



OFFICE OF INSPECTOR GENERAL U.S. ENVIRONMENTAL PROTECTION AGENCY

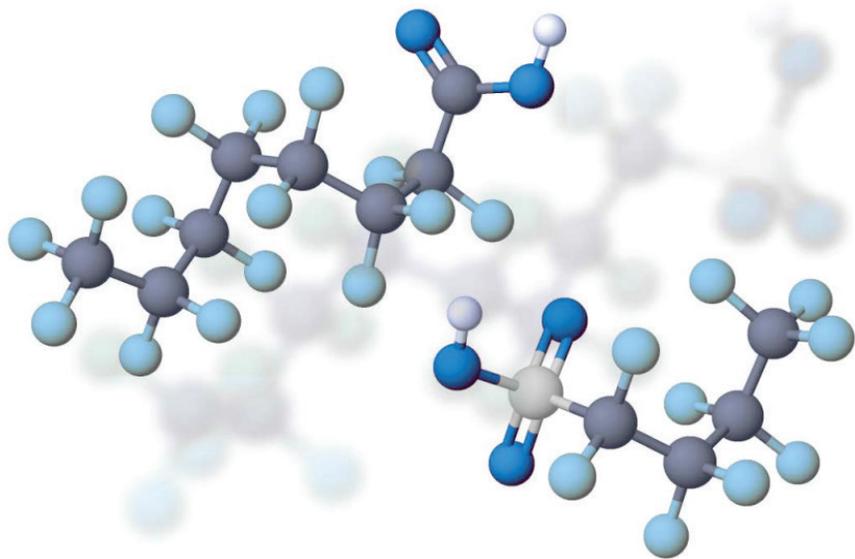
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*Congressionally Requested Report:
Ensuring the safety of chemicals*

The EPA Was Not Transparent About Changes Made to a Long-Chain PFAS Rule After Administrator Signature

Report No. 22-E-0052

July 7, 2022



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Abbreviations:	E.O.	Executive Order
	EPA	U.S. Environmental Protection Agency
	LCPFAC	Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances
	OCSP	Office of Chemical Safety and Pollution Prevention
	OIG	Office of Inspector General
	OIRA	Office of Information and Regulatory Affairs
	PFAS	Per- and Polyfluoroalkyl Substances
	SNUR	Significant New Use Rule

Cover Image: Visual representation of the chemical formulation of PFAS. (EPA image from the February 2019 *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan*)

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Office of Inspector General U.S. Environmental Protection Agency

At a Glance

22-E-0052
July 7, 2022

Why We Did This Evaluation

The U.S. Environmental Protection Agency's Office of Inspector General conducted this evaluation to determine the extent to which the EPA followed applicable policies, procedures, and guidance for the changes made to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule between the EPA administrator's signing of the final rule on June 22, 2020, and the publication of the final rule in the *Federal Register* on July 27, 2020. We initiated this evaluation based on a congressional request.

The substances in question are types of per- and polyfluoroalkyl substances, which are manufactured chemicals widely used in industry and consumer products. Some of these substances break down very slowly; build up in people, animals, and the environment; and may lead to adverse health outcomes. Significant New Use Rules require that the EPA be notified before regulated chemical substances are used in new ways that might cause environmental or human health concerns.

This evaluation supports an EPA mission-related effort:

- *Ensuring the safety of chemicals.*

This evaluation addresses a top EPA [management challenge](#):

- *Ensuring safe use of chemicals.*

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[List of OIG reports.](#)

The EPA Was Not Transparent About Changes Made to a Long-Chain PFAS Rule After Administrator Signature

What We Found

The EPA did not follow all applicable policies, procedures, and guidance when making changes to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances, or LCPFAC, Significant New Use Rule after the administrator signed it and before it was published in the *Federal Register*. Specifically:

Because the EPA did not follow docketing procedures, the public was not notified of the changes to the final LCPFAC Significant New Use Rule.

- Although the Agency identified changes made to the Significant New Use Rule in a postsignature change memorandum, which was signed by the administrator, as required by the EPA's *Changes to Rule Documents Prepared for the Administrator's Signature* procedures, the EPA did not docket that memorandum, as stipulated in the EPA's *Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers* guidance.
- Because the request for changes was communicated via telephone, we could not identify the origin of the requested changes and could not determine whether the EPA complied with the transparency provisions of Executive Order 12866, *Regulatory Planning and Review*.

By not following all docketing procedures, the EPA did not meet transparency expectations and risked compromising the public's trust in the rulemaking process. However, the Agency followed the Office of the Federal Register's *Document Drafting Handbook* guidance for requesting changes to the final rule.

Recommendations and Planned Agency Corrective Actions

We recommend that the assistant administrator for Chemical Safety and Pollution Prevention update the LCPFAC Significant New Use Rule docket by posting the postsignature change memorandum that outlines the changes made to the final rule after the administrator signed it but before it was published in the *Federal Register*. We also make two recommendations to the associate administrator for Policy, which include updating the applicable policies, procedures, and guidance regarding making changes to a regulatory action after it is submitted to the Office of Information and Regulatory Affairs for review and before it is published in the *Federal Register*. The Agency agreed with our first two recommendations and provided acceptable corrective actions. The first recommendation is completed, and the second is resolved with corrective actions pending. The Agency disagreed with our third recommendation, and it remains unresolved.



