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ENVIRONMENTAL PROTECTION AGENCY

[FRL-10001-78-ORD; Docket ID No. EPA-HQ-ORD-2019-0275]

Availability of the Systematic Review Protocol for the PFDA, PFNA, PFHxA, PFHxS, and PFBA IRIS Assessments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 45-day public comment period associated with release of the Systematic Review Protocol for the perfluorodecanoic acid (PFDA), perfluorononanoic acid (PFNA), perfluorohexanoic acid (PFHxA), perfluorohexanesulfonate (PFHxS), and perfluorobutanoic acid (PFBA) Integrated Risk Information System (IRIS) assessments. This protocol document presents the methods for conducting the systematic reviews and dose response analyses for these assessments as well as summarizes the Agency's problem formulation activities. Public input will help to inform the subsequent development of draft assessments for these per- and polyfluoroalkyl substances (PFAS) chemicals.

DATES: The 45-day public comment period begins **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]** and ends **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Comments must be received on or before

[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The Systematic Review Protocol for perfluorodecanoic acid (PFDA), perfluorononanoic acid (PFNA), perfluorohexanoic acid (PFHxA), perfluorohexanesulfonate (PFHxS), and perfluorobutanoic acid (PFBA) assessments will be available via the Internet on the IRIS website at <https://www.epa.gov/iris/iris-recent-additions> and in the public docket at <http://www.regulations.gov>, Docket ID No. **EPA-HQ-ORD-2019-0275**. Information on these chemicals is provided in the Supplementary Information section of this notice.

FOR FURTHER INFORMATION CONTACT: For information on the docket, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202-566-1752; facsimile: 202-566-9744; or e-mail: Docket_ORD@epa.gov.

For technical information on the protocol, contact Dr. James Avery, Center for Public Health & Environmental Assessment; telephone: 202-564-1494; or email: avery.james@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information on PFAS and Systematic Review Protocols

Per- and polyfluoroalkyl substances (PFAS) are a large class of man-made chemicals widely used in consumer products and industrial processes. The basic structure of PFAS consists of a carbon chain surrounded by fluorine atoms, with different chemicals possessing different end groups. The five toxicity assessments being developed according to the scope and methods outlined in this protocol build upon several other PFAS assessments that have already been

developed, and represent only one component of the broader PFAS action plan underway at the U.S. EPA (<https://www.epa.gov/pfas/epas-pfas-action-plan>).

This protocol document presents the methods for conducting the systematic reviews and dose response analyses for assessments of perfluorodecanoic acid (PFDA), perfluorononanoic acid (PFNA), perfluorohexanoic acid (PFHxA), perfluorohexanesulfonate (PFHxS), and perfluorobutanoic acid (PFBA). This includes a summary of why these specific PFAS chemicals were prioritized for evaluation, description of the objectives and specific aims of the assessments, draft PECO (Populations, Exposures, Comparators, and Outcomes) criteria, and identification of key areas of scientific complexity. Public input received on the protocol is considered during preparation of the draft assessments and any adjustments made to the protocol will be reflected in an updated version released in conjunction with the draft assessments.

II. How to Submit Technical Comments to the Docket at <http://www.regulations.gov>

Submit your comments on the Systematic Review Protocol for the PFDA, PFNA, PFHxA, PFHxS, and PFBA IRIS Assessments to Docket ID No. **EPA-HQ-ORD-2019-0275**, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- E-mail: Docket_ORD@epa.gov.
- Fax: 202-566-9744.

- Mail: U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. The phone number is 202-566-1752.
- Hand Delivery: The ORD Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue, N.W., Washington, DC 20004.

The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by mail or hand delivery, please submit three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments on the systematic review protocol to Docket ID No. EPA-HQ-ORD-2019-0275. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at <https://www.regulations.gov>, including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information

for which disclosure is restricted by statute. Do not submit information through <https://www.regulations.gov> or e-mail that you consider to be CBI or otherwise protected. The <https://www.regulations.gov> website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <https://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA’s public docket visit the EPA Docket Center homepage at <https://www.epa.gov/dockets>.

Docket: Documents in the docket are listed in the <https://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in <https://www.regulations.gov> or hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Dated: October 20, 2019.

Wayne E. Cascio,

Director,

Center for Public Health & Environmental Assessment.

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