservation orders. By signing below, I attest that all such records have been preserved on EPA systems in a manner consistent with EPA guidance and are not solely preserved on this mobile device.

_____
Print Name

_____ _____
Employee Signature Date

Employee Mobile Device Acknowledgement Form (Page 4 of 5)

Required for all instances of lost, stolen, or broken devices: **Box 2 Cont.**

Please provide a brief description of your use of the device, including any potential agency records, as described above, that may have been present on the device when lost, stolen or broken, and a description of the circumstances surrounding the loss including approximate date of loss. By signing below, you certify that this description is true and correct to the best of your knowledge and belief:

_____
Print Name

Supervisor's Name: _____

_____
Employee Signature

_____
Date

For Supervisors and/or RLOs: Required for instances when employee is unable to certify that records are managed:

You are required to manage any records and/or content on this device! Before the device may be canceled / repurposed, you will need to contact EZ-Tech or your local helpdesk to reset the device password. At that point, you will be required to manage any records and/or content on the device required for preservation and certify below. Litigation hold information can be obtained at the OEI-OEIP Intranet site (http://intranet.epa.gov/ediscovery) or by contacting your Records Liaison Officer.

Please note that eBusiness will be unable to process a cancellation for any device without this signed certification form.

I hereby attest that, I have met my obligation to preserve agency records transmitted or stored on this device in the course of official agency business that may be subject to preservation or production requirements under the Federal Records Act, the Privacy Act, the Freedom of Information Act, litigation holds, or court preservation orders. By signing below, I attest that all such records have been preserved on EPA systems in a manner consistent with EPA guidance and are not solely preserved on this mobile device.

_____
Print Name (Supervisor/RLO)

_____
Supervisor/RLO Signature

_____
Date

If you are unable to reset the password, please provide a brief description of the reason(s) that you are unable to certify as to the use and management of content on this device.

Employee Mobile Device Acknowledgement Form (Page 5 of 5)

Box 2 Cont.

Final disposition decisions regarding unmanaged content and/or inaccessible devices must be made on a case-by-case basis, depending on factors such as the likely content of the device and role of the individual(s) who used the device. Please contact your Records Liaison Officer and/or counsel to determine next steps. Next steps may include additional documentation or, in some cases, contacting the National Records and Archives Administration and/or the Department of Justice for advice on appropriate disposition of unmanaged devices.

_____
Print Supervisor Name

_____ _____
Supervisor Signature Date

EPA Policies and Procedures Referenced in this Document

Mobile Computing Management Policy: http://intranet.epa.gov/oeiintra/imitpolicy/qic/ciopolicy/CIO-2150.4.pdf

Mobile Computing Management Procedures: http://intranet.epa.gov/oeiintra/imitpolicy/qic/ciopolicy/CIO-2150.4-P-01.1.pdf

Records Management Policy: http://intranet.epa.gov/oei/imitpolicy/qic/ciopolicy/CIO-2155.3.pdf

EPA's Limited Personal Use of Government Equipment: http://intranet.epa.gov/oei/imitpolicy/qic/ciopolicy/2101-0.pdf

EPA's Web Guide: http://www2.epa.gov/webguide/policies-and-procedures#governance

International Travel Procedure for Mobile Devices: http://intranet.epa.gov/oeiintra/imitpolicy/qic/ciopolicy/CIO-2150.3-P-18.1.pdf

Terms of Service Agreements: http://www2.epa.gov/webguide/terms-service-agreements

Managing Social Media Records Procedure: http://intranet.epa.gov/oei/imitpolicy/qic/ciopolicy/2155-P-06.pdf

Last Modified 10-28-16 v1.0

United States Environmental Protection Agency

EPA RECORDS MANAGEMENT CHECKLIST FOR SEPARATING/TRANSFERRING OR SEPARATED PERSONNEL

ALL PERSONNEL ARE REQUIRED TO COMPLETE THIS CHECKLIST AND EPA FORM 3110-1 BEFORE SEPARATING FROM EPA OR TRANSFERRING TO ANOTHER PROGRAM OFFICE OR REGION WITHIN EPA. ALL PERSONNEL ARE REMINDED THERE ARE ADDITIONAL RESPONSIBILITIES TO MAINTAIN ANY INFORMATION THAT MAY BE SUBJECT TO A LITIGATION HOLD. EMPLOYEES AND SUPERVISORS MUST FOLLOW SEPARATE CLEARANCE PROCEDURES FOR LITIGATION HOLDS. SEE THE BACK OF THIS PAGE FOR ADDITIONAL INFORMATION.

PERSONNEL BACKGROUND INFORMATION

Name: _____ Job Title: _____ Date: _____

Employment Status: EPA Employee ____ Other ____ (Specify: _____) Location: _____

____ Already Separated ____ Will be Separating Approximate date of Separation: _____

____ Already Transferred ____ Will be Transferring Approximate date of Transfer: _____

Supervisor: _____ Office: _____ Records Liaison Officer: _____

Brief description of job duties: _____

Describe major records that you maintain: _____

POTENTIAL RECORD SOURCES TO BE REVIEWED

Each box below must be initialed by the employee, supervisor, and Records Liaison Officer (RLO) or designee after records in each location have been identified and appropriately managed. If not applicable, boxes should be marked as N/A.

Documents & Records in all media, personal or government owned (including email, hard drives, portable electronic storage devices, LAN, servers, collaboration tools, etc.), including working documents of completed, ongoing and pending activities (e.g., special projects and workgroups) should be transferred to an EPA recordkeeping system, when possible, or transferred to your supervisor or successor.

		Initial When Completed					Initial When Completed		
		Emp	Supv* IMO	RLO			Emp	Supv* IMO	RLO
1.	Email records including accounts such as private/personal or secondary (group and/or special purpose) email accounts *Indicate new custodian in comments section, if applicable				8.	Program File Rooms (RCRA, Air, Water, etc.) and Federal Records Center (FRC) *Initialed by Records Contact /Designee.* • Returned all files checked out • Submitted new records to be filed			
2.	Portable electronic storage devices (CDs, DVDs, USBs, floppies, etc.) *(List in comments)*				9.	Superfund Records Center *initialed by Superfund Records Contact/Designee* • Returned all files checked out • Submitted new records to be filed			
3.	PDAs (BlackBerry, Windows Phone, iPhone, cell phone, text messages, IM, etc.)				10.	Employee's Workspace Checked for Records • If not transferred, who will transfer? (List name in comments.)			
4.	Local Area Network Drive Files and Shared drive(s), transfer electronic files to OneDrive *(List the drives in comments.)*				11.	Confidential Business Information *initialed by Document Control Officer (DCO)* • Returned all files checked out • Request submitted to DCO to terminate CBI Authorized Access			
5.	Local hard drive and records on personal computer				12.	Identify any known open FOIA requests assigned to you for which the collection has not been completed by name/number; list in comments.			
6.	Lotus Notes and Microsoft Office Collaboration Tools (SharePoint, OneDrive, etc.) *(List the tools in comments.)*				13.	Identify and preserve current or potential litigation hold materials by name/number for which you have been or may be identified as a custodian. Review litigation hold portal at http://litholdandcollect.epa.gov/portal. List name/number in comments			
7.	Desktop GIS, local GIS servers, and GeoPlatform				14.	Identify and preserve existing audit or Congressional inquiry materials for which you have been identified as a custodian by name/number in comments.			