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

THE INSPECTOR GENERAL

July 7, 2022

MEMORANDUM

SUBJECT: The EPA Was Not Transparent About Changes Made to a Long-Chain PFAS Rule
After Administrator Signature
Report No. 22-E-0052

FROM: Sean W. O'Donnell

A handwritten signature in blue ink that reads "Sean W O'Donnell".

TO: Michal Ilana Freedhoff, Assistant Administrator
Office of Chemical Safety and Pollution Prevention

Victoria Arroyo, Associate Administrator for Policy
Office of the Administrator

This is our report on the subject evaluation conducted by the Office of Inspector General of the U.S. Environmental Protection Agency. The project number for this evaluation was [OSRE-FY22-0024](#). 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 Chemical Safety and Pollution Prevention and the Office of Policy, within the Office of the Administrator, are responsible for the issues discussed in this report. In accordance with EPA Manual 2750, the Office of Chemical Safety and Pollution Prevention completed corrective actions for Recommendation 1 on June 2, 2022. In accordance with EPA Manual 2750, the Office of Policy provided acceptable planned corrective actions and estimated milestone date in response to Recommendation 2. This recommendation is resolved with corrective actions pending. A final response pertaining to these recommendations is not required; however, if you submit a response, it will be posted on the OIG's website, along with our memorandum commenting on your response.

Action Required

Recommendation 3 is unresolved. 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 recommendation. 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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Purpose

The U.S. Environmental Protection Agency's Office of Inspector General [initiated](#) this evaluation to determine the extent to which the EPA followed applicable policies, procedures, and guidance for the changes made to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule, or LCPFAC SNUR, between the EPA administrator's signing of the final rule on June 22, 2020, and the publication of the final rule in the *Federal Register* on July 27, 2020. We initiated this evaluation based on a congressional request.

Top Management Challenge Addressed

This evaluation addresses the following top management challenge for the Agency, as identified in OIG Report No. [22-N-0004](#), *EPA's Fiscal Year 2022 Top Management Challenges*, issued November 12, 2021:

- Ensuring safe use of chemicals.

Background

Federal regulations are codified requirements that may apply to individuals, businesses, state or local governments, nonprofits, and others. Executive agencies issue regulations through the rulemaking process, which typically involves the publication of a draft rule, public comment on the draft rule, and issuance of a final rule. The EPA is one of the most active regulatory agencies in the federal government, and rules and regulations are among the most significant tools that the EPA uses to protect human health and the environment. According to the EPA, developing environmental regulations is one of the Agency's principal tasks, and the EPA's environmental success and organizational credibility are directly linked to the quality of its regulatory work. There are multiple federal and EPA policies, procedures, and guidance documents that govern the rulemaking process.

A SNUR is a type of chemical-specific rule issued pursuant to section 5(a) of the Toxic Substances Control Act. The EPA uses SNURs to require that the Agency be notified before the named chemical substances and mixtures are manufactured (including imported)¹ or processed for particular uses that are identified in the rule as significant new uses. The required significant new use notification initiates the EPA's evaluation of the conditions of use associated with the significant new use. Manufacturing or processing for the significant new use is prohibited from commencing until the EPA has conducted a 90-day review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination. However, ongoing uses cannot be subject to a SNUR.

Per- and polyfluoroalkyl substances, or PFAS, are a group of manufactured chemicals that have been used in industry and consumer products since the 1940s because of their useful properties. There are thousands of different PFAS, some of which have been more widely used and studied than others. One common concern regarding PFAS is that many break down very slowly and build up in people, animals, and the environment over time. Research suggests that exposure to high levels of certain PFAS may lead to adverse health outcomes. Research is still ongoing to determine how various levels of exposure to different PFAS can lead to a variety of health effects. LCPFAC is a type of PFAS, specifically a long-chain

¹ For the LCPFAC SNUR, the term "manufactured" also applies to the import of LCPFAC-containing products and items into the United States.

category of perfluorinated carboxylate chemical substances with perfluorinated carbon chain lengths that are equal to or greater than seven carbons and less than or equal to 20 carbons.

The LCPFAC SNUR

The EPA's LCPFAC SNUR was initially proposed on January 21, 2015. The National Defense Authorization Act for Fiscal Year 2020 stipulated a June 22, 2020 deadline for the completion of the LCPFAC SNUR. On June 22, 2020, Then-Administrator Andrew Wheeler signed the final LCPFAC SNUR, and on July 27, 2020, the final rule was published in the [Federal Register](#). The July 2020 final LCPFAC SNUR requires that notice be provided to the EPA before manufacturing, importing, or processing LCPFAC chemical substances for specific uses identified in the rule as significant new uses. The SNUR precludes the commencement of such manufacturing, importing, and processing until the EPA has conducted a review of the notice, made an appropriate determination on whether the new use presents an unreasonable risk, and taken such actions as are required in association with that determination. The July 2020 final LCPFAC SNUR also states that articles containing certain long-chain PFAS as a surface coating and that carpet containing PFAS can no longer be manufactured in the United States without the EPA's review and approval. In other words, articles like textiles, carpet, furniture, electronics, and household appliances that contain these long-chain PFAS cannot be manufactured in the United States unless the EPA reviews and approves the use of the long-chain PFAS or the EPA puts in place the necessary restrictions to address any unreasonable risks.

