

ENVIRONMENTAL PROTECTION AGENCY**[EPA-HQ-OW-2024-0454; FRL 12023-01-OW]****Draft National Recommended Ambient Water Quality Criteria for the Protection of Human Health for Perfluorooctanoic Acid, Perfluorooctane Sulfonic Acid, and Perfluorobutane Sulfonic Acid****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of draft Clean Water Act (CWA) national recommended ambient water quality criteria (AWQC) for the protection of human health for three per- and polyfluoroalkyl substances (PFAS)—perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), and perfluorobutane sulfonic acid (PFBS)—for a 60-day public comment period. The EPA has developed these draft PFAS national recommended human health criteria (HHC) to reflect the latest scientific information, consistent with current EPA guidance, methods, and longstanding practice. When PFAS national recommended HHC are finalized, they will provide information that States and Tribes may consider when adopting water quality standards.

DATES: Comments must be received on or before February 24, 2025.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OW-2024-0454, by any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov/> (our preferred method). Follow the online instructions for submitting comments.
- **Email:** ow-docket@epa.gov. Include Docket ID No. EPA-HQ-OW-2024-0454 in the subject line of the message.
- **Mail:** U.S. Environmental Protection Agency, EPA Docket Center, Water Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- **Hand Delivery or Courier:** EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this document. Comments received may be posted without change to <https://www.regulations.gov/>, including any

personal information provided. For detailed instructions on sending comments and additional information, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Brandi Echols, Office of Water, Health and Ecological Criteria Division (4304T), Environmental Protection Agency, 1301 Constitution Ave. NW, Washington, DC 20460; telephone number: (202) 566-2717; email address: Echols.Brandi@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Public Participation**

A. How can I get copies of these documents and other related information?

The EPA has established Docket ID No. EPA-HQ-OW-2024-0454 for three draft PFAS human health criteria: "Draft Human Health Ambient Water Quality Criteria: Perfluorooctanoic Acid (PFOA) and Related Salts;" "Draft Human Health Ambient Water Quality Criteria: Perfluorooctane Sulfonic Acid (PFOS) and Related Salts;" and "Draft Human Health Ambient Water Quality Criteria: Perfluorobutane Sulfonic Acid (PFBS) and Related Salts." Publicly available docket materials are available either electronically through <https://www.regulations.gov/> or in hard copy at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal holidays). For further information on the EPA Docket Center services and the current status, see: <https://www.epa.gov/dockets>.

The three draft human health criteria documents can be accessed on the EPA's website through the following link: <https://www.epa.gov/wqc/human-health-water-quality-criteria-pfas>

B. Written Comments

Submit your comments, identified by Docket ID No. EPA-HQ-OW-2024-0454, at <https://www.regulations.gov> (our preferred method) or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to the EPA's docket at <https://www.regulations.gov> any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be

accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). Please visit <https://www.epa.gov/dockets/commenting-epa-dockets> for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

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

In preparation for submitting comments to the EPA on this action, please review the draft chemical-specific criteria documents the EPA is publishing in the public docket for this action under Docket ID No. EPA-HQ-OW-2024-0454. Provide the EPA with comments regarding scientific views related to the draft national recommended water quality criteria for protecting human health. Include any recommended references for data and other scientific information to be considered by the EPA. To ensure that the EPA can properly respond to comments, commenters should cite the section(s) or chemical(s) in the draft criteria documents to which each comment refers. Commenters should use a separate paragraph for each issue discussed and submit any references cited in their comments. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment. Electronic files should avoid any form of encryption and should be free of any defects or viruses.

II. Background

A. What are PFAS and what are PFOA, PFOS, and PFBS?

Per- and polyfluoroalkyl substances (PFAS) are a large class of thousands of synthetic chemicals that have been in use in the United States and around the world since the 1940s. The ability for PFAS to withstand heat and repel water and stains makes them useful in a wide variety of consumer, commercial, and industrial products, and in the manufacturing of other products and chemicals. Current scientific research and available evidence have shown the potential for harmful human health effects after being exposed to some PFAS, even at very low levels. PFAS' persistence and resistance to hydrolysis,

photolysis, metabolism, and microbial degradation raise additional concerns about human exposure and health effects.