COMMENTS: For any items requiring additional notation or if any box above is left blank, you must provide explanation. If there are any other areas where you have stored records, please describe them and their disposition here. If the list of litigation holds is too lengthy to fit in the comments box, please attach the list to the 3110-49.

CERTIFICATIONS

To the best of my knowledge, I certify that all U.S. Government documentary materials (preservation of litigation holds, audits, and congressional inquiry materials), in any format, have been identified and transferred to the appropriate recordkeeping system or designee and that the statements made on this Checklist are true, accurate, and complete.

1.	**Employee (signature)**	**(print/type name)**
2.	**Supervisor/designee (signature)**	**(print/type name)**
	OR for Senior Officials	
	IMO/designee (signature)	**(print/type name)**
3.	**RLO/designee (signature)**	**(print/type name)**

INSTRUCTIONS

This Checklist is to be utilized as detailed in EPA Information Procedures on Preservation of Separating, Transferring or Separated Personnel's Records in Accordance with the Federal Records Act. The purpose of the Checklist is to help EPA personnel identify all potential locations of records in their custodianship. For personnel who have separated, the supervisor/manager should review the person's records first, when at all possible and ensure actions taken on records are documented on EPA Form 3110-49. See Preservation of Separating, Transferring or Separated Personnel's Records in Accordance with the Federal Records Act, Section III A and B, Separated Personnel, http://intranet.epa.gov/oei/imitpolicy/qic/ciopolicy/CIO-2155-P-04.0.pdf; 44 U.S.C. § 3106; Unlawful removal, destruction of records https://www.law.cornell.edu/uscode/text/44/3106; 36 CFR § 1230 Unlawful or Accidental Removal, Defacing, Alteration or Destruction of Records http://www.ecfr.gov/cgi-bin/text-idx?SID=8ca786c32479fb9fba535f5d1c3c61d9&mc=true&tpl=/ecfrbrowse/Title36/36cfr1230_main_02.tpl

PERSONNEL BACKGROUND INFORMATION SECTION to be completed by Employee or Supervisor.

For the statement "**Describe major records that you maintain,"** if the individual does not have specific records management responsibilities, "routine recordkeeping responsibilities" may be entered.

POTENTIAL RECORD SOURCES TO BE REVIEWED SECTION

Personnel, Supervisor/Designee, Records Liaison Officer (RLO)/Designee must *all* initial the Checklist for each numbered item. * For Senior Officials, the IMO or designee should initial in the Supv box in lieu of a supervisor.

1. Initial in the "completed" box next to each description to note that records have been identified, captured in an approved recordkeeping system or transferred to another employee, or enter "N/A" if that item is not applicable for that individual. (Not every description will be applicable to all personnel, i.e., not all personnel have an EPA provided Blackberry, iPhone, etc.)
2. If any box is left blank, provide explanation in the Comment field.
3. For items requiring additional notations, use the Comment field, noting the item number being clarified.
4. Supervisor and RLO/designee is responsible to resolve any item which has not been initialed. Final resolution should be noted on the Checklist when completed.

CERTIFICATIONS SECTION

If the individual has already separated from EPA, insert "N/A-already separated" on the Employee signature line. The supervisor or designee and the RLO will be responsible for completing this checklist and certifying, to the best of their knowledge, that all records were properly identified and saved to a recordkeeping system. This completed, certified original Checklist should be maintained by the local Records Liaison Officer/designee in accordance with Schedule 0568 or appropriate subsequent schedule.

REQUIREMENT: Notify OGC/Ethics within 3 business days of commencing the negotiation or agreement for post-government employment or compensation

NOTIFICATION OF NEGOTIATION OR AGREEMENT

Your full name	Your telephone number*	Date negotiation or agreement began
Your Title / Office / AAship or Region	Your email address*	Name of non-federal entity that you are negotiating with or have an agreement for employment or compensation

* *Provide information for OGC/Ethics to use to contact you as part of our official duty. For this purpose, you may provide a personal email address or cell number.*

RECUSAL STATEMENT

To assist in identifying your recusal obligations, check the appropriate boxes below:

	Yes	No	
1.	☐	☐	EPA's programs, policies, or operations affect the non-federal entity with which I am seeking employment.
2.	☐	☐	My office in EPA does work that affects the non-federal entity with which I am seeking employment.
3.	☐	☐	The work I participate in affects or will affect the non-federal entity with which I am seeking employment.

Need help answering these statements? See page 2.

For as long as I am negotiating for, or have an agreement of, employment or compensation with the entity listed above, I will not participate personally and substantially in any particular matter that has a direct and predictable effect on the financial interests of this entity, unless I first obtain from OGC/Ethics a written authorization or waiver consistent with 5 C.F.R. § 2635.605 or 18 U.S.C. § 208(b)(1). I understand that it is my responsibility to consult with OGC/Ethics if I have questions regarding my recusal obligations.

Sign and submit to ethics@epa.gov:

Your signature

OGC/Ethics Use Only:

Last Updated: November 2020

Statement 1: EPA's programs, policies, or operations affect the non-federal entity with which I am seeking employment.

If your answer is "yes" to any of the following questions, then you must answer "yes" to statement 1.

- Is the non-federal entity seeking official action from EPA (even if not your own office)?
- Does the non-federal entity do business or seek to do business with the EPA (even if not your own office)?
- Does the non-federal entity conduct activities that EPA regulates (even if not in your own office)?
- Does the non-federal entity have interests that may be substantially affected by the performance or non-performance of your official duties?
- Is the non-federal entity a membership organization in which the majority of the members are described in the preceding questions?