The Changes Made to the LCPFAC SNUR After Administrator Signature

In the 35 days between the June 22, 2020 signing of the final rule by the EPA administrator and the July 27, 2020 publication of the final rule, changes to the LCPFAC SNUR were made, including:

- Removal of a paragraph discussing the Frank R. Lautenberg Chemical Safety for the 21st Century Act that amended the Toxics Substances Control Act in 2016.
- Removal of language that described what constitutes a surface coating for imported articles. This language was replaced with a statement that a forthcoming LCPFAC SNUR compliance guide would address the topic.
- Renumbering of references and paragraphs as a result of the Lautenberg Act paragraph being removed.
- Updating the Agency's "Response to Comments" corresponding to the above changes made to the LCPFAC SNUR.

In January 2021, the EPA, under Then-Administrator Wheeler, issued the LCPFAC SNUR compliance guide, which addressed what imported articles were covered by the final rule. However, in June 2021, the EPA, under Administrator Michael Regan, withdrew the compliance guide and provided a statement on the EPA's website indicating that the compliance guide did not consider or address comments submitted by the public, inappropriately narrowed the scope of the rule, and weakened the final rule. The July 2020 LCPFAC SNUR continues to be in effect.

The EPA's Transparency, Rulemaking, and Dockets

The credibility of the EPA's work is bolstered when the Agency conducts its work in the most transparent manner possible. In 1983, the EPA first committed to transparency when Then-Administrator Bill

Ruckelshaus issued a [memorandum](#) promising that the EPA would operate “in a fishbowl,” meaning that it would attempt to communicate with everyone—from environmentalists to regulated entities—as openly as possible and to create a culture of integrity. Subsequent EPA administrators reaffirmed this commitment to openness in a series of messages referred to as the “fishbowl memorandums.” For example, Then-Administrator Wheeler’s July 30, 2018 *Public Participation and Transparency in EPA Operations* [message](#) to all EPA employees said, “Much of the EPA’s business is conducted through rulemaking. EPA employees must ensure that the basis for the agency’s decision appears in the public record. ... [I]t is essential to ensure that the public receives timely notice, as far as practicable, of information or views that have influenced the EPA’s decisions.” In April 2021, Administrator Regan reiterated that public trust requires transparency in his [Message to EPA Employees on Transparency and Earning Public Trust in EPA Operations](#). The EPA fishbowl memorandums emphasize the importance of transparency and openness in the rulemaking process and identify public dockets as a way to be transparent about EPA decision-making.

The Administrative Procedure Act governs the process by which federal agencies develop and issue rules. EPA rulemaking typically begins with the Agency proposing a rule. The proposed rule is published in the *Federal Register* so that members of the public can consider it and submit comments. The proposed rule and supporting documents are also filed in the rule’s docket on [Regulations.gov](#). The EPA considers the comments received, revises the rule as it deems appropriate, and issues a final rule. This final rule is also published in the *Federal Register* and in the rule’s docket

A **docket** is a collection of documents made available by an agency for public viewing and is associated with an opportunity for public comment. There are many types rulemaking dockets and nonrulemaking dockets, or general dockets, for agency actions not related to the development of a rule. **Rulemaking dockets** document an agency’s efforts to propose, amend, repeal, or issue a rule or regulation. An EPA rulemaking docket consists of materials related to that particular rule, such as documents referenced in the *Federal Register*, public comments received, and other information used by the Agency to explain or support its decisions. Table 1 outlines what is typically included or excluded from an EPA rulemaking docket.

Public Participation in Rulemaking

The Administrative Procedure Act requires federal agencies to publish their proposed rules in the *Federal Register* so that the public can review and comment on them. The agencies consider and respond to significant comments received during the public comment period. Key points:

- Anyone can comment on any rule proposed by any federal agency.
- All comments must be addressed and discussed in a document that is published in the docket.

Table 1: Contents of an EPA rulemaking docket

Information typically included	Information not typically included
<ul style="list-style-type: none"> • <i>Federal Register</i> Notices, including: <ul style="list-style-type: none"> ○ Notice of Proposed Rulemaking. ○ Final Rule Notice. ○ Direct Final Rule Notice. • Supporting documents. • Submitted comments. 	<ul style="list-style-type: none"> • Internal documents that capture predecisional internal discussions that are deliberative in nature and consist of materials generated prior to the making of a decision, such as day-to-day staff notes. • Briefing papers, action memorandums, and other staff advice and recommendations. • Confidential attorney-client communications. • Confidential attorney work products. • Draft decision documents. • Internal EPA memorandums.