The EPA has developed draft recommended criteria for three PFAS: perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), and perfluorobutane sulfonic acid (PFBS). In the United States, most production of PFOA and PFOS, along with other long-chain PFAS, has been phased out and generally replaced by production of other PFAS. PFOA and its precursors have been used in flame repellents, cosmetics, paints, polishes, and processing aids used in the manufacture of nonstick coatings on cookware. PFOS has been used in a variety of products including surface treatments for soil and stain resistance, coating of paper, and in specialized applications such as firefighting foams. PFBS has been used as a replacement chemical for PFOS. Prior to its use as a PFOS replacement, PFBS had been produced as a byproduct and was present in consumer products as an impurity. Environmental releases of PFBS may result directly from the production and use of PFBS itself, production and use of PFBS-related substances for various applications, and/or from the degradation of PFBS precursors (*i.e.*, substances that may form PFBS during use, as a waste, or in the environment). Adverse human health effects associated with exposure to PFOA or PFOS include but are not limited to effects on the liver, growth and development (*e.g.*, low birth weight), the immune system (*e.g.*, reduced response to vaccines), lipid levels (*e.g.*, high cholesterol), as well as increased risk of certain types of cancer. Adverse human health effects associated with exposure to PFBS include but are not limited to thyroid, developmental, and kidney effects.

B. What are the EPA’s national recommended ambient water quality criteria for the protection of human health?

Section 304(a)(1) of the CWA requires the EPA to develop, publish, and, from time to time, revise criteria for protection of water quality and human health that accurately reflect the latest scientific knowledge. HHC developed under CWA section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and human health effects. CWA section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water. HHC are scientifically

derived numeric concentrations of a pollutant that are expected to protect human health from the adverse effects of that pollutant in ambient water. HHC are designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances through drinking water and eating fish and shellfish from inland and nearshore waters.

Under the CWA and its implementing regulations, States and authorized Tribes are required to adopt water quality criteria to protect designated uses (*e.g.*, public water supply, recreational use, or industrial use). The recommended HHC provide scientific information to States and authorized Tribes when they establish water quality standards that ultimately provide a basis for assessing water body health and controlling discharges of pollutants. For each contaminant, the EPA derives two recommended HHC: one criterion is based on the consumption of both water and freshwater/estuarine fish and shellfish (collectively referred to as “organisms”), and the other is based on the consumption of organisms alone. The applicability of one criterion over the other depends on the designated use of a particular water body or water bodies (*e.g.*, public water supply vs. fishable waters). The EPA recommends applying the organism-only HHC to a water body where the designated use includes supporting fishable uses under section 101(a) of the CWA but not a drinking water supply source (*e.g.*, non-potable estuarine waters that support fish or shellfish for human consumption).

The EPA’s national recommended water quality criteria are not regulations, and they do not substitute for the CWA or regulations. The EPA’s recommended criteria do not impose legally binding requirements. States and authorized Tribes have the discretion to adopt, where appropriate, other scientifically defensible water quality criteria that differ from the EPA’s CWA section 304(a) national recommendations.

III. Overview of EPA’s Draft Human Health Criteria for PFOA, PFOS, and PFBS

The EPA is publishing draft national recommended HHC for PFOA, PFOS, and PFBS, based on the latest scientific knowledge and following the EPA’s longstanding, peer reviewed methodology for deriving human health criteria. See *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000), EPA–822–B–00–004, October 2000. HHC are developed using a

mathematical equation that includes information on human health toxicity (non-cancer and cancer effects), exposure factors (specifically, fish consumption rates, body weight and drinking water intake), bioaccumulation potential, and consideration of potentially significant exposure sources beyond drinking water and freshwater/estuarine fish and shellfish consumption (*e.g.*, other foods, dust, consumer products; termed “relative source contribution”).

The EPA derived the draft HHC using the latest scientific information regarding human health toxicity and potential exposures via drinking water and eating fish and shellfish from inland and nearshore waters. Specifically, the EPA derived the draft HHC using final EPA toxicity values (reference doses, cancer slope factors) for each of the three PFAS, which have undergone external peer review and public comment. To account for human exposure to these three individual PFAS from the fish and shellfish consumption pathway, the EPA developed draft bioaccumulation factors for freshwater and estuarine fish and shellfish, according to longstanding Agency methods. Consistent with past practice, the EPA derived the draft HHC using 90th percentile per capita rates for fish and shellfish consumption and drinking water ingestion, and a mean body weight for adults, all based on national survey data. The EPA derived a relative source contribution for each PFAS to ensure that a person’s total exposure to each chemical does not exceed its noncancer toxicity value (reference dose).