Statement 2: My office in EPA does work that affects the non-federal entity with which I am seeking employment.

To answer this question, think about the nexus between the work of your office and the non-federal entity. The closer the nexus, the more likely you will have to check "yes" to statement 2.

- Consider the particular matters your office works on and whether there is any connection to the work of this entity. Does your office work on permits, investigations, litigation, grants, licenses, contracts, applications, enforcement cases, or other similar types of matters where there is an identified non-federal entity (i.e., particular matters involving specific parties)?
- Also consider whether your office is involved in scientific programs, media programs, or other types of policies, procedures, guidance documents, regulations, etc., that would affect this particular industry or sector (i.e., particular matters of general applicability).

Statement 3: The work I participate in affects or will affect the non-federal entity with which I am seeking employment.

Think about the nexus between your work and the non-federal entity as well as its respective class, industry or sector. The closer the nexus between your work and the sector the non-federal entity belongs to, the more likely you will check have to check "yes" to statement 3.

- Will the work you do affect the sector? Don't concentrate on whether your personal contributions will be determinative but rather, overall, how the outcome of the work itself will affect the sector and the non-federal entity with which you are negotiating.
- Do you advise on or consult with your colleagues' projects and work? Does their work affect this sector or the non-federal entity?
- Do you actively supervise or assign work to subordinates? Do those assignments affect the sector or the non-federal entity?

Need help answering these statements? Contact ethics@epa.gov to discuss.

Final Outgoing Appointees Transition

Final Outgoing
Appointees Transition

Message

From: EPA Press Office [press@epa.gov]
Sent: 1/6/2021 3:00:14 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: Prevent Lung Cancer by Testing your Home for Radon, EPA Recommends

Prevent Lung Cancer by Testing your Home for Radon, EPA Recommend

WASHINGTON (January 6, 2021) — This week marks the beginning of National Radon Action Month. Every January, the U.S. Environmental Protection Agency (EPA) urges everyone across the United States to test their homes for radon gas. Radon is a naturally

occurring radioactive gas that can seep into homes from the ground and, in some cases, well water supply.

"Radon is the second leading cause of lung cancer in the United States, and is both colorless and odorless, so I encourage everyone to take time this January to test and prevent radon exposure in your homes," said EPA Administrator Andrew Wheeler. "Millions of homes have been tested for radon and repaired, but millions more homes with high levels of this radioactive gas remain."

Each year we lose over 21,000 American lives due to radon-induced lung cancer. Testing for radon can be as simple as stopping by your local home improvement store to pick up a do-it-yourself testing kit, often found for less than $20. Test kits can also be purchased online, or individuals can hire a qualified professional to conduct a radon test. Contact your state or tribal radon program for advice.

To date, tens of millions of homes have been tested for radon, and nearly two million with high radon levels have been fixed through the efforts of state and local radon programs, radon service providers, non-profit health organizations, and federal agencies. However, EPA estimates that millions of homes with high levels of radon remain. Take the simple step today to protect your loved ones: Test. Fix. Save a Life.

Radon Hero Award

During this year's National Radon Action Month, EPA is honoring long-time employee Lou Witt, who was posthumously awarded the "Radon Hero Award" by the Conference of Radiation Control Program Directors for his lifelong work and commitment to preventing lung cancer risks from radon.

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Message

From: EPA Press Office [press@epa.gov]
Sent: 1/6/2021 4:00:14 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: Agency Releases Annual Automotive Trends Report Showing Manufacturers Still Struggling to Comply with Obama Era Standards without Use of Credits

Agency Releases Annual Automotive Trends Report Showing Manufacturers Still Struggling to Comply with Obama Era Standards without Use of Credits

WASHINGTON (January 6, 2021) — Today, the U.S. Environmental Protection Agency (EPA) released its annual *Automotive Trends Report*, which provides the public with a single source of information about new light-duty vehicle greenhouse gas (GHG) emissions, fuel economy, technology data, and auto manufacturers' performance in meeting the agency's GHG emissions standards. The report shows that fuel economy remains high but has slipped slightly from the record pace set in previous years and that reducing emissions through innovation remains a priority for automotive manufacturers.

"This report shows in detail how few auto manufactures were able to meet the unrealistic emissions standards set by the Obama Administration without resorting to purchasing emission credits," **said EPA Administrator Andrew Wheeler**. "We have set realistic standards in 2020 that will reduce emissions as well as vehicle costs and maintain consumer choice going forward."

Fuel economy for Model Year (MY) 2019 was 24.9 miles per gallon, lower than MY 2018 by only 0.2 mpg. Since MY 2004, when the fleet averaged 19.3 mpg, fuel economy, and CO2 emissions have improved in twelve out of fifteen years.

The report also assesses compliance performance for individual automakers, and for the U.S. fleet, with the GHG emissions standards for light-duty vehicles. This year's report once again shows that only 3 large manufacturers complied with MY 2019 standard based on technology factors of their vehicles alone. When accounting for credits, however, the report shows all large manufacturers are in compliance. Eleven out of 14 large manufacturers used a combination of technology improvements, banked credits, and purchased credits to maintain compliance in MY 2019.

Key Highlights

- Due to a combination of technology, innovation and regulatory flexibility, the average new MY 2019 vehicle sold in the U.S. was near record low GHG emissions and near record high fuel economy.
- New vehicles continue to make progress on GHG emissions while providing consumer choice for Americans. For example, sport utility vehicles reached record high market share, while also achieving record high fuel economy and record low CO2 emissions.
- Manufacturers continue to have a large bank of credits to use toward compliance in future model years, however, about two-thirds of the current credits will expire after model year 2021.

To read the full Automotive Trends Report, please visit: https://www.epa.gov/automotive-trends

Background

Each manufacturer fleet generates credits if the fleet average emissions performance is below the standards, or deficits if it is above the standards. Credits, or deficits, that manufacturers have accrued in previous model years, credits earned as part of the early

credit program, credit trades, credit forfeitures, and credit expirations are also important components in determining the final compliance status of each manufacturer. Manufacturers that maintain a positive, or zero, credit balance are considered in compliance with the GHG program. Manufacturers that end any model year with a deficit have up to three years to offset that deficit to avoid non-compliance.

About the Report

This annual report is part of the EPA's commitment in providing the public with transparent information about new light-duty vehicle GHG emissions, fuel economy, technology data, and auto manufacturers' performance in meeting the agency's GHG emissions standards. EPA has collected data on every new light-duty vehicle model sold in the United States since 1975. Data is collected to support several national programs, including EPA criteria pollutant and GHG standards, the U.S. Department of Transportation's National Highway Traffic Safety Administration (NHTSA) Corporate Average Fuel Economy (CAFE) standards, and vehicle Fuel Economy and Environment labels.