Source: The EPA, “What is a Docket” [webpage](#). (EPA OIG table)

The EPA's Procedures and Guidance for Changing Rule Language After Administrator Signature

A procedure outlined in a 2006 EPA memorandum, *Changes to Rule Documents Prepared for the Administrator's Signature*, states that changes to a final rule can be made to address clerical or typographical errors or other more substantive issues after the EPA administrator's signature but before *Federal Register* publication.² According to this procedure,³ substantive changes to a final rule should be transmitted through the assistant administrator of the EPA program office spearheading the rule, with concurrence from the EPA's Office of General Counsel and the EPA's Office of Policy. To comply with the procedure, the EPA develops a memorandum that lists the proposed changes to the final rule, gathers the signature of the required offices, and obtains the administrator's signature to finalize the decision. The approved changes are then communicated to the Office of the Federal Register. The October 2011 EPA document, *Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers, or Docketing FAQs*, refers to this memorandum as a "post-signature change" memorandum. The *Docketing FAQs* further explain that once the memorandum is signed by the administrator, it becomes a decision memorandum, is no longer considered a deliberative document, and should be included in the docket.

Executive Order 12866

Executive Order 12866, *Regulatory Planning and Review*, was issued in 1993 "to reform and make more efficient the regulatory process." Among other things, E.O. 12866 requires that draft significant regulatory actions, including rulemakings, be submitted for review to the Office of Management and Budget's Office of Information and Regulatory Affairs, or OIRA, in the Executive Office of the President.⁴ The executive order's section 6, "Centralized Review of Regulations," provides that OIRA must, within 90 to 120 days after submission of the regulatory action, waive its review or notify the agency of the results of its review. OIRA input as a result of this "centralized review" may lead to changes in the language of the regulatory action. One objective of E.O. 12866 is to make the regulatory process "more accessible and open to the public." Specifically, section 6(a)(3)(E) of the executive order requires agencies to take the following actions:

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

- (i) Make available to the public the information [provided to OIRA for review];
- (ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

² The procedure does not define "substantive" but states that any questions regarding whether a change is substantive should be discussed with the Office of General Counsel.

³ This procedure is also outlined in the EPA's 2018 *EPA's Action Development Process* guidance document.

⁴ The EPA identified the LCPFAC SNUR as a significant regulatory action.

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.⁵

Agencies typically identify this information for the public through the use of the docket associated with the regulatory action.

The Office of the Federal Register's Document Drafting Handbook Guidance

At times, typographical or substantive errors are identified in final rules either by the *Federal Register's* editorial staff as they review and prepare the rule documents for publication or by the agency that submitted the final rule. The Office of the Federal Register's *Document Drafting Handbook* guides federal agencies in making changes to final rules. According to the *Document Drafting Handbook*, "must" indicates a requirement, "should" indicates a strong recommendation, and "may" indicates an option.

Responsible Offices

The Office of Chemical Safety and Pollution Prevention's, or OCSPP's, mission is to protect the public and the environment from the risks of pesticides and toxic chemicals. The Office of Policy, located in the Office of the Administrator, provides multidisciplinary analytic skills, management support, and special expertise in regulatory policy and management, as well as other areas.

Scope and Methodology

We conducted this evaluation from October 2021 to May 2022. This evaluation was conducted 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 perform the evaluation to obtain sufficient and appropriate evidence to support our findings.

Our evaluation focused specifically on the actions taken by the EPA to make changes to the final LCPFAC SNUR between June 20, 2020, when the document was signed by the EPA administrator, and July 27, 2020, when the final rule was published in the *Federal Register*. This evaluation was a result of a congressional request.

To conduct our work, we interviewed managers and staff from the EPA's OCSPP, Office of General Counsel, and Office of Policy. We reviewed the EPA's applicable policies, procedures, and guidance related to making changes to a final rule after the EPA administrator has signed it. We also reviewed statutes, regulations, and executive orders relevant to the rulemaking and publication process, as well as guidance from the Office of the Federal Register. We reviewed information that was provided by the OCSPP, including the LCPFAC SNUR docket, relevant emails provided by staff, and other supporting documentation.

⁵ The procedures for complying with E.O. 12866 are also outlined in the EPA's 2018 *EPA's Action Development Process* guidance document.

Results

The EPA did not follow all applicable policies, procedures, and guidance when making changes to the LCPFAC SNUR after the administrator signed it and before it was published in the *Federal Register*. In accordance with the procedure outlined in the *Changes to Rule Documents Prepared for the Administrator’s Signature* memorandum, the Agency developed a postsignature change memorandum identifying the changes, but it did not docket that memorandum, as stipulated by the *Docketing FAQs*. EPA staff we interviewed informed us that they were “not aware of any documentation of [the] original request, which was communicated orally to OCSPP staff and management, starting with a [telephone] call on June 23, 2020.” As a result, we could not determine whether the EPA complied with the transparency provisions of E.O. 12866. The Agency did follow the Office of the Federal Register’s *Document Drafting Handbook* guidance for requesting changes to the final rule. Table 2 outlines the applicable policies, procedures, and guidance that we reviewed and indicates whether the EPA followed with the requirements and directives therein. By not following docketing procedures, the EPA did not meet transparency expectations and risked compromising the public’s trust in the rulemaking process.

