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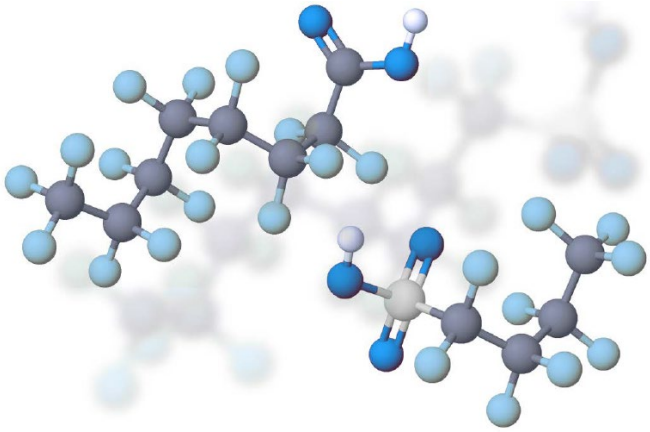
The EPA's January 2021 PFBS Toxicity Assessment Did Not Uphold the Agency's Commitments to Scientific Integrity and Information Quality

Report No. 23-E-0013 **March 7, 2023**



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Abbreviations:

EPA	U.S. Environmental Protection Agency
GenX	GenX Chemicals, the trade name for hexafluoropropylene oxide dimer acid and its ammonium salt*
OCSPP	Office of Chemical Safety and Pollution Prevention
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
PFAS	Per- and Polyfluoroalkyl Substances
PFBS	Perfluorobutane Sulfonic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonate
RfD	Oral Reference Dose

Cover Image: PFAS molecules depicted on the cover of the *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan*, dated February 2019. (EPA image)

***Disclaimer:** Use of product names in this document does not in any way constitute an endorsement by the EPA OIG.

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Office of Inspector General
U.S. Environmental Protection Agency
At a Glance

23-E-0013
March 7, 2023

The EPA's January 2021 PFBS Toxicity Assessment Did Not Uphold the Agency's Commitments to Scientific Integrity and Information Quality

Why We Did This Evaluation

The U.S. Environmental Protection Agency Office of Inspector General conducted this evaluation to determine whether the EPA followed applicable policies and procedures to develop and publish the January 19, 2021 perfluorobutane sulfonic acid toxicity assessment. Two weeks after publication, the EPA removed the toxicity assessment from its website, citing political interference and *Scientific Integrity Policy* violations. The EPA republished the toxicity assessment in April 2021.

The EPA's *Scientific Integrity Policy*, established in 2012, states that science is the backbone of the EPA's decision-making and that the Agency depends on the integrity of its science to protect human health and the environment. All EPA employees—including scientists, managers, and political appointees—must follow the *Scientific Integrity Policy*.

This evaluation supports an EPA mission-related effort:

- *Operating efficiently and effectively.*

This evaluation addresses a top EPA management challenge:

- *Safeguarding scientific integrity.*

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What We Found

The EPA's actions left the public vulnerable to potential negative impacts on human health.

The EPA did not follow the typical intra-agency review and clearance process during the development and publication of the January 2021 perfluorobutane sulfonic acid, or PFBS, toxicity assessment. During final clearance, a political appointee directed that a last-minute review be conducted of the uncertainty factors used to calculate toxicity values, resulting in a scientific disagreement that caused delay, confusion, and significant changes to the near-final, peer-reviewed work product. These changes included replacing single toxicity values with unprecedented toxicity ranges. Users of the PFBS toxicity assessment—for example, regulated entities cleaning up PFBS contamination—could have selected a less stringent value within this range, which may have been less costly but also less protective of human health. While EPA staff expressed scientific integrity concerns about the last-minute review and risks to public health, the EPA lacked policies and procedures to address these concerns. Without updates to policies and procedures, the Agency cannot fulfill its commitment to scientific integrity and information quality.

Recommendations and Planned Agency Corrective Actions

We make a total of five recommendations in this report:

- Three to the assistant administrator for Research and Development to reduce procedural confusion and strengthen existing policies, procedures, and guidance by clarifying if and when comments expressing scientific disagreement can be expressed; making clear if and when toxicity ranges are acceptable; and using the OIG as a resource for high-profile scientific integrity concerns that relate to political interference or that assert risk to human health or the environment.
- One to the assistant administrator for Mission Support to update policies and procedures on environmental information quality to require additional quality assurance reviews for EPA products.
- One to the deputy administrator to strengthen the EPA's culture of scientific integrity, transparency, and accountability of political leadership actions when changes occur as a result of policy decisions.

The EPA disagreed with all five recommendations, which remain unresolved.

Noteworthy Achievement

In fiscal year 2022, the Scientific Integrity Program and the OIG increased the frequency of their meetings from quarterly to every two weeks to facilitate timely communication of scientific integrity issues and discuss appropriate action.

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

THE INSPECTOR GENERAL

March 7, 2023

MEMORANDUM

SUBJECT: The EPA's January 2021 PFBS Toxicity Assessment Did Not Uphold the Agency's Commitments to Scientific Integrity and Information Quality
Report No. 23-E-0013

FROM: Sean W. O'Donnell

TO: Janet McCabe, Deputy Administrator
Office of the Administrator

Dr. Chris Frey, Assistant Administrator and EPA Science Advisor
Office of Research and Development

Kimberly Patrick, Principal Deputy Assistant Administrator
Office of Mission Support

This is our report on the subject evaluation conducted by the U.S. Environmental Protection Agency Office of Inspector General. The project number for this evaluation was OSRE-FY21-0207. 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 Office of Research and Development, the Office of Mission Support, and the Office of the Administrator are responsible for the issues discussed in this report. Also, the Office of Pollution Prevention and Toxics, within the Office of Chemical Safety and Pollution Prevention, contributed to the development of the perfluorobutane sulfonic acid toxicity assessment.

Action Required

This report contains unresolved recommendations. EPA Manual 2750 requires that recommendations be resolved promptly. Therefore, we request that the EPA provide us within 60 days its responses concerning specific actions in process or alternative corrective actions proposed on the recommendations. Your response 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. The Inspector General Act of 1978, as amended, requires that we report in our semiannual reports to Congress on each audit or evaluation report for which we receive no Agency response within 60 calendar days.

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 Office of Inspector General initiated this evaluation to determine whether the EPA followed applicable policies and procedures in the development and publication of the January 19, 2021 perfluorobutane sulfonic acid, or PFBS, toxicity assessment.

Top Management Challenge Addressed

This evaluation addresses the following top management challenge for the Agency, as identified in the OIG's *EPA's Fiscal Year 2023 Top Management Challenges* report, issued October 28, 2022:

- Safeguarding scientific integrity.

Background

The Characteristics of PFBS

PFBS is one of thousands of per- and polyfluoroalkyl substances, or PFAS, which are known as "forever chemicals." PFAS are a group of manufactured chemicals, some of which have been used since the 1940s. Many are chemically and thermally stable and demonstrate resistance to heat, water, and oil. PFAS can be found in almost every U.S. home and business and are widely used in commercial and consumer products, such as stain- and water-resistant coatings and food packaging. Their desirable chemical properties have also made PFAS useful in a variety of industries, including the firefighting, construction, aerospace, electronics, semiconductor, and automotive industries.

The same desirable properties that make PFAS useful in consumer products and industrial processes, however, make these chemicals slow to break down, which means that they can accumulate over time in people, animals, and the environment. The Agency for Toxic Substances and Disease Registry states that "most people in the United States have been exposed to PFAS and have PFAS in their blood." People are often exposed to PFAS in multiple ways, such as through consumer products, occupational exposure, and contaminated food or drinking water. Exposure to some PFAS above certain levels may increase the risk of adverse health effects, including abnormal fetal development, cancer, liver damage, immune effects, thyroid effects, and cholesterol changes.

As there are hundreds of PFAS with chemical structures of various sizes and lengths, conducting a comprehensive analysis of PFAS has been a challenge for scientists at all levels of government. To date, the most widely studied PFAS are long-chain perfluorooctanoic acid, or PFOA, and perfluorooctane sulfonate, or PFOS.[1] However, these two PFAS have been phased out by short-chain chemicals that are generally less bioaccumulative and

Bioaccumulation is the process by which chemicals are taken up by a plant or animal, either directly from exposure to a contaminated medium—such as soil, sediment, and water—or indirectly from ingestion of food containing the chemical.

[1] PFOA and PFOS have eight carbon atoms in their chemical structure and are considered "long chain."

potentially less toxic.[2] PFOS has been replaced by PFBS, a short-chain PFAS chemical used in the manufacture of paints, cleaning agents, and water- and stain-repellent products and coatings. PFOA has been replaced by GenX chemicals.[3]

Although newer PFAS alternatives, such as PFBS and GenX, may be less bioaccumulative and less toxic, the potential danger of these chemicals is a continuing concern for federal, state, tribal, and community partners. For example, PFBS has been detected in surface water, wastewater, and drinking water, and animal toxicity studies have shown that oral PFBS exposure affects development and causes adverse health effects on the thyroid, reproductive organs and tissues, liver, lipids, lipoproteins, and kidneys.

The EPA's Action Plan for the PFBS Toxicity Assessment

According to the EPA, it is leading the national effort to understand PFAS and reduce PFAS risks to the public. The Agency issued its *Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* in February 2019. This *PFAS Action Plan* included four significant PFAS management actions, including the near-term action of "developing toxicity values … for GenX chemicals and perfluorobutane sulfonic acid (PFBS)."[4] This evaluation focused on the development of PFBS toxicity values, also referred to as oral reference doses, or RfDs. An RfD is an estimate of how much of a chemical that the human population, including sensitive subgroups, can be exposed to without an appreciable risk of adverse effects throughout either an entire lifetime, known as chronic RfD, or a period less than a lifetime, known as subchronic RfD. The EPA develops RfDs via a toxicity assessment process. EPA program offices, regulated entities, and states use RfDs in relevant exposure scenarios to assess potential health risks and to determine whether and when it is appropriate to take action to address a chemical. For example, the EPA's Office of Land and Emergency Management uses RfDs to inform specific cleanup levels of PFBS at contaminated sites.

A ***toxicity assessment*** is part of the EPA's established human health risk assessment process. It describes the potential health effects associated with a chemical and identifies the exposure levels at which health effects may occur.

The Center for Public Health and Environmental Assessment within the EPA's Office of Research and Development, or ORD, was tasked with developing the PFBS toxicity assessment, while the EPA's Office of Water developed the GenX toxicity assessment. As the originating offices, the ORD and the Office of Water developed draft toxicity assessments to increase stakeholders' understanding of the potential human health impacts of replacement PFAS chemicals and to facilitate hazard characterization and future risk management decisions. The February 2019 *PFAS Action Plan* stated that "assessments will undergo interagency consultation, public comment, and independent external peer-review prior to finalization."

In the February 2020 *EPA PFAS Action Plan: Program Update*, the EPA stated, "To develop these draft toxicity assessments, the Agency relied on the best available science, including input from independent peer reviewers." The final PFBS and GenX toxicity assessments were initially anticipated to be completed

[2] PFBS has four carbon atoms in its chemical structure and is considered "short chain." Another short-chain PFAS alternative, GenX, has six carbon atoms in its chemical structure.

[3] GenX is a trade name that includes two major chemicals associated with processing-aid technology—hexafluoropropylene oxide dimers and its ammonium salt.

[4] The other three significant PFAS management actions included in the February 2019 *PFAS Action Plan* were "[i]nitiating steps to evaluate the need for a maximum contaminant level (MCL) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS); [b]eginning the necessary steps to propose designating PFOA and PFOS as 'hazardous substances' through one of the available federal statutory mechanisms; [and] developing groundwater cleanup recommendations for PFOA and PFOS at contaminated sites."

by 2019, but in the February 2020 *Program Update*, the EPA said that it expected to finalize them in 2020. The EPA told us that it considered the PFBS toxicity assessment a "high profile" scientific assessment.

The following are applicable EPA processes and guidance related to the development and publication of the PFBS toxicity assessment, each of which are described in the subsections below:

- Toxicity assessment process.
- *Information Quality Guidelines* and Quality Program.
- Quality assurance project plan.
- *Peer Review Handbook.*
- *Scientific Integrity Policy* and guidance.