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Message

From: EPA Press Office [press@epa.gov]
Sent: 1/6/2021 6:00:11 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: ICYMI: Why We're Ending the EPA's Reliance on Secret Science

ICYMI: Why We're Ending the EPA's Reliance on Secret Science

The agency has long made decisions without allowing the public to scrutinize our underlying data.

Andrew Wheeler
The Wall Street Journal
January 4, 2021

The task of science is one of test and retest, analysis and comparison, over and over. It is slow and careful work, done in the open. Only rarely has science benefited from secrecy, and that is usually for reasons of national security. The geniuses of the Manhattan Project who built the atomic bomb, the mavericks of Cape Canaveral who

sent men to the moon, these giants did their work behind high walls, and for good reason.

But the work of the Environmental Protection Agency—to protect human health and the environment—shouldn't be exempt from public scrutiny. This is why we are promulgating a rule to make the agency's scientific processes more transparent.

Too often Congress shirks its responsibility and defers important decisions to regulatory agencies. These regulators then invoke science to justify their actions, often without letting the public study the underlying data. Part of transparency is making sure the public knows what the agency bases its decisions on. When agencies defer to experts in private without review from citizens, distinctions get flattened and the testing and deliberation of science is precluded.

Our rule will prioritize transparency and increase opportunities for the public to access the "dose-response" data that underlie significant regulations and influential scientific information. Dose-response data explain the relationship between the amount of a chemical or pollutant and its effect on human health and the environment—and are the foundation of the EPA's regulations. If the American people are to be regulated by interpretation of these scientific studies, they deserve to scrutinize the data as part of the scientific process and American self-government.

Transparency is a defense of, not an attack on, the important work done by career scientists at the EPA, along with their colleagues at research institutions around the country. Increasing polarization around scientific questions stems in part from too many public policy debates setting science in a category apart from normal discussion or standards. By shining light on the science we use in decisions, we are helping to restore trust in government. We want the EPA to be able to say, "you can check our work."

The rule-making process is itself transparent. This rule-making is the result of several years of work and two separate public comment periods, making this final rule a better product.

Some special interests have demagogued the rule, calling it an attack on privacy that would weaken the science used by the EPA and politicize public health studies. Critics in the media appear to prefer it when regulators feed them conclusions, instead of analyzing the underlying data themselves.

This rule is not a stick for forcing scientists to choose between respecting the privacy and rights of their study participants and submitting their work for consideration. No private information will be released as a result of this rule. We can verify results with independent review and still protect confidential and personal information. Our rule won't allow administrators to cherry pick research to derive politically helpful results. It won't categorically exclude any scientific work from EPA use. We don't seek to limit anyone's ability to conduct sound science.

Transparency has been a guiding principle at the EPA for 50 years. Administrator William Ruckelshaus issued his famous "Fishbowl Memo" in 1983. This memo demanded that EPA employees act in the open and "ensure that the basis for the Agency's decision[s] appears in the record." Ruckelshaus knew the credibility of a regulator depended on clear communication with the public.

Transparency knows no political ideology. My Democratic predecessors often appealed to its importance. In 2014, the Obama administration's Gina McCarthy reassured the National Academy of Sciences that, "In everything we do—EPA relies on transparency, on rigorous peer review, and on robust, meaningful public comment." This final regulation does just that. Please read the rule before you reflexively repeat tired misinformation or make another's interpretation of it your own.

Click here to read the full article.

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Message

From: EPA Press Office [press@epa.gov]
Sent: 1/6/2021 7:00:11 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: EPA Releases Briefing Paper on Renewable Energy Waste Management

EPA Releases Briefing Paper on Renewable Energy Waste Management

WASHINGTON (January 6, 2020) — Today, EPA posted a briefing paper outlining difficulties the U.S. will face recycling and safely disposing of the materials used for green energy technologies. *Renewable Energy Waste Streams: Preparing for the Future*

examines the waste produced once solar panels, lithium-ion batteries and windmills reach the end of their useful life. This briefing paper identifies key challenges that America faces in the near future as the growing use of renewable energy technologies creates a new generation of materials that need to be recycled or properly disposed of in order to protect human health and the environment.

"Recycling is a critical piece of our future for not only consumer commodities like paper and plastic, but also the ever-expanding renewable energy sector," **said EPA Administrator Andrew Wheeler.** "Without a strategy for their end-of-life management, so-called green technologies like solar panels, electric vehicle batteries, and windmills will ultimately place the same unintended burdens on our planet and economy as traditional commodities."

"It is vital that we adequately plan, prepare, and design renewable energy systems for reuse, recycling, and proper end-of-life material management in the present, or we risk creating new environmental and economic burdens in the future," **said Assistant Administrator for the Office of Land and Emergency Management Peter Wright.** "Appropriate and effective preparations need to occur along with the expanded use of renewable energy so that recycling systems and appropriate waste management infrastructures are in place when they are needed."

Inadequate solid waste management systems present serious risks to human health, the environment, and the economy and loss of economic opportunity associated with the recovery of valuable materials. Increasing U.S. investment in renewable energy systems will create new kinds and new volumes of waste. Not only are there byproducts and energy demands associated with the production of so-called green technologies, but these systems also produce materials requiring careful end-of-life management to avoid creating unexpected burdens on individuals and communities and the risk of causing new Superfund sites and wasting of scarce and valuable resources.

To read the briefing paper, visit https://www.epa.gov/sites/production/files/2021-01/documents/renewable_energy_waste_briefing_paper_january_2021.pdf.

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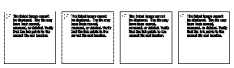

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Message

From: EPA Press Office [press@epa.gov]
Sent: 1/6/2021 5:00:07 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
Subject: ***MEDIA ADVISORY*** Administrator Wheeler to Visit Costa Rica, Highlight Marine Litter and Agriculture Partnerships

FOR PLANNING PURPOSES ONLY

*****MEDIA ADVISORY*****
Administrator Wheeler to Visit Costa Rica, Highlight Marine Litter and Agriculture Partnerships

WASHINGTON (January 6, 2020) — Tomorrow, U.S. Environmental Protection Agency (EPA) Administrator Andrew Wheeler will begin a series of meetings, roundtables, and site visits on marine litter and recycling during a visit to Costa Rica. The trip will also highlight joint agriculture initiatives.