Table 2: The EPA’s compliance with applicable policies, procedures, and guidance

Type	Title, section, and date	Did the EPA follow?
EPA procedure	<i>Changes to Rule Documents Prepared for the Administrator’s Signature</i> memorandum, dated July 2006	Yes
EPA procedure	<i>Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers (Docketing FAQs)</i> , dated October 2011	No
Executive order	E.O. 12866, section 6(a)(3)(E), dated October 1993	Undetermined*
Office of the Federal Register guidance	<i>Document Drafting Handbook</i> , dated 2018	Yes

Source: OIG analysis of compliance with applicable laws, policies, procedures, and guidance. (EPA OIG table)

* Because the EPA could not provide the origin of the requested changes to the rule, we could not determine whether the EPA complied with the transparency provisions of E.O. 12866, section 6(a)(3)(E).

The EPA Did Not Follow All Its Procedures or Abide by Transparency Expectations When Changing the LCPFAC SNUR

The EPA followed the procedure for substantive changes outlined in its *Changes to Rule Documents Prepared for the Administrator’s Signature* memorandum. The EPA gathered the necessary approvals for the proposed changes from the OCSPP assistant administrator, along with concurrence from the Office of General Counsel and the Office of Policy, and submitted the proposed changes to the EPA administrator for approval. That action resulted in a postsignature change memorandum,⁶ which was signed by Then-Administrator Wheeler on July 13, 2020.

However, after the postsignature change memorandum was approved and signed by the administrator, thereby becoming a decision memorandum, the EPA did not follow the procedure outlined in the *Docketing FAQs*. Specifically, the EPA did not include the decision memorandum in the LCPFAC SNUR docket. According to the OCSPP manager responsible for making the changes to the final rule, the

⁶ EPA, *Corrections to the Final Rule for Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule (Tier 3; SAN 5684; RIN 2070-AJ99; FRL- 10010-44; EPA-HQ-OPPT-20 13-0225) - DECISION MEMORANDUM*, dated July 13, 2020.

decision memorandum was not published in the docket because it was labeled as a deliberative internal document. The manager believed this was consistent with Agency guidance and historical OCSPP practice.

Because the EPA did not docket the decision memorandum, the public was not notified of the substantive, post-signature changes to the final LCPFAC SNUR. As a result, the EPA did not follow its *Docketing FAQs* procedure and did not meet the transparency expectations of the fishbowl memorandums.

The EPA Staff Could Not Identify the Source of the LCPFAC SNUR Changes, Preventing the OIG from Verifying Transparency Compliance

We requested that the EPA—including staff from the OCSPP, Office of General Counsel, Office of Policy, and Office of the Administrator—provide documentation showing who requested or directed the changes made to the LCPFAC SNUR between the time the final rule was signed by the administrator on June 22, 2020, and the time it was published on July 27, 2020. The EPA provided several documents relating to the changes made to the final rule language, but these documents did not include the source of the original request for changes. OCSPP staff informed us that the request to change the final rule was provided by someone in the White House, whom they could not identify, to an EPA official. According to the EPA staff and managers we spoke with, the Agency is not aware of any documentation about the origins of the request because it was communicated orally to OCSPP staff and management, starting with a telephone call on June 23, 2020. Because the EPA could not identify the origin of the request, the OIG could not determine whether the changes made to the LCPFAC SNUR after the administrator signed it were the result of OIRA suggestions.

According to one OCSPP manager’s explanation of the events, the White House commenter, who would have participated in the centralized review but was not available during the centralized review time period mandated by E.O. 12866, provided the request for the changes after the centralized review process had concluded and after the administrator signed the final rule. The manager indicated that requests for changes received after the E.O. 12866 centralized review period are not covered by the docketing requirements of E.O. 12866. However, based on the requirements in the executive order, if the changes to the final rule were made at the suggestion or recommendation of OIRA, they would have triggered the EPA’s responsibility under E.O. 12866 section 6(a)(3)(E)(iii) to “[i]dentify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.”

We interpret the docketing requirement of E.O. 12866 section 6(a)(3)(E)(iii) to apply to all changes made at the suggestion or recommendation of OIRA between the time the action is submitted to OIRA for centralized review and the time the action is published in the *Federal Register*. This time frame of applicability is consistent with the time frame articulated in section 6(a)(3)(E)(ii) of the executive order, which requires that agencies “[i]dentify for the public ... the substantive changes between the draft submitted to OIRA for review and the action subsequently announced.” This interpretation is also consistent with guidance in the Office of Management and Budget’s *Guidance for Implementing E.O. 12866*, dated October 1993, which also applies the time frame articulated in section 6(a)(3)(E)(ii) to the information required to be docketed pursuant to section 6(a)(3)(E)(iii). The guidance states that “after the regulatory action has been published in the *Federal Register* or otherwise issued to the public, each agency is to identify for the public ... the substantive changes that it made to the regulatory action between the time the draft was submitted to OIRA for review and [when] the action was subsequently

publicly announced, indicating those changes that were made at the suggestion or recommendation of OIRA (Sec. 6(a)(3)(E)(ii) & (iii)).”