The EPA's Toxicity Assessment Process

The EPA develops RfDs via toxicity assessments that are part of the human health risk assessment process. One priority of the 2019 *PFAS Action Plan* was to use established risk assessment guidelines and methods to develop standard RfDs for PFBS and GenX chemicals. Figure 1 illustrates this four-step human health risk assessment process as it is described on the EPA's website. The development of the PFBS toxicity assessment encompassed the first two steps of the risk assessment process to identify hazards and assess dose response to derive RfDs.

Figure 1: The EPA's four-step human health risk assessment process*

Source: OIG analysis of the EPA's human health risk assessment process. (EPA OIG image)

* Gold boxes indicate the steps used to develop the PFBS toxicity assessment.

As shown in Figure 1, the first step of the risk assessment process is hazard identification, which involves determining whether exposure to a stressor can cause an increase in adverse health effects. For chemical stressors, including PFAS, this step examines the available scientific data and develops a "weight of evidence" to characterize the link between adverse health effects and the chemical agent. The second step of the risk assessment process is the dose-response assessment, which describes the relationship between the dose of the stressor and the severity of adverse health effects. These two steps of the risk assessment process provide qualitative and quantitative information for toxicity assessments that, along with exposure information and other important considerations, can be used to assess health risks to determine whether and when it is appropriate to take action to address the stressor chemical.

Because there is frequently a lack of dose-response data for humans, RfD calculations may include factors that account for variability and uncertainty in five areas, including possible differences between test animals and humans; variability within the human population; and gaps in the available data, referred to as database deficiency uncertainty factors, which are detailed in Table 1. The EPA's historical

practice in deriving RfDs is to assign one value—either 1, 3, or 10—to each of the five areas of uncertainty, then multiply all five uncertainty factors to produce the composite uncertainty for use in the RfD calculation. Uncertainty factors are applied in each area to make reference values more protective of human health to account for gaps in scientific knowledge. An uncertainty value of 1 represents thorough knowledge, while a value of 10 represents significant gaps in scientific knowledge.

Table 1: Uncertainty factors used to calculate RfDs

Factor	Description of uncertainty	Basic principle
UF_H	Human variability	Adjusts the point of departure for the difference between the average human and the most sensitive applicable subpopulation.
UF_A	Animal-to-human extrapolation	Adjusts the point of departure for the difference in sensitivity between animals and the average human when the point of departure is based on animal studies.
UF_S	Subchronic-to-chronic extrapolation	Adjusts for the possibility of identifying a lower point of departure for chronic toxicity when extrapolating from a study of shorter duration.
UF_L	Lowest observed adverse effect level-to-no observed adverse effect level extrapolation	Adjusts for uncertainty in the value of the point of departure as an estimate of the threshold for the onset of effects, if based on a lowest observed adverse effect level rather than a benchmark dose or a no observed adverse effect level.
UF_D	Database deficiencies	Adjusts for the possibility of identifying a lower point of departure (or more sensitive effect) if additional studies were available.

Note: The point of departure is the dose-response point that marks the beginning of a low-dose extrapolation, which is the process of extrapolating risk to lower doses.

Source: OIG summary of uncertainty factors. (EPA OIG table)

The EPA's Information Quality Guidelines and Quality Program

The EPA bases its risk assessment principles and practices, such as that for the PFBS toxicity assessment, on various Agency documents. One such document is the EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency,* dated October 2002. For the purposes of this report, we refer to this document as the *Information Quality Guidelines*. The EPA established the *Information Quality Guidelines* in response to guidelines issued by the Office of Management and Budget, or OMB, to ensure and maximize the quality of information that the EPA disseminates. The *Information Quality Guidelines* provides that:

> [M]ajor scientifically and technically based work products … related to Agency decisions should be peer-reviewed. Agency managers within Headquarters, Regions, laboratories, and field offices determine and are accountable for the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing … . For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice.

Because the Agency, its partners, and the public use the EPA's information to make decisions, the EPA must ensure that its information is accurate and credible. To do so, the EPA uses tools, such as its Quality Program, reviews by senior management, the peer review process, and its communications product review process. According to the ORD, it also integrates quality assurance review and management review within its clearance review process, in accordance with the *ORD Policies and Procedures Manual* Section 14.3, "ORD Clearance Policy and Procedures."

The EPA's chief information officer, who works within the Office of Mission Support and also serves as the deputy assistant administrator for Environmental Information, is responsible for the Agency's Quality Program. Requirements of the EPA's Quality Program are outlined in the *Environmental Information Quality Policy*, EPA CIO 2105.2, updated July 19, 2022. The Quality Program is implemented by the Enterprise Quality Management Division within the Office of Enterprise Information Programs, with partners and stakeholders across EPA regions, program offices, states, and tribes. EPA regions and program offices are required to develop quality management plans to describe how they will implement the Quality Program. In addition, all work performed must have procedures to ensure that project requirements are met; these procedures are referred to as quality assurance project plans.

The EPA's Quality Program

The Quality Program accomplishes the following:

- Provides oversight of and requirements for quality management activities at the Agency.
- Guides all environmental technology programs performed by or for the Agency.
- Provides the framework for planning, implementation, documenting, assessing, and reporting on work for required quality assurance and quality control activities.
- Ensures that the Agency's environmental decisions are supported by information of known and documented quality.

The Quality Assurance Project Plan

Both the *Environmental Information Quality Policy* and the *Information Quality Guidelines* require that environmental information projects have corresponding quality assurance project plans. Accordingly, the *Umbrella Quality Assurance Project Plan for NCEA PFAS Toxicity Assessments*, dated September 2019, supports the ORD management and scientists who conduct PFAS assessments, including the PFBS toxicity assessment.[5] The PFAS *Umbrella Quality Assurance Project Plan* includes information about the sources and types of data that the ORD's Center for Public Health and Environmental Assessment gathers and uses, including the quantity of data, data quality objectives, standard assessment methods, and oversight activities. Oversight activities outlined in the PFAS *Umbrella Quality Assurance Project Plan* include quality assurance audits, quality assurance assessments, and technical system audits and reviews to determine whether the plan is being implemented as approved.

In addition to quality assurance oversight activities, the PFAS *Umbrella Quality Assurance Project Plan* outlines the following development process steps for the PFBS toxicity assessment, which are standard steps for the ORD's PFAS toxicity assessments:

- **Draft development:** The draft assessments will be developed beginning with a systematic review of the scientific literature, which includes evidence evaluation, synthesis, and integration, as well as development of toxicity values, pending the availability of data.
- **Intra-agency review:** The draft assessments will be reviewed by representatives from the EPA's program and regional offices and may be revised based on the comments received.
- **Interagency review:** The draft assessments will be reviewed by representatives from other federal agencies and the Executive Office of the President and may be revised based on the comments received. (The second interagency review for the PFBS toxicity assessment was conducted by the PFAS Technical Working Group. The working group was led by the OMB, which is located within the Executive Office of the President.)

[5] NCEA stands for the National Center for Environmental Assessment. As part of an ORD reorganization in late 2019, the National Center for Environmental Assessment combined with other ORD labs and centers to form the Center for Public Health and Environmental Assessment.

- **Public comment and external peer review:** The draft assessments will be released for public comment and external peer review. The EPA will announce the availability of the draft assessments and draft peer review charge questions for review, as well as the duration of the public comment period. The EPA may host a public meeting during this time. The draft assessments may be revised based on the comments received, and the EPA will prepare responses to major peer review comments.
- **Final assessment:** The final assessments will be made publicly available.[6]

Additional EPA technical documents related to the development, review, and finalization of PFAS assessments include but are not limited to the following materials:

- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*, dated 1994.
- *A Review of the Reference Dose and Reference Concentration Processes*, dated 2002.

The EPA's Peer Review Handbook

The EPA's *Peer Review Handbook* is guidance to reinforce open, transparent, and objective peer review of Agency products and to disseminate scientific products based on sound, credible information. The EPA's *Peer Review Handbook*, dated October 2015 (fourth edition), was developed to provide guidance to EPA staff and managers who are planning and conducting peer reviews. According to the *Peer Review Handbook*, "Peer review of all scientific and technical information that is intended to inform or support Agency decisions is encouraged and expected," which generally would include influential risk assessments. Peer review by experts who have not contributed to the development of a scientific or technical work product helps ensure that Agency positions are based on sound, credible information. The *Peer Review Handbook* also states that influential scientific and technical work products generally undergo internal peer review within the EPA, as well as external peer review.

The *Peer Review Handbook* additionally notes that the *Information Quality Guidelines* provide guidance for "ensuring that the information the Agency disseminates to the public is reliable and accurate, appropriate for its intended use, and protected from compromise." The *Peer Review Handbook* clarifies that, because Agency products that undergo peer review are considered "dynamic documents and are subject to change," a product undergoing external peer review would be considered a "predissemination product," not information that is publicly disseminated. As noted in the *Peer Review Handbook*, once the peer review process is complete, the Agency can publicly disseminate the product as provided in the *Information Quality Guidelines*.

The EPA's Scientific Integrity Policy and Guidance

The EPA relies upon adherence to the principles set forth in its *Scientific Integrity Policy* to conduct toxicity assessments that are based on sound science. The EPA's *Scientific Integrity Policy*, established in 2012, states that science is the backbone of the EPA's decision-making. The Agency depends on the integrity of its science to uphold its mission to protect human health and the environment. Every EPA employee, including scientists, managers, and political appointees, must follow the *Scientific Integrity*

[6] Predissemination review procedures are followed and documented in accordance with the *ORD Policies and Procedures Manual*, Section 14.3, "ORD Clearance and Policy Procedures."

Policy when engaging in or influencing scientific activities, communicating information about Agency scientific activities, and using scientific information in decision-making. All EPA employees are also expected to report any breach of the policy.

The *Scientific Integrity Policy* identifies specific actions and assurances that support a culture of scientific integrity, including that:

- Political appointees or other Agency leadership are prohibited from suppressing, altering, or impeding the timely release of scientific findings or conclusions.
- The Agency must follow its information quality, quality assurance, and peer review policies and procedures to produce scientific products of the highest quality to inform policy decisions.
- Scientific product reviews conducted by Agency leadership should be focused on scientific quality considerations and whether results were presented impartially.
- Managers and other Agency leadership are prohibited from intimidating or coercing scientists to alter scientific data, findings, or professional opinions.
- Policy-makers shall not knowingly misrepresent, exaggerate, or downplay areas of scientific uncertainty associated with policy decisions.

The Agency's Scientific Integrity Program developed the following guidance documents to assist EPA offices in upholding scientific integrity:

- *Approaches for Expressing and Resolving Differing Scientific Opinions*, dated October 8, 2020, which describes avenues staff can take to work through disagreements in scientific opinion. For the purposes of this report, we refer to this as the *Differing Scientific Opinions* guidance.[7]
- *Best Practices for Designating Authorship*, dated July 2016, which provides a common understanding for the way the Agency is to attribute individuals or groups to EPA work products.
- *Best Practices for Clearance of Scientific Products at EPA*, dated 2018, which provides consistent guidance for the Agency to use when developing or reviewing its predissemination review procedures.

The *Scientific Integrity Policy* highlights the Agency's commitment to transparency. Andrew Wheeler, the EPA administrator during the initial development of the PFBS toxicity assessment, stated:

> The mission of EPA is to protect human health and the environment. We exist to serve the public. As such, the public should trust our work. We are committed to earning and maintaining the public's trust through transparency and accountability in our actions and civility and fairness in our public participation processes.

[7] The Agency's definition of guidance per *Guidance for Quality Assurance Project Plans*, dated December 2002, is "[a] suggested practice that is not mandatory, intended as an aid or example in complying with a standard or specification." We interpret the Agency's definition of guidance to include the *Approaches for Expressing and Resolving Differing Scientific Opinions.*

In accordance with the *Scientific Integrity Policy*, the scientific integrity official is responsible for championing scientific integrity throughout the Agency and chairs the EPA's Scientific Integrity Committee, which is responsible for:

- Addressing *Scientific Integrity Policy* concerns.
- Promoting compliance with the policy, including safeguarding against any alteration or manipulation of scientific data by managers or other Agency leadership.
- Implementing mechanisms to ensure accountability for any such alterations and manipulation.