WHO: EPA Administrator Andrew Wheeler

WHERE: San Jose, Costa Rica

WHEN: Thursday, January 7 — Saturday, January 9

Events will be closed press.

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Message

From: Hackel, Angela [Hackel.Angela@epa.gov]
Sent: 1/6/2021 4:16:03 PM
To: Gunasekara, Mandy [gunasekara.Mandy@epa.gov]
CC: Grantham, Nancy [Grantham.Nancy@epa.gov]; Richardson, RobinH [Richardson.RobinH@epa.gov]; Carpenter, Wesley [Carpenter.Wesley@epa.gov]
Subject: Signature Correspondence: Authorization for GOV Home-to-Work
Attachments: MEMO Request GOV Home-to-Work Extension_DV_Jan 2021 signed.pdf; MEMO Authorization for GOV Home-to-Work_Jan 2021.docx; OSC-List Extension Request - Use of GOV for Home to Work During COVID-19 Pandemic - Attachment Dec Update (002).docx

Importance: High

Hello Mandy,

Attached is the delegation for the Use of Government Vehicles between Home and Work by EPA On Scene Coordinators. Please see the additional information below.

Please let me know if I have approval to digitally sign the attached memo.

OMS, would like to get this signed as soon as possible.

If you have any questions, please let me know.

Sincerely,

Angela

The attached authorization memorandum for Use of Government Vehicles between Home and Work by EPA On Scene Coordinators (OSCs) for essential official Agency business during the COVID 19 Pandemic. By way of background, 31 U.S. Code §1344 restricts the operation of government vehicles to official purposes, such as the performance of required field work. The authorization to allow such vehicle use must be made by the agency head.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

January 5, 2021

OFFICE OF MISSION SUPPORT

MEMORANDUM

SUBJECT: Extension of the Authorization for the Use of Government-Owned Vehicles for Home-to-Work Transportation for EPA Personnel During COVID-19 Pandemic Emergency

FROM: Donna J. Vizian, Principal Deputy Assistant Administrator

LYNNANN HITCHENS Digitally signed by LYNNANN HITCHENS Date: 2021.01.05 17:37:18 -05'00'

TO: Andrew R. Wheeler
Administrator

The attached authorization memorandum for Use of Government Vehicles between Home and Work by EPA On Scene Coordinators (OSCs) for essential official Agency business during the COVID 19 Pandemic. By way of background, 31 U.S. Code §1344 restricts the operation of government vehicles to official purposes, such as the performance of required field work. The authorization to allow such vehicle use must be made by the agency head.

This authorization extends the approval of government vehicle use for field essential work during the emergency. Any such vehicle use must be documented by the Field Work Vehicle Use Authorization Form attachment.

I recommend that you approve the attached authorization memo that extends the approval to April 5, 2021. Please contact me if you have any questions regarding this issue.

Attachments
1. Authorization memorandum
2. List of Applicable On-Scene Coordinators

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

[DATE \@ "MMMM d, yyyy"]

THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Authorization for the Use of Government-Owned Vehicles for Home-to-Work Transportation for EPA Personnel During COVID-19 Pandemic Emergency

FROM: Andrew R. Wheeler
Administrator

TO: General Counsel
Assistant Administrators
Inspector General
Chief Financial Officer
Chief of Staff
Associate Administrators
Regional Administrators

Pursuant to 41 C.F.R. Part 102-5, the Agency On-Scene Coordinators are hereby authorized to use Government-Owned Vehicles for transportation between their home residence(s) and place(s) of EPA employment when officially required to do so due to circumstances that constitute an emergency as described in 31 U.S.C. 1344. Each EPA Region has identified agency personnel who may respond to agency mission emergency situations during the COVID 19 Pandemic (attached). Due to the activation of EPA Continuity of Operations plans in select locations nationwide, which includes limited building access and various local travel restrictions, the use of GOVs for home-to-work transportation by the OSCs is essential to ensuring the sustainment of official agency business.

A record of home-to-work use will be maintained by each designated EPA employee in accordance with 41 CFFR 102-5.120 and congressional notification will be coordinated through the Office of Congressional and Intergovernmental Relations. The authorization will expire 90 calendar days after January 5, 2021, or when the event, situation, or circumstance giving rise to the need for home-to-work vehicle use ceases, whichever is earlier. This determination may be extended for additional 90-calendar day periods by subsequent written determinations from the Administrator if the same circumstances underlying this determination and approval continue to exist.

Attachment

ATTACHMENT

LIST OF APPLICABLE ON-SCENE COORDINATORS (DEC 2020)

REGIONS 1 - 5

Region 1	Region 2	Region 3	Region 4	Region 5
Sherry Banks	Patrick Ahern	Eric Armistead	Gary Andrew	Brad Benning
Allyson Bowden	Jeff Bechtel	Myles Bartos	David Andrews	Anita Boseman
Dan Burgo	Thomas Budroe	Kelly Chase	Chuck Berry	Jason Cashmere
James Carew	Gez Bushra	Kevin Clark	Karen Beuerki	Jacquelyn Cole
Cosmo Caterino	Johnathan Byk	Eugene Dennis	Jason Booth	Ralph Dollhopf
Wing Chau	Margaret Chong	Ann DiDonato	Terrence Byrd	Dan Droste
Michael Cofsky	Andrew Confortini	Jessica Duffy	Kevin Eichinger	Tricia Edwards
Thomas Condon	Eric Daly	Charlie Fitzsimmons	Brian Englert	Stavros Emmanoul
Tom Hatzopoulos	Lou DiGuardia	Joseph Gawarzewski	Serdar Ertep	Jon Gulch
Nico James	Chris D'Onofrio	Chris Guzzetti	Ben Franco	Dan Haag
Allen Jarrell	Mark Gallo	Samantha Holtzinger	Jordan Garrard	Jacob Hassan
Gary Lipson	Geoffrey Garrison	Jack Kelly	Perry Gaughan	James Justice
John McKeown	Dan Gaughan	Glen Lapsley	Greg Harper	Sean Kane
Mike Nalipinski	Keith Glenn	Melissa Linden	Matthew Huyser	Brian Kelly
Alex Sherrin	Don Graham	Debbie Lindsey	Rick Jardine	Jeff Kimble
Zachary Taylor	Dwayne Harrington	Dennis Matlock	Joseph Krull	Andrew Kleist
Karen Way	Bonnie Hriczko	Don McLaughlin	Sam Locke	Andrew Kocher
Catherine Young	Carlos Huertas-Hernanc	Ashley Nilsen	Tim Neal	Rob Kondreck
	Chris Jimenez	Todd Richardson	Jose Negron	Shelly Lam
	Terry Kish	Eduardo Rovira	Subash Patel	Danita Larry
	Peter Lisichenko	Rich Rupert	Ken Rhame	Andy Maguire
	Irmgard Lopez	Ruth Scharr	Frank Russell	Lauren McCarrell
	Kelly Lucarino	Raj Sharma	Steve Spurlin	Tom Mendez
	Nicholas Magriples	Dominic Ventura	Terry Stilman	Kristina Miller
	Michael Mannino	Christine Wagner	Courtney Swanson	James Mitchell
	Josephine Martin		Terry Tanner	David Morrison
	Neil Norrell		Christopher Tripp	Elizabeth Nightingale
	Carl Pellegrino		Brian Vasser	Cory Peaslee
	Dilshad Perera		Ted Walden	Eric Pohl
	Joel Petty		Carter Williamson	Steve Renninger
	Reshma Ramkissoon			Paul Ruesch
	Aarti Reddy			Jason Sewell
	Sandra Richards			Verneta Simon
	David Rosoff			Craig Thomas
	Stephen Simonetti			Kevin Turner
	Kim Staiger			Sonia Vega
	Michelle Tabayoyong			Matthew Villicana
	Steven Touw			Adam Vrabec
	Marissa Truono			Stephen Wolfe
				Leonard Zintak