During the course of our evaluation, however, the Office of Policy provided us with a different interpretation of E.O. 12866 section 6(a)(3)(E)(iii). The Office of Policy stated that the docketing requirements of E.O. 12866 section 6(a)(3)(E) apply only to changes in response to OIRA suggestions or recommendations made during the centralized review period of 90 to 120 days and not those made thereafter. The Office of Policy reasoned that the title of section 6, “Centralized Review of Regulations,” supported its interpretation to limit the information docketed pursuant to section 6(a)(3)(E)(iii) to OIRA input made during the centralized review period. However, the Office of Policy did not address how the title of section 6 could compel such an interpretation regarding section 6(a)(3)(E)(iii) but not section 6(a)(3)(E)(ii), which expressly applies to a broader time frame. EPA guidance does not address how to apply the transparency requirements of E.O. 12866 to changes made at the request of OIRA after the conclusion of the centralized review period and prior to publication of the action.

While the LCPFAC SNUR docket contains documentation of changes made as a result of OIRA input received through the centralized review process, the docket does not include the changes made after the administrator’s signature. Because the EPA could not provide the origin of the request for changes, we could not determine whether the suggestion came from OIRA and, therefore, whether the EPA complied with the E.O. 12866 transparency requirements.

The EPA Followed the Office of the Federal Register’s Document Drafting Handbook Guidance

The EPA followed guidance in the Office of the Federal Register’s 2018 *Document Drafting Handbook*. This *Handbook* allows for discretion in implementation; specifically, the section on correcting a document after submission but before publication includes actions that “may” occur. That terminology indicates that those actions are optional. The guidance states that an agency “may request minor corrections by a letter (pdf of signed letter on agency letterhead)” and that if extensive changes to a document are needed, the Office of the Federal Register may request that the Agency withdraw the document from publication and then resubmit it for publication after corrections have been made.

The Office of the Federal Register did not require the EPA to follow the optional portions of the guidance. The Office of the Federal Register editor and the EPA communicated through email and telephone calls, and a signed letter on Agency letterhead was not provided or requested. The Office of the Federal Register editor also did not require the EPA to withdraw the document from publication, and the editor processed the changes to the final LCPFAC SNUR as requested by the EPA.

Recommendations

We recommend that the assistant administrator for Chemical Safety and Pollution Prevention:

1. Update the docket for the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule by posting the decision memorandum, *Corrections to the Final Rule for Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule (Tier 3; SAN 5684; RIN 2070-AJ99; FRL-10010-44; EPA-HQ-OPPT-20 13-0225) - DECISION MEMORANDUM*, which outlines the changes

made to the final rule after the EPA administrator signed it but before it was published in the *Federal Register*.

We recommend that the associate administrator for Policy:

2. Update *Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers (Docketing FAQs)*, dated October 2011, and other applicable policies, procedures, and guidance as needed to require the docketing of decision memorandums that outline substantive changes made to a final rule after the EPA administrator signs it but before it is published in the *Federal Register*.
3. Update applicable policies, procedures, and guidance as needed to require that—when the EPA makes changes to a regulatory action as a result of a suggestion or recommendation received from the Office of Information and Regulatory Affairs between the time the action is submitted to the Office of Information and Regulatory Affairs for review and the time the action is published in the *Federal Register*—the EPA identify those changes for the public, consistent with Executive Order 12866 section 6(a)(3)(E)(iii).

Agency Response and OIG Assessment

In its June 3, 2022 response to the draft report, the Agency concurred with Recommendations 1 and 2 and provided acceptable corrective actions. See Appendix A. Recommendation 1 is resolved with the corrective action completed on June 2, 2022. Recommendation 2 is resolved with corrective actions pending.

The Agency disagreed with Recommendation 3. Prior to receiving the Agency's official response, we met with the Office of Policy to discuss its disagreement with Recommendation 3. In that meeting and in its response, the Agency asserted the report did not provide compelling evidence that the requested changes came from OIRA, and it disagreed with our interpretation of the docketing requirements of E.O. 12866. We discuss support for our interpretation of the docketing requirements of E.O. 12866 in the "Results" section of the report. With respect to whether the requested changes came from OIRA personnel, as outlined above, an OCSPP manager asserted that the requested changes were made by someone who would have participated in the centralized review executive order process but was unavailable during the centralized review period. Given OIRA's principal role in the E.O. 12866 centralized review process and OCSPP staff's understanding that the requested changes originated from the White House (of which OIRA is the primary component overseeing executive branch regulations),⁷ we view the OCSPP manager's statement as support for reasonably concluding that OIRA personnel may have requested the changes at issue. Because the EPA lacks a policy or procedure requiring the docketing of changes made at the suggestion or request of OIRA received after the centralized review period is completed, Recommendation 3 was proposed to eliminate this gap.