The scientific integrity official is part of the ORD's Office of Science Advisor, Policy, and Engagement. Deputy scientific integrity officials represent each EPA program office and region and serve as members of the Scientific Integrity Committee.

According to the *Scientific Integrity Annual Reports* for fiscal years 2018 and 2019, the Scientific Integrity Program drafted a new procedure in 2018 to separate concerns reported to the scientific integrity team into two categories: an advice track and an allegation track. According to the annual reports, the advice track was created as a preventative action to resolve concerns, with minimal senior-level organizational involvement, before they become allegations. In contrast, the allegation track comprises a more formal process, whereby the allegation is screened, an inquiry is conducted, and a determination is made. As of February 2023, that procedure had not been finalized.

Descriptions from the Fiscal Year 2019 *Scientific Integrity Annual Report*

***Advice*:** Informational, anonymous conversation to determine if a concern relates to scientific integrity. Advice does not include high-profile issues or threats to public health.

***Allegation*:** When advice does not resolve an issue, an individual may submit a written report of a potential violation of the *Scientific Integrity Policy*. The Scientific Integrity Program screens the report, gathers additional information, and recommends corrective action or other appropriate preventative measures.

Although the *Scientific Integrity Policy* addresses what procedures should be referred to in the event of scientific or research misconduct, which includes fabrication, falsification, and plagiarism, it does not outline procedures for addressing allegations or advice concerns that would not be considered scientific or research misconduct. According to the scientific integrity official, the EPA's standard process to address *Scientific Integrity Policy* advice inquiries is to:

- Listen and review information provided by the employee.
- Determine whether the issue violated the *Scientific Integrity Policy*.
- Refer the employee reporting the issue to available courses of action.

If the scientific integrity official's assistance does not resolve the issue, the EPA employee can submit a written allegation of a loss of scientific integrity to the scientific integrity official, a deputy scientific integrity official, or to the OIG.

Coordination with the OIG

Employees are responsible for promptly reporting indications of wrongdoing or irregularities to the OIG, including indications of abuse of authority, mismanagement, and misconduct. More specifically, EPA Manual 6500, *Functions and Activities of the Office of Inspector General: 1994 Edition*, states, "Each employee is responsible for promptly reporting indications of wrongdoing or irregularity to the OIG and

for cooperating and providing assistance during any auditor [sic] investigation." Additionally, the *Coordination Procedures between the Scientific Integrity Official and the Office of Inspector General regarding Research Misconduct Allegations*, published on March 30, 2015, outlines procedures, responsibilities, and communication between the OIG and the scientific integrity official that are initiated upon receipt of an allegation of research misconduct. Per the *Scientific Integrity Policy* and EPA Order 3120.5, *Policy and Procedures for Addressing Research Misconduct*, the EPA OIG is responsible for investigating most allegations of EPA-related scientific and research misconduct. Section 7 of the *Policy and Procedures for Addressing Research Misconduct* describes the circumstances under which anyone subject to its terms must immediately notify the OIG of a research misconduct allegation, such as when the allegation involves risk to public health or safety. In addition, the *Coordination Procedures* provide that the scientific integrity official will notify the OIG within seven calendar days of receipt of an allegation involving research misconduct.

Responsible Offices

The ORD's Center for Public Health and Environmental Assessment was the lead office for the PFBS toxicity assessment and authored the assessment through September 2020. From October 2020 through January 2021, the Office of Pollution Prevention and Toxics, or the OPPT, within the Office of Chemical Safety and Pollution Prevention, or the OCSPP, contributed to the PFBS toxicity assessment published in January 2021. The EPA's Scientific Integrity Committee, chaired by the scientific integrity official, is responsible for agencywide implementation of and compliance with the *Scientific Integrity Policy*. The Enterprise Quality Management Division, within the Office of Mission Support, is responsible for overseeing the EPA's Quality System to ensure that the EPA disseminates quality information.

Noteworthy Achievements

In fiscal year 2022, the Scientific Integrity Program and the OIG increased their meeting frequency from quarterly to every two weeks to facilitate timely communication of existing scientific integrity issues and to determine the appropriate office to act, if necessary. Additionally, the Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council, cochaired by the EPA's scientific integrity official, issued a report, *Protecting the Integrity of Government Science*, in January 2022 that is intended to assist federal departments and agencies in creating or updating scientific integrity policies and implementing effective practices.

Scope and Methodology

We conducted this evaluation from June 2021 to September 2022 in accordance with the *Quality Standards for Inspection and Evaluation* published in January 2012 by the Council of the Inspectors General on Integrity and Efficiency. Those standards require that we plan and perform the evaluation to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings, conclusions, and recommendations based on our review objective. We believe that the evidence obtained provides a reasonable basis for our findings, conclusions, and recommendations based on our review.

To address our objective and understand the Agency's decisions at the time of the January 2021 PFBS toxicity assessment development and publication, we reviewed emails and Microsoft Outlook calendars of staff and political appointees within the OCSPP, the ORD, the Office of Water, and the Office of the

Administrator. We also conducted interviews with current or former EPA personnel from the OPPT, the ORD, the Office of Water, the Office of Policy, and the Office of the Administrator. Through these activities, we established a timeline of events.

We reviewed policies, procedures, and guidance relevant to our objective, such as the EPA's *Scientific Integrity Policy*, *Differing Scientific Opinions* guidance*, Best Practices for Designating Authorship*, and *Information Quality Guidelines.* We also analyzed relevant portions of laws and regulations that pertain to human health risk assessments and scientific integrity at the Agency.

Scope Limitation

After the EPA published the January 2021 PFBS toxicity assessment, there was a transition in presidential administration, which changed the EPA's leadership. Most EPA personnel involved in decision-making for the January 2021 PFBS toxicity assessment were therefore no longer employed at the Agency during our evaluation. We requested interviews with eight former EPA officials and staff, but only two of those individuals agreed to be interviewed, which limited our access to information during this evaluation.

Prior Reports

There are no prior EPA OIG reports that specifically address EPA toxicity assessments, but the following reports provide insight into concerns related to scientific integrity and information quality:

- OIG Report No. 21-E-0146, *EPA Deviated from Typical Procedures in Its 2018 Dicamba Pesticide Registration Decision,* issued May 24, 2021.
- OIG Report No. 20-P-0200, *EPA Needs to Address Internal Control Deficiencies in the Agencywide Quality System*, issued June 22, 2020.
- OIG Report No. 20-P-0173, *Further Efforts Needed to Uphold Scientific Integrity Policy at EPA*, issued May 20, 2020. This report included the following two recommendations to the EPA science advisor, which had not yet been implemented as of February 2023:
    - Recommendation 7: "With the assistance of the Scientific Integrity Committee, finalize and release the procedures for addressing and resolving allegations of a violation of the Scientific Integrity Policy, and incorporate the procedures into scientific outreach and training materials." The Agency originally estimated that it would complete corrective actions to address this recommendation by April 30, 2020. As of March 2022, the Agency was estimating that it would complete its corrective actions by March 31, 2023.
    - Recommendation 8: "With the assistance of the Scientific Integrity Committee, develop and implement a process specifically to address and resolve allegations of Scientific Integrity Policy violation involving high-profile issues or senior officials, and specify when this process should be used." The Agency originally estimated that it would complete corrective actions to address this recommendation by June 30, 2021. As of March 2022, the Agency was estimating that it would complete its corrective actions by March 31, 2023.

Chapter 2
Changes to the PFBS Toxicity Assessment Resulted in Potentially Less-Protective Toxicity Ranges

Before it was published in January 2021, the PFBS toxicity assessment was changed from presenting single toxicity values to presenting potentially less-protective toxicity ranges because of a last-minute review by a single office outside of the normal intra-agency review process and an incomplete clearance process. During the ORD's final review and clearance of the PFBS toxicity assessment, which was initiated in September 2020, another EPA office rereviewed the assessment at the direction of a political appointee, resulting in a memorandum that expressed a scientific disagreement on the uncertainty factors used in calculating the RfDs. The office expressed this last-minute scientific disagreement after two rounds of intra-agency, interagency, and external peer review had already been conducted. Political appointees then used the last-minute scientific disagreement to create unprecedented RfD ranges that were not scientifically peer-reviewed, delaying the release of the toxicity assessment and weakening the EPA's commitments to scientific integrity and information quality.

The PFBS toxicity assessment published in January 2021 was effective for three weeks, from January 19, 2021, to February 9, 2021. While we do not have evidence that the public relied on this version of the PFBS toxicity assessment, it is possible that parties charged with cleaning up PFBS contamination could have selected less stringent value within the RfD range to implement less costly, but possibly insufficient, risk management actions. If such insufficient actions occurred, public health could have been adversely impacted.

Through October 2020, the PFBS Toxicity Assessment Was Developed and Reviewed According to the Development Process

Development of the PFBS toxicity assessment began in March 2018. The ORD led the PFBS toxicity assessment through several major review steps before finalizing and preparing it for publication.[8] For the purposes of this report, we refer to this version as the October 2020 PFBS toxicity assessment. The major review steps conducted during development of the October 2020 PFBS toxicity assessment were:

- First intra-agency review by EPA program and regional offices.
- First interagency review by other federal agencies.
- First external peer review.
- Public comment period.[9]
- Second external peer review.
- Second intra-agency review by EPA program and regional offices.
- Second interagency review, including by the OMB-led PFAS Technical Working Group.
- Technical and quality assurance review.

[8] The review steps in the ORD's development process for toxicity assessments were done in accordance with the EPA's *February 2019 PFAS Action Plan* and the *PFAS Quality Assurance Project Plan*.
[9] After the public comment period, the EPA revised the PFBS toxicity assessment to address comments before conducting the second round of peer, intra-agency, and interagency reviews.

On October 6, 2020, the October 2020 PFBS toxicity assessment was submitted to the ORD's deputy assistant administrator for predissemination review as part of the ORD's final routine clearance process before publication, in accordance with the *ORD Clearance Policy and Procedures*. The anticipated publication date of this version was October 30, 2020.

The October 2020 PFBS toxicity assessment was altered, as described below, and delayed for nearly three months until January 19, 2021. For the purposes of this report, we refer to this altered version as the January 2021 PFBS toxicity assessment.

The OPPT's Last-Minute Review Created Confusion and Influenced Significant Changes to the PFBS Toxicity Assessment

Publication of the PFBS toxicity assessment was delayed because of a last-minute third review, which focused on uncertainty factors, and which was conducted by the OCSPP's OPPT after the ORD deputy assistant administrator shared the near-final draft assessment with the OCSPP deputy assistant administrator during the final clearance process. Specifically, on October 26, 2020, four days before the originally anticipated publication date, the OCSPP deputy assistant administrator—a political appointee who reports to the politically appointed OCCPP assistant administrator—intervened and directed that OPPT scientists rereview the October 2020 PFBS toxicity assessment. The last-minute rereview focused on the scientific rationale for the application of the uncertainty factors used for calculating the chronic and subchronic RfDs.[10]

In interviews, EPA scientists stated that this third, focused review of the PFBS toxicity assessment, directed at the last minute by a high-level political appointee, was not typical of the EPA's intra-agency review practices and the ORD's clearance process. During the first two intra-agency review periods for the October 2020 PFBS toxicity assessment, the OPPT reviewed the PFBS toxicity assessment but did not provide comments or express concerns about the uncertainty factors used. After its third review, however, the OPPT issued a memorandum on November 9, 2020, expressing a disagreement with the ORD's application of the database uncertainty factors for chronic and subchronic RfDs. In the October 2020 PFBS toxicity assessment, the ORD presented the highest database uncertainty factor of 10 for the chronic RfD and the medium database uncertainty factor value of 3 for subchronic RfD because of gaps in the available data regarding PFBS effects on thyroid hormone levels and a lack of neural development studies. In its November 2020 memorandum, the OPPT asserted a scientific disagreement and provided the rationale that it "does not view the lack of … studies as a limitation to the database" and that the application of greater database uncertainty factors was not warranted.