ATTACHMENT

LIST OF APPLICABLE ON-SCENE COORDINATORS - CONTINUED

REGIONS 6 - 10

Region 6	Region 7	Region 8	Region 9	Region 10
Adam Adams	Tim Curry	Joyce Ackerman	Ramon Albizu	Stephen Ball
Pratistha Adams	Joe Davis	Valeriy Bizyayev	Harry Allen	Madison Baxter
Roberto Bernier	Michael Davis	Shun-Ping Chau	Patricia Bowlin	Dale Becker
Nicolas Brescia	Jessica Evans	Todd DeGarmo	Steve Calanog	Michael Boykin
Eric Delgado	Doug Ferguson	Joyel Dhieux	Ben Castellana	Jeffrey Fowlow
Paige Delgado	John Frey	Kerry Guy	Tom Dunkelman	Richard Franklin
Jhana Enders	Andrew Gieseke	Martin McComb	Tara Fitzgerald	Randy Nattis
Kelsey Fisher	James Johnson	Craig Myers	Jeremy Johnstone	Eric Nuchims
Craig Giggleman	Sharon Kennedy	Duane Newell	Bret Moxley	Dave Rees
Randy Guidry	Kirk Mammoliti	Duc Nguyen	Jason Musante	Michael Sibley
Matt Loesel	Eric Nold	Paul Peronard	Chris Myers	Brooks Stanfield
Mike McAteer	Daniel O'Crowley	David Romero	Amanda Pease	Monica Tonel
Gary Moore	Jeffery Pritchard	Joni Sandoval	Chris Reiner	Eric Vanderboom
Nabil Mzee	Randy Schademann	Eric Sandusky	Michelle Rogow	Bob Whittier
Idrissa Ouedraogo	Manuel		Olivia Trombadore	
Anish Patel	Schmaedick		Robert Wise	
David Robertson	Megan Schuette			
Nick Roff	Heath Smith			
Philip Rouse	Yvonne Smith			
Dan Zahner	Krystal Stotts			
Warren Zehner				

Message

From: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F639EA28AF4C455493939E3129260707-GUNASEKARA,]
Sent: 1/6/2021 12:07:47 PM
To: Fotouhi, David [Fotouhi.David@epa.gov]
Subject: Re: update - waiting for Clerks / Staff Sec to complete style review of draft E O

Great

Sent from my iPhone

On Jan 5, 2021, at 5:45 PM, Fotouhi, David <Fotouhi.David@epa.gov> wrote:

Current status

Sent from my iPhone

Begin forwarded message:

From: "Varcoe, Andrew R. EOP/WHO" Ex. 6
Date: January 5, 2021 at 5:35:15 PM EST
To: "Fotouhi, David" <Fotouhi.David@epa.gov>
Subject: update - waiting for Clerks / Staff Sec to complete style review of draft E O

Just fyi.

Andrew R. Varcoe
Special Assistant to the President
Associate Counsel to the President
Office of White House Counsel
Ex. 6

Message

From: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F639EA28AF4C455493939E3129260707-GUNASEKARA,]
Sent: 1/6/2021 5:10:04 PM
To: Dickerson, Aaron [dickerson.aaron@epa.gov]
Subject: Re: your calendar from September - December

Will do

Sent from my iPhone

On Jan 6, 2021, at 11:56 AM, Dickerson, Aaron <dickerson.aaron@epa.gov> wrote:

Hi Mandy

OEX is asking for your calendar from September – December. When you get a chance, can you review so I can send it. Thank you.

Aaron Dickerson
Senior Advisor
Office of the Administrator
U.S. EPA

Message

From: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F639EA28AF4C455493939E3129260707-GUNASEKARA,]
Sent: 1/6/2021 5:51:49 PM
To: Hewitt, James [Hewitt.James@epa.gov]
CC: Bolen, Brittany [bolen.brittany@epa.gov]; Bolen, Derrick [bolen.derrick@epa.gov]
Subject: RE: Nancy Beck

Yes – good.

From: Hewitt, James <hewitt.james@epa.gov>
Sent: Wednesday, January 6, 2021 12:51 PM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>
Cc: Bolen, Brittany <bolen.brittany@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>
Subject: Re: Nancy Beck

You had a typo there. So fine to say "she remains in detail at the White House and retains her current position with OCSPP"?

Sent from my iPhone

> On Jan 6, 2021, at 12:09 PM, Gunasekara, Mandy <gunasekara.Mandy@epa.gov> wrote:
>
> She is on detail to the WH and accoedinlu, has retained her most recent epa position of deputy in OCSPP.
>
> Sent from my iPhone
>
>> On Jan 6, 2021, at 10:15 AM, Bolen, Brittany <bolen.brittany@epa.gov> wrote:
>>
>> Not officially, but my understanding is that she's still on detail.
>>
>> ---
>>
>> **From:** Hewitt, James <hewitt.james@epa.gov>
>> **Sent:** Wednesday, January 6, 2021 9:59 AM
>> **To:** Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
>> **Cc:** Bolen, Derrick <bolen.derrick@epa.gov>
>> **Subject:** FW: Nancy Beck
>>
>> Do any of you know?
>>
>> **From:** Rebecca Beitsch <rebecca@thehill.com>
>> **Sent:** Wednesday, January 6, 2021 9:51 AM
>> **To:** Press <Press@epa.gov>
>> **Subject:** Nancy Beck
>>
>> Hey team,

Could someone shoot me an explanation of Nancy Beck's current status with EPA? Looking to just get some clarification on her role the agency, whether she's still on loan to OMB, etc etc. Would love a response by noon.