The Agency also suggested that we should have conducted an email search of former employees to find possible documentation of the request. We did not conduct a search of former employees' emails

⁷ According to the White House's website, "OIRA is the United States Government's central authority for the review of Executive Branch regulations, approval of Government information collections, establishment of Government statistical practices, and coordination of Federal privacy policy." OIRA is a statutory part of the Office of Management and Budget within the Executive Office of the President.

because we determined that it was unlikely to yield any documentary evidence. We were repeatedly told by EPA staff we interviewed that the request was made orally via a telephone call, and they were unaware of any documentation of the call. We added clarifying language to the report regarding the information available about the source of the requested changes. Recommendation 3 remains unresolved.

Status of Recommendations

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date
1	8	Update the docket for the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule by posting the decision memorandum, <i>Corrections to the Final Rule for Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule (Tier 3; SAN 5684; RIN 2070-AJ99; FRL- 10010-44; EPA-HQ-OPPT-20 13-0225) - DECISION MEMORANDUM</i> , which outlines the changes made to the final rule after the EPA administrator signed it but before it was published in the <i>Federal Register</i> .	C	Assistant Administrator for Chemical Safety and Pollution Prevention	6/1/22
2	9	Update <i>Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers (Docketing FAQs)</i> , dated October 2011, and other applicable policies, procedures, and guidance as needed to require the docketing of decision memorandums that outline substantive changes made to a final rule after the EPA administrator signs it but before it is published in the <i>Federal Register</i> .	R	Associate Administrator for Policy	12/31/22
3	9	Update applicable policies, procedures, and guidance as needed to require that—when the EPA makes changes to a regulatory action as a result of a suggestion or recommendation received from the Office of Information and Regulatory Affairs between the time the action is submitted to the Office of Information and Regulatory Affairs for review and the time the action is published in the <i>Federal Register</i> —the EPA identify those changes for the public, consistent with Executive Order 12866 section 6(a)(3)(E)(iii).	U	Associate Administrator for Policy	

¹ C = Corrective action completed.

R = Recommendation resolved with corrective action pending.

U = Recommendation unresolved with resolution efforts in progress.

Agency Response to Draft Report



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

OFFICE OF POLICY

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Draft Report entitled “The EPA Was Not Transparent About Changes Made to a Long-Chain PFAS Rule After Administrator Signature”
Report No. OSRE-FY-22-0024.

FROM: Victoria Arroyo
Associate Administrator
Office of Policy

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Michal Freedhoff, Ph.D.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention

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TO: Sean O'Donnell
Inspector General

This memorandum responds to the OIG’s Draft Report entitled “The EPA Was Not Transparent About Changes Made to a Long-Chain PFAS Rule After Administrator Signature,” Report No. OSRE-FY22-0024, dated May 4, 2022.

I. General Comments:

The Office of Policy and the Office of Chemical Safety and Pollution Prevention appreciate the OIG’s efforts in evaluating the extent to which the EPA followed applicable policies, procedures, and guidance for the changes made to the final rule entitled *Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule* between the EPA Administrator’s signing of the final rule on June 22, 2020, and the publication of the final rule in the Federal Register on July 27, 2020. Thank you for the opportunity to respond to the issues and recommendations in the draft report.

It is important to note that the events and issues outlined in the draft report occurred in 2020, before the arrival of the current senior leadership team at EPA. The current leadership of the agency supports the goals of public transparency and of following internal rule development procedures.

While there were some post signature changes made to the *Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule* (LCPFAC SNUR rule) that were more than strictly editorial, and therefore required a post signature change memo, it is important to understand that those changes did not alter the requirements of the rule in any meaningful way.

OP and OCSPP share the following significant concerns with the draft report:

- **Source of requested post signature change.** The draft report mischaracterizes the discussions and documentation associated with the source of the suggested post-signature changes. The draft report states that the OCSPP participants in the OIG evaluation could not identify the original source of the requested changes. However, in discussions with OIG, the OCSPP participants clearly communicated that they received the request from the former OCSPP Assistant Administrator, Alexandra Dapolito Dunn, who characterized it as having been made to EPA political leadership by a political official working for President Trump. This information is also supported by the documentation provided by OCSPP to the OIG, which includes emails and meeting invitations from the former OCSPP Assistant Administrator. OCSPP participants also specifically inquired about OIG's intentions to access the archived emails of former EPA political officials likely involved in the transaction and were told that OIG did not intend to conduct any searches involving former EPA officials. Since OIG chose not to conduct a search for documentation related to the former EPA officials, it is incorrect to conclude that there is no documentation that might identify the original source of the request.
- **Office of Information and Regulatory Affairs and EO 12866.** The draft report states that since the original source of the requested changes could not be identified, the OIG could not determine that the changes did not come from the Office of Management and Budget's OIRA. However, in discussions with OIG, the EPA participants confirmed that OIRA concluded its review under EO 12866 prior to signature. In EPA's experience, and supported by historical records, OIRA does not conclude EO 12866 review until they have verified that all of their recommended changes to the rulemaking package have indeed been made. The documentation in the OIRA docket for this action required by section 6(b)(4)(C) of EO 12866 also does not include the post signature change identified in this report, further corroborating that the change was not made at the suggestion or recommendation of OIRA. As such, the Agency believes that it is incorrect to conclude that the source of the post-signature changes could still be someone from OIRA because they had already concluded their EO 12866 review and the documentation of the EO 12866 review does not provide any evidence that could be used to support that possibility.
- **Recognized issue with records management and case for clearer guidance.** The draft report identifies several inadvertent errors that may have been avoided with clearer guidance. For example, the July 13, 2020 post signature change memorandum was not included in the docket because the following heading appears on each page: "Deliberative Internal Document – Do Not Cite, Quote or Release," which created understandable confusion in terms of the releasability of that memorandum. EPA appreciates the