As a result of the OPPT's last-minute review, the following events occurred in the development and publication of the January 2021 PFBS toxicity assessment, which did not adhere to the planned development process for the toxicity assessment or to the EPA's commitment to information quality:

- **Because there was no procedure to consider comments after the intra-agency review period, the OPPT's last-minute third review delayed publication of the PFBS toxicity assessment and**

[10] The OCSPP deputy assistant administrator's direction for the OPPT scientists to rereview the PFBS toxicity assessment was similar to the direction given in late September 2020 for the GenX toxicity assessment, the other near-term deliverable under the *PFAS Action Plan*. The GenX toxicity assessment was not as far along as the PFBS toxicity assessment, however. The intra-agency review for GenX resulted in an October 2, 2020 memorandum from the OPPT that expressed disagreement regarding database uncertainty factors used in the calculation of the RfDs.

created uncertainty about the applicability of the EPA's *Differing Scientific Opinions* guidance. Both the ORD and the OPPT scientists we interviewed agreed that the request by a political appointee to rereview the October 2020 PFBS toxicity assessment occurred late in the development process. This last-minute review led to the November 2020 OPPT memorandum, which in turn contributed to the delayed release of scientific information and created confusion about the path forward.

- **A scientific disagreement regarding database uncertainty factors used in calculating the RfDs resulted in an unprecedented presentation of RfD ranges.** Political appointees directed changes to portions of the October 2020 PFBS toxicity assessment by incorporating the OPPT's difference of opinion on the database uncertainty factors, thereby creating chronic and subchronic RfD ranges in the January 2021 PFBS toxicity assessment. The decision by political appointees to change portions of the assessment was not promptly communicated to the ORD scientists who developed the October 2020 PFBS toxicity assessment. Uncertainty factors and RfD values from the November 2020 OPPT memorandum, unlike the uncertainty factors and RfD values from the ORD scientists, were not scientifically peer reviewed. Although there was an OMB review of the January 2021 PFBS toxicity assessment as a "significant guidance document" pursuant to Executive Order 13891, *Promoting the Rule of Law Through Improved Agency Guidance Documents*, dated October 9, 2019, this review was not part of the prior OMB-led PFAS Technical Working Group that reviewed the prior October 2020 toxicity assessment.
- **The EPA's commitment to information quality was not upheld.** The required technical, quality assurance, and peer reviews were conducted for the October 2020 PFBS toxicity assessment. However, the January 2021 PFBS toxicity assessment incorporated the values expressed in the OPPT's scientific disagreement, in addition to the ORD's peer reviewed values. This resulted in chronic and subchronic RfD ranges that did not undergo technical and quality assurance review with respect to the OPPT's uncertainty factors and RfD values.

Ultimately, under a new administration that began on January 20, 2021, the EPA issued a press release on February 9, 2021, indicating that "EPA career scientists … made an initial determination that conclusions posted in the PFBS Toxicity Assessment … were compromised by political interference as well as infringement of authorship and the scientific independence of the authors' conclusions. This constitutes a violation of the agency's Scientific Integrity Policy." As of February 2023, political interference was not defined in EPA policies and procedures. As we note in Chapter 1 of this report, how to address and resolve allegations of *Scientific Integrity Policy* violations remains unclear in the absence of processes and procedures.[11] In April 2021, the new administration revised and republished the PFBS toxicity assessment. For the purposes of this report, we refer to this version as the April 2021 PFBS toxicity assessment.

Unaddressed concerns relating to scientific integrity that were raised during development and prior to publication of the January 2021 PFBS toxicity assessment are presented in Chapter 3.

Appendix A provides a timeline of key events during the development and publication of the PFBS toxicity assessment.

[11] Developing such processes and procedures are unresolved recommendations from OIG Report No. 20-P-0173, *Further Efforts Needed to Uphold Scientific Integrity Policy at EPA*, issued May 20, 2020.

The Last-Minute Review Created Confusion About the Applicability of the New Differing Scientific Opinions Guidance

Because the OPPT's unexpected, politically directed review and resulting November 2020 memorandum expressing scientific disagreement came at such a late stage in the development of the PFBS toxicity assessment, the memorandum derailed the process and created confusion about the path forward. Absent policies, procedures, or guidance, it was unclear how EPA career staff should proceed with a scientific disagreement expressed by a single office outside of the normal intra-agency review period and during the final clearance of the PFBS toxicity assessment.

On October 6, 2020, as part of the ORD's clearance process, the ORD deputy assistant administrator began final review of the October 2020 PFBS toxicity assessment. This review was not completed, however, because the ORD deputy assistant administrator had unaddressed technical concerns and was aware of the OCSPP deputy assistant administrator's October 26, 2020 request that OPPT scientists rereview the uncertainty factors. Although the *ORD Clearance Policy and Procedures* do not expressly prohibit additional comments from being provided by other offices during the clearance process, these events impeded the timely release of the PFBS toxicity assessment. To support a culture of scientific integrity within the Agency, the EPA's *Scientific Integrity Policy* prohibits all EPA employees, including Agency leadership, "from suppressing, altering, or otherwise impeding the timely release of scientific findings or conclusions."

The ORD and the OPPT scientists we interviewed agreed that the OCSPP deputy assistant administrator's request for the PFBS toxicity assessment to be rereviewed, which resulted in the OPPT's November 2020 memorandum, was unprecedented and late in the PFBS toxicity assessment development process. Up to this point, the ORD-led assessment had undergone two rounds of intra-agency, interagency, and external peer review in addition to technical and quality assurance reviews in accordance with the EPA's *February 2019 PFAS Action Plan* and the *PFAS Quality Assurance Project Plan*. However, ORD and OPPT career management—in other words, management that was not politically appointed—had opposing views on whether the OPPT's November 2020 memorandum should be considered a differing scientific opinion or political interference. The OPPT considered its November 2020 memorandum as being a differing scientific opinion, which stated "OPPT disagrees with the application of a 3-fold and a 10-fold factor for [database uncertainty factor] for the subchronic and chronic reference doses, respectively. … OPPT would recommend applying a factor of 1 and 3 for the subchronic and chronic [database uncertainty factor] values, respectively." In contrast, the ORD viewed the OPPT's November 2020 memorandum as political interference, but it did not inform the OIG that such political interference had occurred.

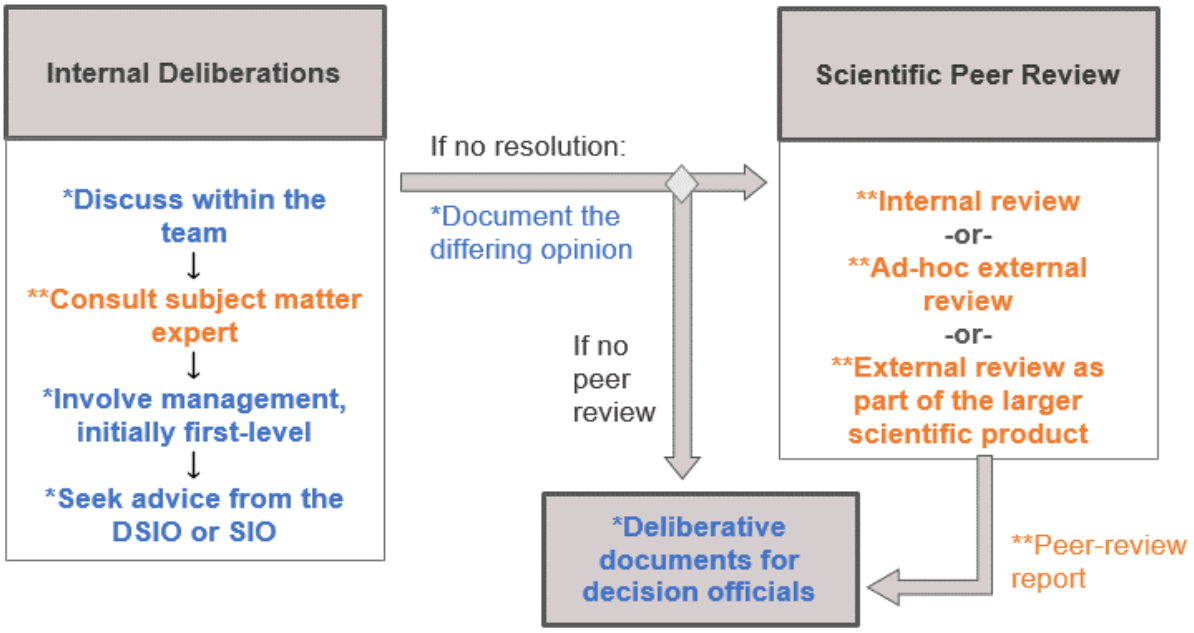
Opposing views between ORD and OPPT career staff highlight that there is no clear policy or procedure to follow when a last-minute review occurs, nor is there a policy or procedure that states whether additional comments can be considered if they are received during the final clearance process. For example, the *Peer Review Handbook* states, "Comments from formally conducted internal EPA peer reviews should be documented and included in the peer review record. This process does not substitute for Agency clearance. Informal input from EPA colleagues and input from Agency personnel helping to develop the work product need not be included." In addition, the *ORD Clearance Policy and Procedure* states, "The peer review process utilized should follow, at a minimum, the procedures documented in the EPA *Peer Review Handbook. …* Peer review should be complete, including resolution of the reviewers' comments, prior to initiating clearance of the final product." Neither the *Peer Review Handbook* nor the *ORD Clearance Policy and Procedure*, however, specifies whether additional

comments or informal input from EPA colleagues may be accepted during the clearance process and how to proceed if there are additional comments during the clearance process.

Some Steps of the *Differing Scientific Opinions* Guidance Were Followed

The *Differing Scientific Opinions* guidance states, "Although differing opinions ordinarily would arise within a team developing a scientific product, there may be other subject-matter experts at EPA whose advice would improve the scientific quality of the product." We determined that some of the steps presented in the *Differing Scientific Opinions* guidance were followed as a path toward resolving the OPPT's comments expressing scientific disagreement. Figure 2 details this path.

Figure 2: Path toward resolution of differing scientific opinions



Notes: DSIO = Deputy Scientific Integrity Official; SIO = Scientific Integrity Official.

Source: OIG adaptation of the EPA's *Approaches for Expressing and Resolving Differing Scientific Opinions*. (EPA OIG graphic)

* Blue = Recommended or optional steps that occurred for the PFBS toxicity assessment.
** Orange = Recommended or optional steps that did not occur for the PFBS toxicity assessment.

For example, on November 18, 2020, the ORD and the OPPT scientists held a meeting to resolve the disagreement about the application of database uncertainty factors. This meeting was outside the normal intra-agency review process but appeared to follow the path toward resolution as described in the EPA's *Differing Scientific Opinions* guidance. Based on the PFAS planned development process and guidance, the ORD scientists did not agree with the OCSPP's suggestion of less-protective uncertainty factors and did not want to revise the ORD-developed, peer-reviewed October 2020 PFBS toxicity assessment. However, the two offices did not come to a resolution.

Per the *Differing Scientific Opinions* guidance, if the discussions between the disagreeing offices do not yield an agreement, the next steps would be to consult impartial subject-matter experts, involve management, and seek advice from the scientific integrity official. If there is still no resolution, the deputy scientific integrity officials and the scientific integrity official can assist the team in determining

which path to take, whether it be conducting internal or external peer reviews or providing deliberative documents to the deciding officials. For the PFBS toxicity assessment, the ORD deputy scientific integrity official was included in discussions, however, the scientific integrity official was not invited to or involved in discussions and was not consulted about the applicability of the *Differing Scientific Opinions* guidance.

In the absence of a resolution through internal deliberation, on December 17, 2020, the EPA administrator and political appointees from the Office of the Administrator, the ORD, the OCSPP, and the Office of Water met to discuss a path forward to resolve the scientific disagreement between the ORD and the OPPT. Rather than proceeding with a scientific peer review, as outlined in Figure 2, the OPPT's November 2020 memorandum was presented directly to the decision-makers for their consideration. The OCSPP deputy assistant administrator proposed to include both the OPPT's suggested database uncertainty factors from the November 2020 memorandum and the ORD's original database uncertainty factors, thereby creating ranges for the chronic and subchronic RfDs. The EPA administrator at the time decided to accept the OCSPP's proposed approach. According to a meeting debrief between the OCSPP political appointees who attended the meeting and the OPPT scientists who did not attend the meeting, the EPA administrator indicated that the selection of the database uncertainty factors was a policy decision and not subject to additional peer review.