Thanks!

Rebecca Beitsch
Energy and Environment Reporter
The Hill
rebecca@thehill.com | @rebeccabeitsch

Message

From: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F639EA28AF4C455493939E3129260707-GUNASEKARA,]
Sent: 1/6/2021 6:22:29 PM
To: Johnson, Taylor [Johnson.Taylor.C@epa.gov]; Molina, Michael [molina.michael@epa.gov]
CC: Block, Molly [block.molly@epa.gov]; Hewitt, James [Hewitt.James@epa.gov]; Murray, William [Murray.William@epa.gov]; McFaul, Jessica [mcfaul.jessica@epa.gov]; Grantham, Nancy [Grantham.Nancy@epa.gov]
Subject: RE: FOR APPROVAL: R5 Trash Free Waters Grant

No additional edits – all good.

From: Johnson, Taylor <Johnson.Taylor.C@epa.gov>
Sent: Wednesday, January 6, 2021 11:26 AM
To: Molina, Michael <molina.michael@epa.gov>
Cc: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Block, Molly <block.molly@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Murray, William <Murray.William@epa.gov>; McFaul, Jessica <mcfaul.jessica@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>
Subject: RE: FOR APPROVAL: R5 Trash Free Waters Grant

Thanks, Michael! Mandy, please let me know if you have any additional edits.

From: Molina, Michael <molina.michael@epa.gov>
Sent: Wednesday, January 6, 2021 8:04 AM
To: Johnson, Taylor <Johnson.Taylor.C@epa.gov>
Cc: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Block, Molly <block.molly@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Murray, William <Murray.William@epa.gov>; McFaul, Jessica <mcfaul.jessica@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>
Subject: Re: FOR APPROVAL: R5 Trash Free Waters Grant

"Fighting litter pollution in freshwater and marine environments is one of EPA's highest priorities," **said EPA Administrator Andrew Wheeler.** These GLRI grants will support communities in their clean up efforts of harbors,coastlines and waterfronts, preventing trash from reaching our Great Lakes waterways."

Sent from my iPhone

> On Jan 5, 2021, at 2:26 PM, Johnson, Taylor <Johnson.Taylor.C@epa.gov> wrote:
>
> "Fighting litter pollution in freshwater and marine environments is one of EPA's highest priorities," **said EPA Administrator Andrew Wheeler.** "Through the Trash-Free Great Lakes Grant Program, EPA supports communities that clean up harbors and waterfronts in order to keep trash from reaching our Great Lakes waterways in the first place."

Message

From: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F639EA28AF4C455493939E3129260707-GUNASEKARA,]
Sent: 1/6/2021 8:35:16 PM
To: Connor, Cameron M. EOP/WHO Ex. 6
CC: Basica, LJ D. EOP/WHO Ex. 6
Subject: Re: Cabinet Chair - Admin. Wheeler

Cami- thank you for the connection.

LJ- nice to meet you and thank you in advance for your help. Can you let me know the process?

Is it as simple as writing a check and then organizing the pick-up? Feel free to give me a ring if easier to discuss: Ex. 6 Ex. 6

Best,
Mandy

Sent from my iPhone

On Jan 6, 2021, at 3:25 PM, Connor, Cameron M. EOP/WHO Ex. 6 wrote:

Mandy—connecting you by way of email with LJ Basica on our WH Management team. She will be able to assist you with purchasing Administrator Wheeler's Cabinet chair.

LJ—let me know if you need anything else from me.

Thanks, all!

Best,
Cami

Cameron Connor
Office of Cabinet Affairs
The White House
M: Ex. 6

Message

From: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F639EA28AF4C455493939E3129260707-GUNASEKARA,]
Sent: 1/6/2021 6:56:45 PM
To: Burgess, Michael [Burgess.Michael@epa.gov]; Molina, Michael [molina.michael@epa.gov]; Carter, Brittany S. [carter.brittanys@epa.gov]; Pic, Jordan [pic.jordan@epa.gov]; Frye, Tony (Robert) [frye.robert@epa.gov]; Washam, Todd [Washam.Todd@epa.gov]; Brazauskas, Joseph [brazauskas.joseph@epa.gov]; Hewitt, James [Hewitt.James@epa.gov]; Block, Molly [block.molly@epa.gov]; Walker, Mary [walker.mary@epa.gov]; Meadows, Carrie Vicenta [Meadows.CarrieVicenta@epa.gov]
CC: Teresa, Tyler [Teresa.Tyler@epa.gov]; Ex. 7(C), 7(F); Ex. 7(C), 7(F); Ex. 7(C), 7(F)
Subject: RE: Tentative Schedule - Mississippi
Attachments: MS Agenda_DRAFT .docx

Below and attached is a revised schedule based on some updates from a few entities and a convo with Mary regarding the Vicksburg event.

Sunday, January 10th 2021

9:00 am (CDT) Briefing on Pumps with Mary Walker and Blake

10:00 am **Breakfast with (tentative) MDEQ Director Chris Wells at Brent's Drugs in Fondren District of Jackson, MS**

12:00pm Administrator Wheeler guided tour of Civil Rights Museum in Jackson, Mississippi

2:00pm Administrator Wheeler arrives for meeting with Governor Reeves + Lunch at Governor's Residence

4:00pm Administrator Wheeler tours the Capitol building in Jackson, Mississippi with Lt. Gov Hosemann (300 East Capitol Street)

7:00pm Administrator Wheeler arrives at CHAR for Dinner with elected officials (4500 Interstate 55 North Frontage Rd, Jackson, MS 39211)

Monday, January 11th 2021

7:30am Administrator Wheeler arrives at SuperTalk for Radio Interview in Jackson, Mississippi (6311 Ridgewood Road, Jackson, MS)

8:30am Administrator Wheeler arrives at the US ACE Vicksburg District for briefing with elected officials (4155 Clay St. Vicksburg, MS)