opportunity to clarify appropriate internal procedures related to post signature change memos.

Recommendation 1: Update the docket for the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule by posting the decision memorandum, *Corrections to the Final Rule for Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule (Tier 3; SAN 5684; RIN 2070-AJ99; FRL- 10010-44; EPA-HQ-OPPT-20 13-0225) - DECISION MEMORANDUM*, which outlines the changes made to the final rule after the EPA administrator signed it but before it was published in the *Federal Register*.

- **Proposed Corrective Action 1:** OCSPP will add to the final rule docket a copy of the EPA Administrator memorandum signed on July 13, 2020, with accompanying attachments.
- **Target Completion Date:** June 1, 2022.

Recommendation 2: Update *Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers (Docketing FAQs)*, dated October 2011, and other applicable policies, procedures, and guidance as needed, to require the docketing of decision memorandums that outline substantive changes made to a final rule after the EPA administrator signs it but before it is published in the *Federal Register*.

- Proposed Corrective Action 2: OP will revise the 2011 Docketing FAQs, the 2006 EPA memorandum *Changes to Rule Documents Prepared for the Administrator's Signature*, and the ADP Guidance to clarify expectations regarding the docketing of final post signature change memos that have been signed by the Administrator.
- Target Completion Date: December 31, 2022.

Recommendation 3: Update applicable policies, procedures, and guidance as needed to require that—when the EPA makes changes to a regulatory action as a result of a suggestion or recommendation received from the Office of Information and Regulatory Affairs between the time the action is submitted to the Office of Information and Regulatory Affairs for review and the time the action is published in the *Federal Register*—the EPA identify those changes for the public, consistent with Executive Order 12866 section 6(a)(3)(E)(iii).

EPA does not agree with this recommendation. While the origin of the post-signature change request has not been established with absolute certainty, this report does not provide any compelling evidence that the request originated from OIRA. The LCPFAC SNUR was under EO 12866 interagency review, and that review concluded without the changes identified in the draft report having been made. Typically OIRA would not conclude review if one of their suggestions or recommendations had not been adequately addressed. In addition, the request for the change is characterized in the draft report as originating from the White House, not from OIRA. The available information does not indicate that any requests for changes were made by OIRA outside the formal EO 12866 review period and the changes made during the review period were docketed when the rule was finalized. Any concerns about the transparency of post signature changes, whether in this specific case or

in the future, are being addressed by EPA's response to the other recommendations in the draft report.

The OIG interpretation of EO 12866 is not consistent with EPA's nearly three decades of implementation of that Executive Order, or our understanding of its docketing requirements. As shared previously with the OIG, the docketing requirements in EO 12866 are contained a section of the Executive Order describing the centralized review of regulation and are therefore most naturally read as the docketing of changes made during that formal centralized review period. The reference in the EO to publication in the Federal Register simply indicates when information about the changes made during the centralized review period should be available to the public.

EPA continues to believe that its interpretation of EO 12866 is the best reading of the text, and on the basis of the information presented in the draft report does not believe it would be appropriate to change its interpretation or implementation of an Executive Order that was issued by the White House and also applies to multiple other federal agencies. This is particularly true in a case where the revised interpretation may not even address the issue identified in the report, that is, the residual ambiguity about the origin of the requested change. In order to address that issue, EPA offers the corrective action below.

- Proposed Corrective Action 3: EPA will reiterate to senior political leadership the importance of records management, including to document verbal decisions and instructions
- Target Completion Date: December 31, 2022.

Attachments

cc: Tala Henry, Deputy Director, Office of Pollution Prevention and Toxics, OCSPP
Hayley Hughes, Director, Office of Program Support, OCSPP
Janet L. Weiner, OCSPP Audit Liaison, OPS/OCSPP
Katherine Sleasman, OPPT Program Office Audit Liaison, OPS/OCSPP
Jackie Mosby, Director, Mission Support Division, OPS/OCSPP
Angela Hofmann, Chief, Regulatory Support Branch, OPS/OCSPP
William Nickerson, Director, Office of Regulatory Policy Management, OP
Michael Benton, Audit Follow-Up Coordinator, Office of the Administrator
Charles J. Sheehan, Deputy Inspector General

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