The *Differing Scientific Opinions* guidance does not establish a right to peer review and also states, "If the scientific product or a subsequent decision is time-sensitive or if other circumstances warrant, these approaches may be expedited or otherwise adapted, ideally in consultation with management." However, there are no policies, procedures, or guidance that specify whether and under which circumstances comments asserting scientific disagreement can be provided for a scientific product that has already undergone all the reviews set forth in the applicable action or project plans.

The OPPT's Last-Minute Scientific Disagreement Resulted in an Unprecedented Presentation of RfD Ranges that Were Not Promptly Communicated to Originating Authors

The RfD ranges published in the January 2021 toxicity assessment deviated from the EPA's historical practice of presenting single RfDs in toxicity assessments. When performing toxicity assessments, EPA scientists use technical documents, such as *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* and *A Review of the Reference Dose and Reference Concentration Processes*, to derive chronic and subchronic RfD values. As discussed in Chapter 1, the ORD's scientific approach when deriving RfDs is to consider five areas of uncertainty, one of which is the database uncertainty factor, and to assign a single value of 1, 3, or 10 depending on the level of uncertainty. An uncertainty factor of 1 represents thorough knowledge, while a factor of 10 represents significant gaps in scientific knowledge.

In its calculation of RfDs for the October 2020 PFBS toxicity assessment, the ORD selected a database uncertainty factor of 10 for the chronic RfD value and a factor of 3 for the subchronic RfD value because of the uncertain PFBS effects on thyroid hormone levels and the lack of neural development studies. These single database uncertainty factor values for the chronic and subchronic RfDs had been through two rounds of intra-agency, interagency, and external peer reviews, as well as a quality assurance review, before the OPPT's November 2020 memorandum expressing disagreement with the ORD's application of the database uncertainty factors. In its November 2020 memorandum, the OPPT suggested a database uncertainty factor of 3, rather than 10, for the chronic RfD value and a database uncertainty factor of 1,

rather than 3, for the subchronic RfD value. Unlike the ORD's database uncertainty factors, the OPPT's suggested database uncertainty factors had not undergone peer review.

Following the December 17, 2020 meeting and with agreement from the EPA administrator, the OCSPP deputy assistant administrator directed the OPPT staff to create a "redline mark-up" version of the October 2020 PFBS toxicity assessment that included the OPPT's proposed RfD values along with the ORD's peer-reviewed RfD values, thus creating chronic and subchronic RfD ranges.

Although the EPA's human health risk assessment guidance does not prohibit presenting RfD values as ranges, scientists across the OCSPP, the ORD, and the Office of Water told us that they had never seen two database uncertainty factors used to create an RfD range. An ORD scientist described an RfD range as illogical because it suggests that all the values within the range are "protective," which is contrary to the EPA scientists' responsibility to identify the most protective data point of concern and then develop an RfD value from it. Former senior EPA career officials expressed concern that a range would create challenges for EPA program offices, the regulated community, and states that use the RfDs to address and clean up PFBS contamination. Additionally, some ORD scientists told us that publication of RfD ranges, rather than single values, created confusion and uncertainty among users. For example, because the PFBS toxicity assessment looked different than past toxicity assessments published by the ORD, some EPA regional offices requested clarification regarding which value in the range to use.

Political appointees who attended the December 17, 2020 decision meeting did not communicate the decision to change single RfD values to RfD ranges to the ORD staff who developed the assessment or to the ORD principal deputy assistant administrator, who also served as the EPA science advisor. On January 6, 2021, several weeks after the EPA administrator decided to revise the October 2020 PFBS toxicity assessment, the OPPT shared this "redline mark-up" version with the ORD originating authors. In addition, on the same day, the OCSPP assistant administrator called the ORD principal deputy assistant administrator with questions about the changes. These communications were the first time the ORD staff were made aware of the changes, even though the ORD was the lead office developing the PFBS toxicity assessment. The EPA's *Differing Scientific Opinions* guidance states that "policy makers are encouraged to communicate final decisions and their basis back to the team and anyone who has formally expressed a differing scientific opinion on that particular matter." Because the guidance encourages, rather than requires, such communication, scientific changes could—and in this case, were—made without the originating authors being notified. Without a requirement to communicate decisions regarding the resolution of differing scientific opinions, there could be future incidents of changes made to scientific information without promptly informing the scientists who completed the work.

Although the January 2021 PFBS toxicity assessment was only effective for three weeks, from January 19, 2021, to February 9, 2021, companies and businesses responsible for risk management actions, such as PFBS cleanups, could have benefitted by choosing the less-protective end of the range. In other words, using the higher RfD value could result in cheaper cleanup costs and risk management actions that are less protective of human health.

Significant Changes Did Not Undergo Additional Scientific Peer Review

On January 7, 2021, the ORD principal deputy assistant administrator told the senior advisor to the EPA administrator that the PFBS toxicity assessment's significant proposed changes in the "redline mark-up" version—specifically, the OPPT's proposed lower database uncertainty factors in the RfD ranges—would require another round of intra-agency, interagency, and external peer reviews, per the planned development process. Per the EPA's *Peer Review Handbook*, modifications of existing, adequately

peer-reviewed scientific products that significantly depart from the situations for which they were originally designed may require additional peer review. According to interviews with ORD and OPPT officials, the "redline mark-up" changes were then accepted by someone in the Office of the Administrator rather than the ORD, the lead office developing the PFBS toxicity assessment. This version of the toxicity assessment was published in January 2021, with only the lower chronic and subchronic RfD values of these ranges having been peer reviewed.

EPA CIO 2105.2, *Environmental Information Quality Policy*, requires that all environmental information projects have a prepared quality assurance project plan that describes the "requirements and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance and acceptance criteria." In accordance with the *Environmental Information Quality Policy*, the *Umbrella Quality Assurance Project Plan* for the PFBS toxicity assessment provided for internal and external peer reviews to take place. As such, in accordance with the *Umbrella Quality Assurance Project Plan*, the original ORD-developed October 2020 toxicity assessment went through an interagency scientific peer review from June 1 to September 22, 2020, by the OMB-led PFAS Technical Working Group, as noted in the timeline of key events in Appendix A. However, an additional scientific peer review was not performed on the significant changes made in the January 2021 PFBS toxicity assessment because of the previous administration's desire to issue the PFBS toxicity assessment before the change in administration.

ORD and OPPT officials who we interviewed stated that altering the PFBS toxicity assessment by incorporating changes that were not peer reviewed violated the *Scientific Integrity Policy* which states that political appointees or other Agency leadership are prohibited from altering scientific findings or conclusions. Before the January 2021 PFBS toxicity assessment was published, the OPPT official contacted an ORD official about these concerns. We detail these concerns in Chapter 3. EPA officials did not inform the OIG of potential political interference at the time the events occurred, nor did the Scientific Integrity Program consider there to be a formal allegation of a *Scientific Integrity Policy* violation. As we note in Chapter 1, the EPA has yet to finalize corrective actions to address a previous OIG recommendation that it develop and implement a process specifically to address and resolve allegations of *Scientific Integrity Policy* violations involving high-profile issues or senior officials.

On January 8, 2021, the OMB Office of Information and Regulatory Affairs administrator issued a memorandum to the EPA administrator that classified the PFBS toxicity assessment as a "significant guidance document" pursuant to Executive Order 13891 and, therefore, subject to OMB review as set forth in Executive Order 12866, *Regulatory Planning and Review*, dated September 30, 1993. The ORD scientists, however, expressed concern with the new OMB review and stated their belief that the timing, nature, and content of the January 8, 2021 memorandum was highly irregular, as well as a departure from, and expansion of, how Executive Order 12866 had been implemented at the EPA.

Although Executive Order 12866 had not been applied to toxicity assessments in the past, the scope of Executive Order 12866 was expanded by Executive Order 13891, which applied more broadly to "significant guidance documents." The OMB review process, as provided in Executive Order 12866, includes ensuring that "decisions made by one agency do not conflict with the policies or actions taken or planned by another agency." While the OMB review process under Executive Order 12866 is limited to regulatory or rulemaking actions, Executive Order 13891 expanded the scope to include a broader

category of guidance documents.[12] Pursuant to the January 8, 2021 memorandum, the January 2021 PFBS toxicity assessment underwent a five-day interagency regulatory review from January 11 through 15, 2021, prior to publication on January 19, 2021. EPA scientists and Office of Policy staff were concerned that the executive order review mechanism did not allow for the rigorous interagency scientific review that occurred during the previous OMB-led PFAS Technical Working Group review.

The January 2021 PFBS Toxicity Assessment Did Not Attribute Individual Authors

Authors and reviewers of EPA health assessments have historically been acknowledged in scientific documents disseminated for public use; however, the January 2021 PFBS toxicity assessment broke precedent by not attributing authors or reviewers. In contrast, the October 2020 PFBS toxicity assessment, which was ready for publication, and the April 2021 PFBS toxicity assessment attributed the authors and the reviewers.

Attributing individual authorship is an element of public transparency because it identifies who is responsible for the information and conclusions presented in EPA products, as well as how these products were developed. Lack of individual authorship for EPA scientific products diminishes public confidence in the scientific integrity of the product because it is not clear who at the Agency assumes responsibility. As stated in the EPA's *Best Practices for Designating Authorship*, the EPA "is committed to transparency in its interactions with the public."

In addition, the EPA's *Scientific Integrity Policy* states that EPA employees are expected to "appropriately characterize, convey, and acknowledge the intellectual contributions of others." The EPA's *Best Practices for Clearance of Scientific Products at EPA* and *Scientific Integrity Policy* also state that there is an expectation for EPA scientists and managers to review the scientific content of a proposed Agency document that is based on their scientific activities before public release. The *Best Practices for Designating Authorship* also states that "at least one author, usually the primary author, should take responsibility for the integrity of the work product as a whole from inception to publication."

The contributing ORD scientists did not agree to be attributed as authors because the qualitative and quantitative changes made to the October 2020 PFBS toxicity assessment did not undergo another round of intra-agency, interagency, and external peer reviews. These changes included the addition of the OPPT's lower database uncertainty factors to create the RfD range. Multiple ORD and OPPT scientists were opposed to presenting chronic and subchronic RfD ranges because that approach broke historic precedent. Additionally, an OPPT scientist who conducted the third focused review did not want to be attributed as an author to avoid media criticism on a high-profile product. As a result, there was no individual attribution of authorship or acknowledgement of contributors in the January 2021 PFBS toxicity assessment; instead, the EPA was cited as the general author.

According to the EPA's *Best Practices for Designating Authorship,* failure to attribute individuals who meet the criteria for authorship is known as ghost authorship, which can be used to "purposefully obfuscate the involvement of an individual or institution in a work product." However, while *Best Practices for Designating Authorship* describes authorship criteria and EPA employee responsibilities for authorship, these are best practices, not requirements. It is not required for EPA scientists to be attributed on published scientific work products, but the *Best Practices for Designating Authorship*

[12] Executive Order 13891 was revoked on January 20, 2021, by Executive Order 13992, and the OMB's January 8, 2021 memorandum was rescinded by the OMB's Office of Information and Regulatory Affairs acting administrator on June 17, 2021.

outlines practices for doing so. The events that took place resulted in scientists not wanting attribution in the final work product. This obfuscated the involvement of individuals in the final work product.

The EPA Did Not Uphold Its Commitment to Information Quality

In accordance with the ORD's predissemination review procedures as prescribed in the *ORD Clearance Policy and Procedures* and *Umbrella Quality Assurance Project Plan*, the October 2020 PFBS toxicity assessment underwent quality assurance review on September 18, 2020. The EPA documented this review in the ORD's Scientific and Technical Information Clearance System,[13] which serves as the ORD's electronic clearance system. However, the October 2020 PFBS toxicity assessment was significantly changed to produce the January 2021 PFBS toxicity assessment, which included the OPPT's determination of database uncertainty factors used to calculate the RfD ranges. According to the ORD, its technical, management, and quality assurance personnel were not made aware that the scientific product had significantly changed after the OPPT's last-minute, third review of the October 2020 PFBS toxicity assessment. The ORD also stated that the January 2021 toxicity assessment did not undergo technical, peer, and quality assurance reviews to provide assurance that the information disseminated was consistent with the EPA's *Information Quality Guidelines*.