9:00am Administrator Wheeler begins press conference

Mandy Gunasekara will MC event
Administrator Wheeler remarks 10 Minutes
Col. Hilliard remarks 5 Minutes
Senator Wicker remarks 5 Minutes
Senator Hyde-Smith remarks 5 Minutes
Gov. Reeves remarks 5 Minutes
Q&A 10-15 Minutes

9:50am Administrator Wheeler departs US ACE Vicksburg District HQ

10:00am Administrator Wheeler tours the US ACE ERDC facility (3909 Halls Ferry Rd, Vicksburg MS 39180)

10:30am Administrator Wheeler departs Vicksburg en route to Bolton, MS for AG event

11:00am Administrator Wheeler begin AG event at Nutrien Ag Solutions (6800 I-20, Bolton, MS 39041)

TBC Remarks

12:00pm Administrator Wheeler departs Bolton, MS for lunch in Jackson, MS

1:00pm Lunch

2:00pm Administrator Wheeler arrives at Airport

2:52pm Departure

From: Burgess, Michael <Burgess.Michael@epa.gov>
Sent: Wednesday, January 6, 2021 10:17 AM
To: Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Molina, Michael <molina.michael@epa.gov>; Carter, Brittany S. <carter.brittanys@epa.gov>; Pic, Jordan <pic.jordan@epa.gov>; Frye, Tony (Robert) <frye.robert@epa.gov>; Washam, Todd <Washam.Todd@epa.gov>; Brazauskas, Joseph <brazauskas.joseph@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Block, Molly <block.molly@epa.gov>; Walker, Mary <walker.mary@epa.gov>; Meadows, Carrie Vicenta <Meadows.CarrieVicenta@epa.gov>
Cc: Teresa, Tyler <Teresa.Tyler@epa.gov> Ex. 7(C), 7(F); Ex. 7(C), 7(F) Ex. 7(C), 7(F)
Subject: Re: Tentative Schedule - Mississippi

All,

Here is the initial invite list for Sunday's Dinner in Mississippi.

Mike McGrevey
Surya Gunasekara
Phil bryant
Joey songy
George Flaggs
Jeremy hirsch
Johnny Brunini
Bill Lampton
Lynn Fitch
David McRae
Deion sanders
Mayor Lumumba

Regards,
Owen Burgess

Sent from my iPhone

On Jan 5, 2021, at 6:09 PM, Burgess, Michael <Burgess.Michael@epa.gov> wrote:

All,

Please see the tentative schedule below. I will be receiving a list of attendees for Sunday's dinner by tomorrow and will forward it along.

Sunday, January 10th 2021

TBCpm (CDT) Administrator Wheeler tours Civil Rights Museum in Jackson, Mississippi

2:00pm Administrator Wheeler arrives for meeting with Governor Reeves + Lunch at Governor's Residence

4:00pm Administrator Wheeler tours the Capitol building in Jackson, Mississippi with Lt. Gov Hosemann (300 East Capitol Street)

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Gov. Reeves remarks 5 Minutes
RA Mary Walker remarks 5 Minutes
Q&A 10-15 Minutes

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11:00am Administrator Wheeler begin AG event at Nutrien Ag Solutions (6800 I-20, Bolton, MS 39041)

TBC Remarks

12:00pm Administrator Wheeler departs Bolton, MS for lunch in Jackson, MS

1:00pm Lunch

2:00pm Administrator Wheeler arrives at Airport

2:52pm Departure

Best,
Owen Burgess

Deputy Director of Logistics
U.S. Environmental Protection Agency
O: (202)-564-8599
C: (202)-816-1090

Sunday, January 10th 2021

9:00 am **Briefing on Pumps with Mary Walker**

10:00 am **Breakfast with MDEQ Director Chris Wells at Brent's Drugs in Fondron District**

12:00~~TBC~~pm (CDT) Administrator Wheeler guided tour ofs Civil Rights Museum in Jackson, Mississippi

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Administrator Wheeler remarks 10~~5~~ Minutes
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Senator Hyde-Smith remarks 5 Minutes
Gov. Reeves remarks 5 Minutes
~~RA Mary Walker remarks 5 Minutes~~
Q&A 10-15 Minutes

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1:00pm Lunch

2:00pm Administrator Wheeler arrives at Airport

2:52pm Departure

Message

From: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F639EA28AF4C455493939E3129260707-GUNASEKARA,]
Sent: 1/6/2021 11:38:00 PM
To: Meadowcroft, Micah [Meadowcroft.Micah@epa.gov]
CC: Barker, Kendal [Barker.Kendal@epa.gov]; Dziadosz, Patricia [Dziadosz.Patricia@epa.gov]; Garber, Kyle [Garber.Kyle@epa.gov]
Subject: Re: Questions and tomorrow

Micah,

Per our conversation, this sounds good. Please work with Kendal tomorrow to draft a note and ensure we have the most up-to-date email list. To your specific questions:
1. Yes- good to specify in the message.
2. I will send out the note to ADs as well.
3. That is correct for Abby.

Thank you and everyone stay safe.

Mandy
Sent from my iPhone

On Jan 6, 2021, at 3:18 PM, Meadowcroft, Micah <Meadowcroft.Micah@epa.gov> wrote:

Hi Mandy,

Barring there being a state of national emergency tomorrow or something, my understanding is resignation requests will need to be sent out. Kathryn Smith passed along the attached resignation letter template, which has apparently been approved by OGC, to guide people. That request will prompt Lance McCluney's team to send 1/20-dated SF-52s out to appointees, and the various offices to set up OneDrives for offboarding.

If that all sounds right, there are three things to clarify:
1. I think when we met on Monday you said that letters can be sent to the Administrator's public email, cc'ing you and myself. Since that is not included instructions in the attached template or in the OMS guidance, that should probably be specified in the body of the instruction/request email.
2. Kathryn and Dorothy wondered if, since the AD's serve directly at the discretion of the Administrator, a resignation request to ADs should come from his office rather than your office.
3. Related to ADs, since this would mean she was not to be included in such an email, is it true that Abigail Linsk, Ex. 6 will not be asked to resign? Just want to confirm what I've heard, and if so, note that the above won't apply to her so all involved are on the same page.

To those cc'ed: keep your chin up and don't let the news ruin your day.

Thank you,

Micah Meadowcroft

White House Liaison

U.S. Environmental Protection Agency
William Jefferson Clinton Building North, Room 2402A
1200 Pennsylvania Ave, NW
Washington, DC 20460
Office Phone: (202) 564-0015
Work Cell: (202) 768-4924

<Resignation Letter Template 2021.docx>