The draft national recommended HHC for the three PFAS are summarized in table 1. Each of the draft criteria documents transparently describes the human health toxicity and exposure information that the EPA used to derive the HHC. Each draft criteria document also provides an illustrative example to assist States and Tribes in the consideration of water quality standards for PFAS mixtures.

TABLE 1—DRAFT HUMAN HEALTH CRITERIA (HHC) FOR PFOA, PFOS, AND PFBS

PFAS	Water + Organism HHC (ng/L)	Organism Only HHC (ng/L)
PFOA	0.0009	0.00036
PFOS	0.06	0.07
PFBS	400	500

IV. The EPA's Request for Comments and Next Steps

The EPA will consider the comments received, revise the criteria documents, and prepare final national recommended HHC for PFOA, PFOS, and PFBS that reflect EPA's consideration of those comments. The EPA will announce the availability of the final national recommended HHC for these three PFAS in the **Federal Register**. When final, these HHC will provide information that States and Tribes may consider when adopting water quality standards for PFOA, PFOS, and PFBS. The EPA expects to develop additional HHC for PFAS as scientific information becomes available.

Bruno Pigott,

Principal Deputy Assistant Administrator.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2023-0129; FRL-12524-OMS-01]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Consolidated Air Rule for the Synthetic Organic Chemical Manufacturing Industry (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Consolidated Air Rule for the Synthetic Organic Chemical Manufacturing Industry (EPA ICR Number 1854.14, OMB Control Number 2060-0443) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through December 31, 2024. Public comments were previously requested via the **Federal Register** on May 18, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before January 27, 2025.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OAR-2023-0129, to EPA online using <https://www.regulations.gov/> (our preferred method), by email to *a-and-r-*

docket@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

The EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Muntasir Ali, Sector Policies and Program Division (D243-05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-0833; email address: *ali.muntasir@epa.gov*.

SUPPLEMENTARY INFORMATION: This is a request for approval of a new collection. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at <https://www.regulations.gov> or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: The Consolidated Federal Air Rule (CAR) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) (40 CFR part 65) was promulgated on December 14, 2000; and amended on August 27, 2007, November 12, 2010, August 11, 2011, June 25, 2013, and January 19, 2021. The CAR regulations are an optional compliance approach for new and existing SOCMI facilities that must comply with existing subparts in the Code of Federal Regulations (CFR). The CAR is a consolidation of major portions of 15 different New Source Performance

Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) pertaining to storage vessels, process vents, transfer racks, equipment leaks, and the general provisions for the three applicable parts (40 CFR parts 60, 61, and 63). These subparts are referred to as "referencing Subparts" because they have been amended to refer to the CAR as a compliance alternative. New facilities include those that commenced construction, modification or reconstruction after the date of proposal of the applicable referencing subpart(s). The referencing subparts include 40 CFR part 60, subparts Ka, Kb, VV, VVa, DDD, III, NNN, and RRR; 40 CFR part 61, subparts BB, Y, and V; 40 CFR part 63, subparts F, G, H, and I. This ICR does not incorporate burden from recently proposed amendments to referencing subparts VV, VVa, III, NNN, RRR, F, G, H, or I (88 FR 25080) or subpart Kb (88 FR 68535). This information is being collected to assure compliance with 40 CFR part 65.

Compliance with the CAR is a voluntary alternative. Sources may either continue to comply with existing applicable rules or may choose to comply with the consolidated rule. All existing sources must be in compliance with the requirements of the CAR and/or its referencing Subparts within three years of the effective date (*i.e.*, promulgation date) of the appropriate standard for the affected source. All new sources must be in compliance with the requirements of the CAR and/or its referencing Subparts upon startup or the promulgation date of standards for an affected source, whichever is later.

In general, all the NSPS, NESHAP, CAR, and maximum achievable control technology (MACT) standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to these standards.

Form Numbers: None.

Respondents/affected entities: Synthetic organic chemical manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subparts Ka, Kb, VV, VVa, DDD, III, NNN, and RRR; 40 CFR part 61, subparts V, Y, and BB; and 40 CFR part 63, subparts F, G, H, and I; 40 CFR part 65).