Per the *Information Quality Guidelines*, the EPA is dedicated to the dissemination of high-quality information and has established policy and procedural guidance to ensure the objectivity, integrity, and reliability of information. The EPA's *Scientific Integrity Policy* "requires adherence to applicable Agency information quality, quality assurance, and peer review policies and procedures, ensuring that the Agency produces scientific products of the highest quality, rigor, and objectivity for use in policy decisions."

There is no requirement that technical or quality assurance personnel be notified of substantive changes to documents that have been previously reviewed to determine the need for additional review. In addition, after technical and quality assurance reviews are completed and documented in the ORD's Scientific and Technical Information Clearance System, there is no notification system that would alert the quality assurance manager of revisions to a product.

In the absence of technical, management, and quality assurance reviews of the January 2021 PFBS toxicity assessment, the EPA did not uphold its commitment to disseminating high-quality, accurate, and credible information. According to the EPA's *Peer Review Handbook*, quality assurance and peer review are "complementary activities" but are also distinct. As stated in the *Peer Review Handbook,* peer review "focuses on the scientific soundness of the results and conclusions" whereas quality assurance is focused on "determining precision, accuracy, representativeness, comparability, completeness and sensitivity of the data." Without a requirement to notify technical and quality assurance personnel of substantive changes, and without a procedure to ensure that documents are reviewed after significant changes are made, the EPA risks losing public confidence in the research and development of its scientific and technical products.

As outlined in Chapter 1, EPA program offices are required to develop, implement, and maintain the Quality Program, including evaluating information using the *Information Quality Guidelines.* Each program office is also responsible for incorporating information quality principles into their predissemination review procedures. The ORD integrates technical and quality assurance reviews within

[13] The Scientific and Technical Information Clearance System is an electronic clearance system used in the review and approval process of the ORD's scientific and technical products. It allows managers to track products and provides an electronic record.

its clearance, or predissemination, review process. According to the ORD, it is updating its clearance procedures to state that major changes to a product after reviews are conducted or after the clearance process is completed will be subject to an additional full clearance review, including reviews by technical staff, the quality assurance manager, and other appropriate management. The ORD said that these additional reviews will be documented in the Scientific and Technical Information Clearance System. The EPA's Quality Program could be strengthened by implementing a similar update to the EPA's policies and procedures on environmental information quality.

Conclusions

The EPA did not follow the typical intra-agency review and clearance process during development and publication of the January 2021 PFBS toxicity assessment. A focused review of the PFBS toxicity assessment, directed at the last minute by a political appointee, created procedural confusion and influenced significant changes to the scientifically peer-reviewed product. Although there were no formal allegations of *Scientific Integrity Policy* violations prior to publication of the PFBS toxicity assessment on January 19, 2021, the assessment included potentially less-protective RfD ranges, which was unprecedented and created nondefinitive chronic and subchronic health toxicity values. Users of the January 2021 PFBS toxicity assessment, including parties responsible for cleaning up PFBS contamination, could have selected a less-stringent value within the range to implement less costly and potentially less-protective risk management actions. Updating policies, procedures, and technical documents will help restore public trust in the EPA's decision-making and ensure that the EPA disseminates sound, high-quality scientific documents.

Recommendations

We recommend that the assistant administrator for Research and Development:

1. Develop or update existing policies, procedures, or guidance to specify whether and under which applicable circumstances comments expressing scientific disagreement can be provided for a scientific product that has undergone all peer reviews and required developmental steps set forth in applicable actions or project plans.

2. Develop or update existing policies, procedures, or technical documents to specify whether reference dose ranges are acceptable in toxicity assessments. If acceptable, specify circumstances under which reference dose ranges may be applied.

We recommend that the assistant administrator for Mission Support:

3. Update EPA policies and procedures on environmental information quality to require additional quality assurance reviews for EPA products that undergo major changes to scientific results or conclusions after quality assurance reviews have been completed.

We recommend that the deputy administrator:

4. Develop or update existing policies, procedures, or guidance to require policy-makers and decision officials to uphold transparency through timely, formal communication of decisions and the scientific bases to change results or conclusions of a scientific product to originating authors in the absence of peer review.

Agency Response and OIG Assessment

Appendix B includes the Agency's November 2, 2022 response to our draft report. The ORD and the OPPT also provided technical comments, which we considered and applied as appropriate.

The EPA did not agree with our recommendations and said that we mischaracterized the events surrounding the changes made to the scientific conclusions presented in the October 2020 PFBS toxicity assessment as deviations from Agency processes rather than violations of the EPA's *Scientific Integrity Policy*. Further, the EPA stated that political interference was the underlying cause of the cascading sequence of events. We note that the Agency determined in its February 9, 2021 press release that the January 2021 toxicity assessment was compromised by political interference, which constituted a violation of the *Scientific Integrity Policy*. As the policy prohibits alteration of scientific findings and conclusions, we agree that a scientific integrity violation occurred when the "redline markup" changes were accepted by someone in the Office of the Administrator at the time. We further note, however, that this report describes the findings from our evaluation of policies and procedures, not an investigation into potential misconduct.

The Agency's benefit of hindsight in attributing all breakdowns to political interference obscures the fact that our recommendations, when considered collectively, seek to improve the efficiency and effectiveness in the EPA's scientific integrity and information quality programs. We note in our report that political interference is not defined in EPA policies and procedures. As we finalized this report, *A Framework for Federal Scientific Integrity Policy and Practice* was released in January 2023 by the National Science and Technology Council, which is within the Executive Office of the President. This framework defines interference and political interference.

Specifically, the EPA did not agree with Recommendations 1 and 2, which were formerly Recommendations 1a and 1b in our draft report, stating that "political interference that coerces scientists and alters scientific results and conclusions of a peer reviewed document, while delaying publication, is not a form of 'differing scientific opinion' – it is a violation of EPA's Scientific Integrity Policy." While the *Scientific Integrity Policy* prohibits Agency leadership "from intimidating or coercing scientists to alter scientific data, findings, or professional opinions," we found no evidence that intimidation or coercion took place in the OCSPP deputy assistant administrator's directive for the OPPT scientists to rereview the October 2020 PFBS toxicity assessment. We also found no evidence that the EPA OPPT scientists were coerced to produce their position that the application of greater database uncertainty factors was not warranted. We take allegations of coercion seriously, but the EPA did not provide us with any additional evidence to demonstrate that coercion took place.

The intent of Recommendation 1 is to strengthen the ORD's existing policies, procedures, and guidance to clarify whether and when comments asserting scientific disagreement can be expressed. We modified the recommendation to state "comments expressing scientific disagreement." The intent of Recommendation 2 is to make clear whether and when reference dose ranges are acceptable. These recommendations should reduce procedural confusion in the future. Recommendations 1 and 2 remain unresolved.

In addition, the EPA did not agree with Recommendation 3, which was formerly Recommendation 2 in our draft report, stating:

> The premise of this recommendation implies that there is or could be some degree of legitimacy to political interference that leads to major changes to scientific results or conclusions after a quality assurance review was already completed. Altering scientific results or conclusions without the authors' consent—as was the case in the PFBS toxicity assessment—is a violation of EPA's *Scientific Integrity Policy*.

In response to the ORD's technical comments regarding quality assurance reviews, we clarified related sections of our report to indicate that technical and quality assurance reviews were conducted for the October 2020 PFBS toxicity assessment in accordance with the *ORD Clearance Policy and Procedures*. In addition, we updated the report to clarify our main finding related to information quality. The personnel responsible for technical and quality assurance activities, who ultimately ensure that the quality assurance project plan is being carried out as intended, should be notified when significant changes occur. During our evaluation, the ORD said that it was updating its clearance procedures to state that major changes to a product after reviews were conducted or after the clearance process is completed will be subject to an additional full clearance review, including reviews by technical staff, the quality assurance manager, and other appropriate management. Recommendation 3 remains unresolved.

In response to Recommendation 4, which was formerly Recommendation 3 in our draft report, the EPA stated:

> The premise of this recommendation is not only that policy makers and decision officials may change results or conclusions of a scientific product, but also that transparency in notifying the originating authors of such a change makes it acceptable. Furthermore, altering scientific results or conclusions without the authors' consent, based on coercion of other scientists who were not authors to support a political appointee preference for a different scientific approach and finding—as was the case in the PFBS toxicity assessment—is a violation of EPA's Scientific Integrity Policy.

In consideration of the EPA's November 2022 technical comments, we clarified the sections of the report relating to authorship, differing scientific opinions, and changes to the October 2020 PFBS toxicity assessment as being at the direction of political appointees. We noted in Chapter 2 that the then-EPA administrator considered the revision, including the selection of the database uncertainty factors, to be a policy decision and not subject to additional peer review. The intent of Recommendation 4 is to strengthen the EPA's culture of scientific integrity, transparency, and accountability of political leadership actions when changes occur in the name of policy. In acknowledgement of the Agency's response, we also noted in Chapter 3 that there were concerns expressed about scientific integrity but that there were no allegations of a violation of the *Scientific Integrity Policy* relating to altering scientific findings or conclusions prior to the publication of the January 2021 PFBS toxicity assessment. Recommendation 4 remains unresolved.

Chapter 3
The EPA's *Scientific Integrity Policy* Is Silent on Procedures to Address Concerns

EPA scientists and officials raised concerns about lapses in scientific integrity and public health related to the January 2021 PFBS toxicity assessment. The EPA's *Policy and Procedures for Addressing Research Misconduct* requires that certain matters involving fraud and research misconduct, which include falsification and fabrication, be immediately referred to the OIG, and the *Scientific Integrity Policy* requires that the scientific integrity official coordinate with the OIG on issues of scientific misconduct. However, neither the *Scientific Integrity Policy* nor the procedures address how concerns, including advice queries or allegations, that fall short of fraud or research misconduct should be addressed. Instead, the *Scientific Integrity Policy* states only that the Agency's Scientific Integrity Committee, which is chaired by the scientific integrity official, will address concerns relating to the *Scientific Integrity Policy*. As we note in Chapter 1, although the Agency drafted a procedure to outline how employees should submit both advice inquiries and allegations regarding scientific concerns, that procedure has not yet been finalized. In response to recommendations issued in OIG Report No. 20-P-0173, the Agency agreed to finalize this procedure by April 2020, as well as to develop and implement a process specifically to address allegations involving high-profile or senior officials by June 2021. As of February 2023, however, corrective actions to address these recommendations had not been completed. Further, while the *Scientific Integrity Annual Reports* for fiscal years 2018 and 2019 generally discuss how the advice and allegation process works, they do not provide a concrete procedure for addressing concerns about violations of the *Scientific Integrity Policy*.

Consistent with the expectations of the EPA's *Scientific Integrity Policy*, two Agency employees expressed scientific integrity concerns related to the January 2021 PFBS toxicity assessment:

- First, on January 11, 2021, an ORD scientist presented concerns to the scientific integrity official, citing an "assault on scientific integrity" and "an assessment that is not protective of human health."
- Second, on January 13, 2021, an OPPT official presented concerns to the ORD's principal deputy assistant administrator, who also served as the science advisor, about irregularities in how the EPA followed policies and procedures throughout the assessment process.

On November 11, 2020, two months before these employees expressed their concerns, there was an email exchange among ORD managers following the release of the OPPT's November 2020 memorandum. The ORD principal deputy assistant administrator asserted that this memorandum was "blatant political interference." As we note in Chapter 2, when "blatant political interference" was asserted, political interference was not defined in EPA policies and procedures. There was also no formal allegation of a *Scientific Integrity Policy* violation, nor is there evidence of contemporaneous action taken by ORD managers to involve the Agency's Scientific Integrity Committee or scientific integrity official to address this concern of political interference.

Although scientific integrity concerns were expressed before the January 2021 PFBS toxicity assessment was published on January 19, 2021, the *Scientific Integrity Policy* does not describe how to classify concerns, address such concerns, or determine which concerns must be treated as formal allegations.

According to the fiscal year 2019 *Scientific Integrity Annual Report*, concerns involving high-profile issues or threats to public health should not be considered in the advice lane. Despite the public health concern expressed by the ORD scientist, however, the scientific integrity official stated that the concern was submitted via the advice lane and that the employee did not want to submit a formal allegation. In addition, according to a scientific integrity official, after the scientific integrity official and the ORD principal deputy assistant administrator discussed the ORD scientist's concern, the ORD principal deputy assistant administrator assumed the lead for handling both concerns. This is contrary to the Scientific Integrity Committee's responsibility to address concerns relating to the *Scientific Integrity Policy*.

In the absence of a formal allegation or procedures to address scientific integrity concerns that assert risks to public health, the EPA did not address these scientific integrity concerns before publishing the January 2021 PFBS toxicity assessment. On February 9, 2021, the EPA removed the PFBS toxicity assessment from the Agency's website. According to an EPA press release dated that same day, EPA career scientists made an initial determination that the conclusions in the January 2021 toxicity assessment "were compromised by political interference as well as infringement of authorship and the scientific independence of the authors' conclusions." The press release further stated that, as a result, there was a violation of the *Scientific Integrity Policy* and the January 2021 PFBS toxicity assessment was being removed from the EPA website until the Agency could complete its review. When the EPA published its April 2021 PFBS toxicity assessment, it issued a corresponding press release on April 8, 2021, stating that the updated version:

> [H]as gone through appropriate reviews, includes input EPA received from external peer review, upholds the tenets of scientific integrity, was authored by expert career scientists in EPA's Office of Research and Development, and has not been compromised by political staff – these were all issues with a version of the assessment that was posted during the previous administration.

In addition, the scientific integrity concerns submitted by the two EPA staff in January 2021 were not relayed to the OIG before the first toxicity assessment was published on January 19, 2021, even though *Functions and Activities of the Office of Inspector General: 1994 Edition* broadly provides that all EPA employees should promptly report indications of wrongdoing to the OIG.[14] The advice inquiry submitted on January 11, 2021, asserted human health concerns, but the scientific integrity official said there was uncertainty about whether this concern fit the definition of research misconduct. The *Coordination Procedures* between the scientific integrity official and the OIG require the scientific integrity official to notify the OIG of allegations of research misconduct within seven days, and the *Policy and Procedures for Addressing Research Misconduct* requires that the OIG be notified immediately of any allegations of research misconduct involving public health or safety. Neither the *Coordination Procedures* nor the *Policy and Procedures for Addressing Research Misconduct*, however, addresses actions to be taken for concerns that relate to political interference or assert risks to public health or safety that are not considered research misconduct.

Conclusions

Without procedures to address advice inquiries and allegations related to scientific integrity, the *Scientific Integrity Policy* does not fully advance a culture of scientific integrity and may reduce

[14] The scientific integrity official informed the OIG of the employees' concerns on February 2, 2021, at a regularly scheduled coordination meeting.

employee confidence in the EPA's ability to effectively safeguard against alteration of scientific data by senior Agency leadership. Ineffectively addressing scientific integrity concerns relating to human health could also lower public confidence in the Agency's ability to sufficiently and effectively protect human health and the environment.

Recommendation

We recommend that the assistant administrator for Research and Development:

5. Update the EPA's *Scientific Integrity Policy* to require that the OIG be immediately notified of scientific integrity concerns, including advice queries and allegations, that relate to political interference or that assert risks to human health or the environment.

Agency Response and OIG Assessment

In response to Recommendation 5, which was formerly Recommendation 4 in our draft report, the EPA stated that it did not agree:

> The actions that resulted in changes to the scientific conclusions presented in the October 2020 PFBS toxicity assessment were a violation of the EPA's existing Scientific Integrity Policy. Additionally, everything that EPA does has potential impacts to human health or the environment, and these policies already apply to scientific concerns relating to potential impacts to human health or the environment. Therefore, this recommendation is unnecessary, and implementation of this recommendation will not provide reasonable assurance that future attempts at political interference in the development or use of agency science will not occur.

In consideration of the EPA's response and the ORD's technical comments, we modified our recommendation to require that the OIG be notified of scientific integrity concerns that are related to political interference or that assert risks to human health or the environment. We note in the report that political appointees took last-minute actions that impacted the January 2021 PFBS toxicity assessment. Our evaluation of these events underscores the need for the EPA to update the *Scientific Integrity Policy* so that the OIG is immediately notified of "blatant political interference," which in this case was asserted as early as November 11, 2020, and of requests for scientific integrity advice that involve risks to public health and safety, which in this case was requested as early as January 11, 2021. We also note that the Agency's process for handling these concerns, which is currently inconsistent, could be improved. The Agency, in its fiscal year 2019 *Scientific Integrity Annual Report*, stated that the scientific integrity official's advice lane does not include high-profile issues or threats to public health; however, this concern, which did allege a threat to public health, was handled via the advice lane. The intent of Recommendation 5 is to help strengthen the EPA's dedication to upholding a culture of scientific integrity and to use the OIG as an independent resource for high-profile scientific integrity concerns that relate to potential political interference or risks to human health and the environment. Recommendation 5 remains unresolved.

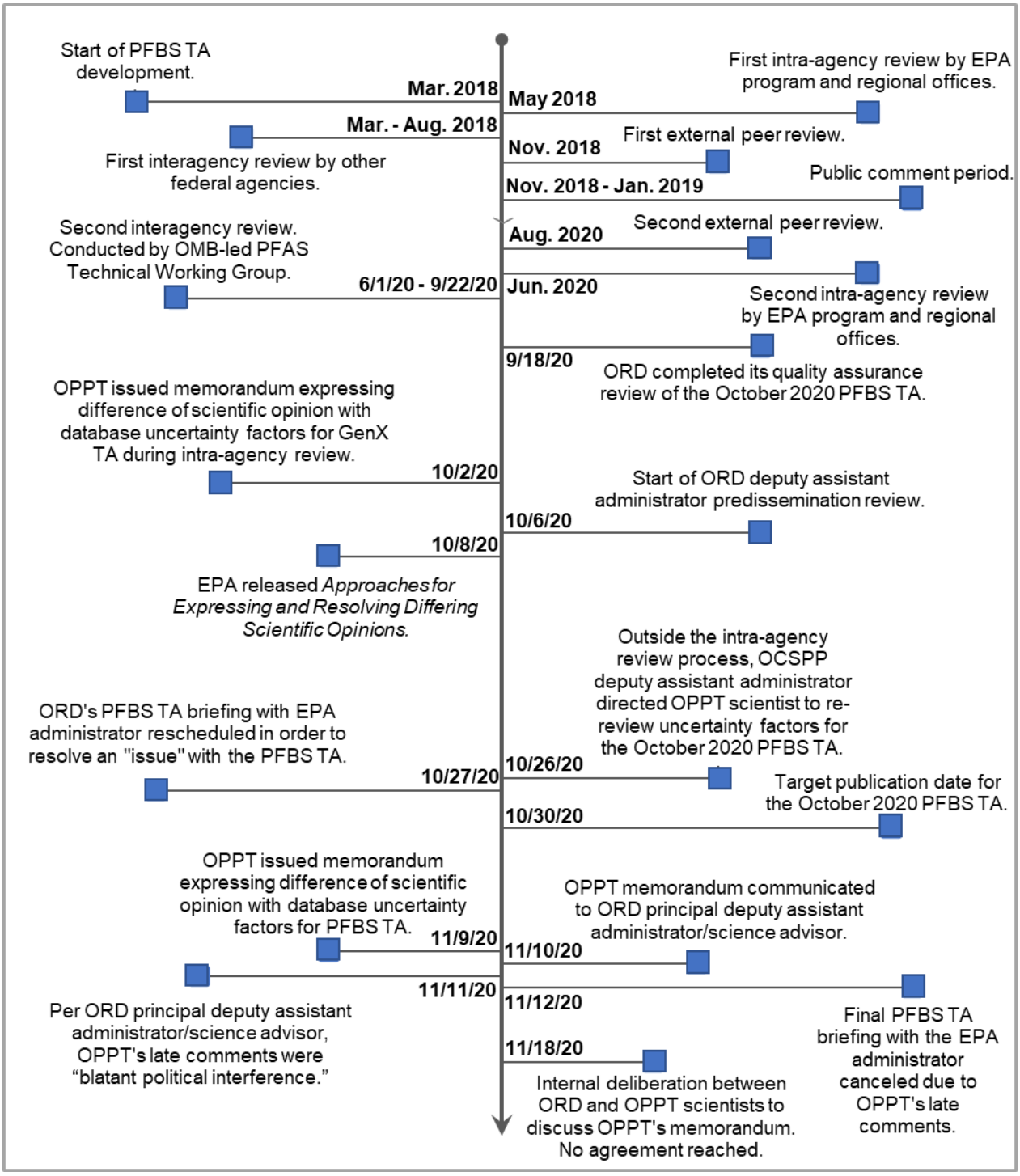
Status of Recommendations

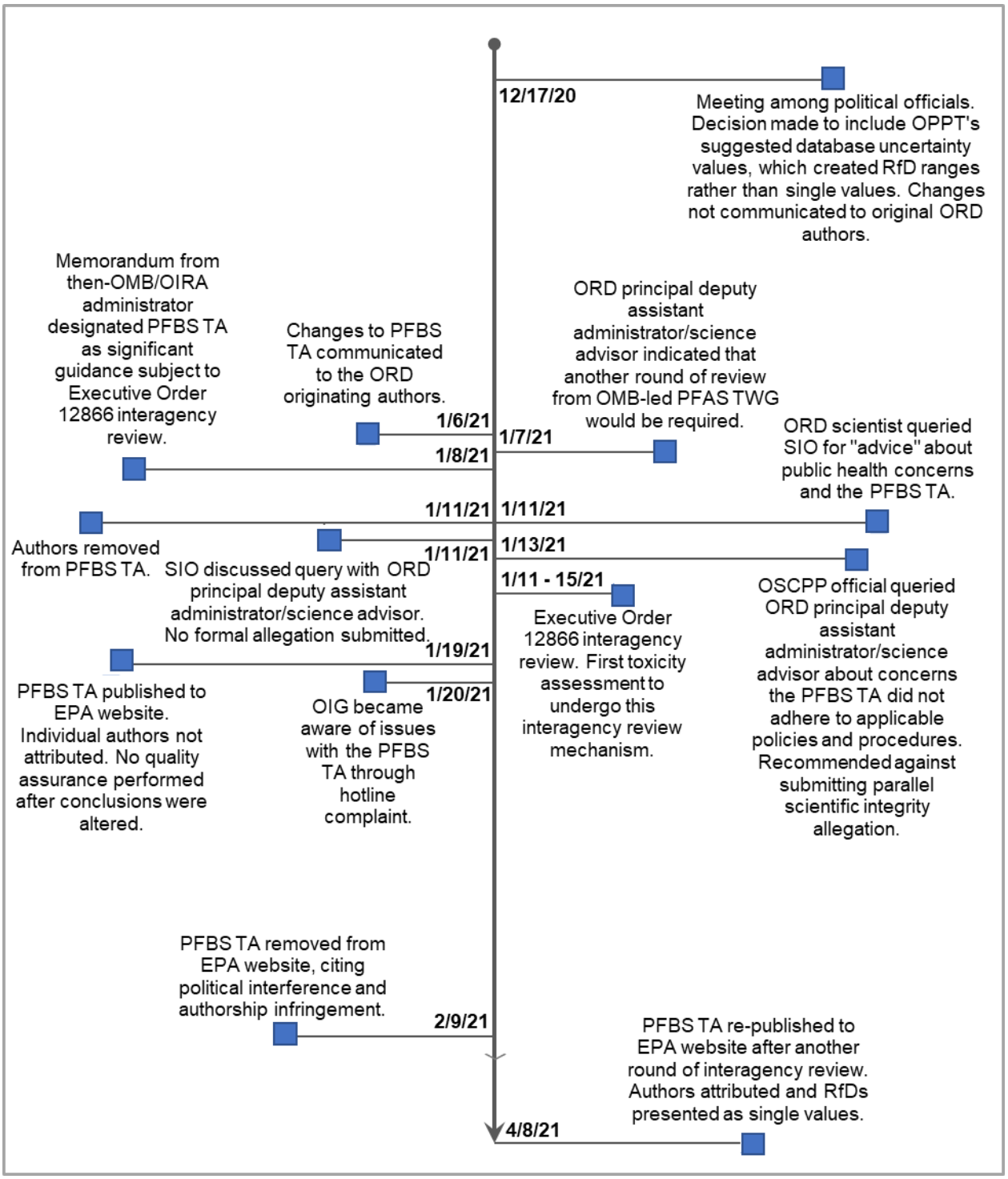
RECOMMENDATIONS					
Rec. No.	**Page No.**	**Subject**	**Status[1]**	**Action Official**	**Planned Completion Date**
1	21	Develop or update existing policies, procedures, or guidance to specify whether and under which applicable circumstances comments expressing scientific disagreement can be provided for a scientific product that has undergone all peer reviews and required developmental steps set forth in applicable actions or project plans.	U	Assistant Administrator for Research and Development	
2	21	Develop or update existing policies, procedures, or technical documents to specify whether reference dose ranges are acceptable in toxicity assessments. If acceptable, specify circumstances under which reference dose ranges may be applied.	U	Assistant Administrator for Research and Development	
3	21	Update EPA policies and procedures on environmental information quality to require additional quality assurance reviews for EPA products that undergo major changes to scientific results or conclusions after quality assurance reviews have been completed.	U	Assistant Administrator for Mission Support	
4	21	Develop or update existing policies, procedures, or guidance to require policy-makers and decision officials to uphold transparency through timely, formal communication of decisions and the scientific bases to change results or conclusions of a scientific product to originating authors in the absence of peer review.	U	Deputy Administrator	
5	26	Update the EPA's *Scientific Integrity Policy* to require that the OIG be immediately notified of scientific integrity concerns, including advice queries and allegations, that relate to political interference or that assert risks to human health or the environment.	U	Assistant Administrator for Research and Development	

[1] C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress

Appendix A

Timeline of Key Events in the Development and Publication of the PFBS Toxicity Assessment





Notes: OIRA = Office of Information and Regulatory Affairs; SIO = Scientific Integrity Official; TA = Toxicity Assessment; TWG = Technical Working Group.

Source: OIG summary of events. (EPA OIG image)

Agency Response to Draft Report

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

November 2, 2022

OFFICE OF
THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Response to Office of Inspector General (OIG) Draft Report, *The EPA's January 2021 PFBS Toxicity Assessment Did Not Uphold the Agency's Commitments to Scientific Integrity and Information Quality* (Project No. OSRE-FY21-0207), dated September 26, 2022

FROM: Dan Utech
Chief of Staff
Office of the Administrator

DAN UTECH Digitally signed by DAN UTECH Date: 2022.11.04 16:15:00 -04'00'

TO: Sean W. O'Donnell
Inspector General
Office of Inspector General

The Environmental Protection Agency (EPA) appreciates the opportunity to comment on the OIG's draft report titled, *The EPA's January 2021 PFBS Toxicity Assessment Did Not Uphold the Agency's Commitments to Scientific Integrity and Information Quality* (Project No. OSRE-FY21-0207).

Before I discuss the report recommendations, I want to express EPA's appreciation for the OIG's attention to this matter. Restoring and adhering to scientific integrity principles are important priorities for the Biden Administration and Administrator Regan. In this regard, the events of October 2020 clearly merit close scrutiny. EPA staff had several discussions with OIG staff regarding their findings and preliminary recommendations prior to the release of the draft report[1]. These meetings, however, did not result in a mutually agreeable path forward. On October 13, 2022, I had the opportunity to participate in the Exit Conference. It was clear to me from that session that EPA and the OIG are in strong agreement that EPA appointee interference in EPA's PFBS toxicity assessment that occurred in October 2020 was wrong, and that EPA

[1] ORD Senior Management met with the OIG on June 23 and July 18, 2022, to discuss concerns regarding the preliminary recommendations and findings.

should take steps to prevent similar actions in the future. However, EPA has subtle but important points of disagreement with the OIG's characterizations of the events of October 2020, and these points of disagreement lead EPA to disagree with the draft report's recommendations.

EPA's response to the draft report and recommendations, summarized below and included in the attached technical comments, is consistent with the concerns expressed by the Office of Research and Development (ORD) in a *notice of concern* memorandum sent to the OIG on July 29, 2022. EPA is hopeful that the OIG will address the agency's comments and avoid dispute resolution.

The OIG draft report characterizes actions that resulted in changes to the scientific conclusions presented in the October 2020 PFBS toxicity assessment as "deviations from established agency processes," rather than violations of EPA's Scientific Integrity Policy. We strongly believe that the appropriate characterization is the latter:

- Late in the stage of completion of the PFBS toxicity assessment, a high-level political appointee directed staff to have a third review; this direction was outside the normal review process, resulted in politically directed changes to scientific conclusions, and impeded the timely release of a scientific assessment. Such behavior is political interference in the development of agency science, which is a clear violation of EPA's Scientific Integrity Policy.
- Although the political interference that violated EPA's Scientific Integrity Policy set in motion a cascade of subsequent events, the root cause of the cascade of subsequent events was the violation of the agency's Scientific Integrity Policy.

The OIG recommendations diminish the severity of the actions taken by senior political appointees to alter the conclusions in the October 2020 PFBS toxicity assessment and misdirects the blame for these actions onto the agency and career staff. The proposed actions in the OIG recommendations would not have prevented, nor could prevent, political appointees, or career staff acting under the direction of such appointees, from intentionally circumventing well-established processes and procedures or violating existing agency policies and guidance. Therefore, EPA disagrees with the recommendations included in the draft report. EPA believes that effectively preventing political interference in the development and use of scientific information requires different actions, including actions that increase accountability and transparency when violations of EPA's Scientific Integrity Policy occur.

Responses to the Recommendations in the OIG Draft Report

Recommendation 1: Develop or update existing policies, procedures, and guidance to:

a. **Specify whether and under which applicable circumstances differing opinions can be expressed for a scientific product that has undergone all peer reviews and required developmental steps set forth in applicable actions or project plans.**
b. **Specify whether and under which applicable circumstances reference dose ranges are acceptable in human health risk assessments.**

EPA Response to Recommendation 1: EPA disagrees with this recommendation. Political interference that coerces scientists and alters scientific results and conclusions of a peer reviewed

document, while delaying publication, is not a form of "differing scientific opinion" – it is a violation of EPA's Scientific Integrity Policy.

Political interference that alters scientific results and conclusions presented in a peer-reviewed report authored by career scientists is not a form of a "differing scientific opinion." Political interference that introduces reference dose ranges, not consistent with existing policies, procedures, or guidance, or long-standing precedent and contradictory to the scientific choices of scientific authors, does not imply acceptability or legitimacy of the changes made. Thus, the interference is not an appropriate motivation to either update EPA's *Approaches for Expressing and Resolving Differing Scientific Opinions* or reconsider applicable dose-response policies, procedures, or guidelines. The implementation of this recommendation will not provide reasonable assurance that future attempts at political interference in the development or use of agency science will not occur, it may instead have the opposite effect of empowering an appointee to circumvent or change longstanding scientific process because such behavior was legitimized in the past.

Recommendation 2: Update EPA policies and procedures on environmental information quality to require additional quality assurance reviews for EPA products that undergo major changes to scientific results or conclusions after a quality assurance review was already completed.

EPA Response to Recommendation 2: EPA disagrees with this recommendation. The premise of this recommendation implies that there is or could be some degree of legitimacy to political interference that leads to major changes to scientific results or conclusions after a quality assurance review was already completed. Altering scientific results or conclusions without the authors' consent—as was the case in the PFBS toxicity assessment—is a violation of EPA's Scientific Integrity Policy. Further, this recommendation reflects a lack of understanding of the quality assurance review process. The implementation of this recommendation will not provide reasonable assurance that future attempts at political interference in the development or use of agency science will not occur.

Recommendation 3: Develop or update existing policies, procedures, and guidance to require policy makers and decision officials to uphold transparency through timely, formal communication of decisions to change results or conclusions of a scientific product to originating authors in the absence of peer review.

EPA Response to Recommendation 3: EPA disagrees with this recommendation. The premise of this recommendation is not only that policy makers and decision officials may change results or conclusions of a scientific product, but also that transparency in notifying the originating authors of such a change makes it acceptable. Furthermore, altering scientific results or conclusions without the authors' consent, based on coercion of other scientists who were not authors to support a political appointee preference for a different scientific approach and finding—as was the case in the PFBS toxicity assessment—is a violation of EPA's Scientific Integrity Policy. It is inappropriate, and contradictory to EPA's Scientific Integrity Policy, to base a recommendation on the premise that policy makers and decision officials may violate the policy. Furthermore, this recommendation appears to be based on a misinterpretation of the

agency's *Approaches for Expressing and Resolving Differing Scientific Opinions* document, which encourages policy makers to communicate how they accounted for differing scientific opinions in making a policy decision; it does not encourage communicating how a decision is made (in violation of EPA's Scientific Integrity Policy) to modify scientific conclusions or a completed scientific product outside of a normal process.

Recommendation 4: Update the EPA's *Scientific Integrity Policy* and EPA Order 3120.5, *Policy and Procedures for Addressing Research Misconduct,* to require specific actions to address scientific integrity concerns relating to potential impacts to human health or the environment.

EPA Response to Recommendation 4: EPA disagrees with this recommendation. The actions that resulted in changes to the scientific conclusions presented in the October 2020 PFBS toxicity assessment were a violation of the EPA's existing Scientific Integrity Policy. Additionally, everything that EPA does has potential impacts to human health or the environment, and these policies already apply to scientific concerns relating to potential impacts to human health or the environment. Therefore, this recommendation is unnecessary, and implementation of this recommendation will not provide reasonable assurance that future attempts at political interference in the development or use of agency science will not occur.

If the political appointees who coerce staff, alter an assessment, and delay an assessment are not held accountable, it is difficult to envision when future political appointees who may be inclined to violate EPA's Scientific Integrity Policy will be dissuaded. This is an important and potentially seminal OIG report. The underlying cause of the changes to the scientific conclusions was political interference. The evidence supports findings, conclusions, and recommendations that address this underlying cause of the cascading sequence of events. The political appointees who engaged in such interference should be held accountable, to restore public trust in the government.

When issuing the final report, we request the OIG to include our full response to the draft report, including the agency technical comments and the *notice of concern* memo submitted to Patrick Gilbride in July 2022. If you have any questions regarding this memo, please contact Kelly van Bronkhorst, Office of Research and Development, Office of Resource Management at 202-566-2907.

Attachment

cc: Patrick Gilbride, OIG
Morgan Collier, OIG
Alicia Buchanan, OIG
Paul Bergstrand, OIG
Erin Barnes-Weaver, OIG
H. Christopher Frey, ORD
Maureen Gwinn, ORD
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Michael Benton, AO
Marilyn Armstrong, OMS
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Susan Perkins, OCFO

Appendix C

Distribution

The Administrator
Deputy Administrator
Assistant Deputy Administrator
Chief of Staff, Office of the Administrator
Deputy Chief of Staff for Management, Office of the Administrator
Assistant Administrator for Chemical Safety and Pollution Prevention
Assistant Administrator for Mission Support
Assistant Administrator for Research and Development
Principal Deputy Assistant Administrator for Mission Support
Principal Deputy Assistant Administrator for Research and Development
Deputy Assistant Administrator for Chemical Safety and Pollution Prevention
Deputy Assistant Administrator for Pesticide Programs, Office of Chemical Safety and Pollution Prevention
Deputy Assistant Administrator for Management, Office of Chemical Safety and Pollution Prevention
Deputy Assistant Administrator for Mission Support
Agency Follow-Up Official (the CFO)
Agency Follow-Up Coordinator
General Counsel
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Director, Office of Continuous Improvement, Office of the Chief Financial Officer
Director, Office of Resources and Business Operations, Office of Mission Support
Audit Follow-Up Coordinator, Office of the Administrator
Senior Audit Advisor, Office of Chemical Safety and Pollution Prevention
Audit Follow-Up Coordinator, Office of Mission Support
Audit Follow-Up Coordinator, Office of Research and Development