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6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

EPA-HQ-OW-2018-0614; FRL_XXXX-X

Request for Public Review and Comment: Draft Human Health Toxicity Assessments for Hexafluoropropylene Oxide Dimer Acid and its Ammonium Salt (GenX Chemicals) and for Perfluorobutane Sulfonic Acid (PFBS) and Related Compound Potassium Perfluorobutane Sulfonate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 60-day public comment period associated with the release of two draft toxicity assessments for public

PREPUBLICATION VERSION

comment:

- Draft Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and its Ammonium Salt (GenX Chemicals).
- Draft Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (PFBS) and Related Compound Potassium Perfluorobutane Sulfonate.

The EPA developed the draft assessments to provide the health effects information available for GenX chemicals and PFBS and describe how that information was used to derive draft toxicity values. These draft toxicity assessments underwent independent, external expert peer review in June-July 2018. Following closure of this 60-day public comment period, the EPA will consider the comments, revise the draft documents, and consider the need for additional peer review, as appropriate, and then publish final toxicity assessments. The toxicity assessments for GenX chemicals and PFBS are scientific and technical reports that include toxicity values associated with potential noncancer health effects following oral exposure (in this case, oral reference doses [RfDs]). These assessments evaluate human health hazards. The toxicity assessments and the values contained within are not risk assessments as they do not include exposure assessments or provide a risk characterization. Further, the toxicity assessments do not address the legal, political, social, economic, or technical considerations involved in risk management. When issued, the toxicity assessments can be used by the EPA, states, tribes, and local communities, along with specific exposure and other relevant information, to determine, under the appropriate regulations and statutes, if and when it is necessary to take action to address potential risk associated with human exposures to these per- and polyfluoroalkyl substances (PFAS) chemicals.

DATES: Comments must be received on or before [insert date 60 days after publication in the Federal Register].

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2018-0614, to the public docket at: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) 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). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: For information on the docket, contact the docket manager: Assem Akram, Docket Manager, EPA Docket Center, telephone: (202) 566-0226; or e-mail: Akram.Assem@epa.gov.

For technical information on GenX chemicals: Dr. Jamie Strong, Health and Ecological Criteria Division, Office of Water (Mail Code 4304T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone: (202) 566-0056; or e-mail: strong.jamie@epa.gov.

For technical information on PFBS: Dr. Samantha Jones, National Center for Environmental Assessment, Office of Research and Development (Mail Code 8602R), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone: 202-564-6794; or e-mail: jones.samantha@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

Supporting documents are available in the public docket for this ICR (under Docket ID number **EPA-HQ-OW-2018-0614**). The docket can be viewed online at <http://www.regulations.gov> or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about the EPA's public docket, visit <http://www.epa.gov/dockets>.

A. Does this Action Apply to Me?

This request for public comment will not impose any requirements on anyone. Instead, this action notifies interested parties of the availability of draft toxicity assessments for GenX Chemicals and PFBS for public comment. It should be noted that when final these toxicity assessments may be used by the EPA, states, tribes, and local communities, along with specific exposure and other relevant information, to determine, under the appropriate regulations and statutes, if and when it is necessary to take action to address potential risk associated with human exposures to these PFAS chemicals.

B. What Should I Consider as I Prepare My Comments for the EPA?

1. Submit your comments, identified by Docket ID No. **EPA-HQ-OW-2018-0614**, 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 electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in the *Code of Federal Regulations* (CFR) at 40 CFR part 2. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. What are GenX Chemicals and PFBS?

GenX chemicals and PFBS are man-made, fluorinated organic chemicals that are part of a larger group of manmade chemicals referred to as per- and polyfluoroalkyl substances (PFAS). PFAS are used in many applications because of their unique physical properties such as

resistance to high and low temperatures, resistance to degradation, and nonstick characteristics. GenX is a trade name for a processing aid technology used to make high-performance fluoropolymers without the use of perfluorooctanoic acid (PFOA). Hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt are the major chemicals associated with the GenX processing aid technology and the focus of the draft assessment. PFBS is a four-carbon PFAS that was developed as a replacement for longer-chain PFAS, which have demonstrated environmental persistence, long half-lives and bioaccumulation in humans. PFBS has been integrated into various consumer products and applications.

III. What are EPA's Draft Toxicity Assessments?

The EPA's draft toxicity assessments for GenX Chemicals and PFBS provide information on hazard identification and dose-response, including draft subchronic and chronic oral reference doses (RfDs) for each chemical. Overall, the available oral toxicity studies demonstrate that the liver is particularly sensitive to GenX chemicals, and the thyroid and kidney are sensitive to PFBS. The draft toxicity assessments underwent independent, external peer review in June and July 2018 and were revised accordingly.

In the risk assessment/risk management paradigm, a toxicity assessment is on the risk assessment side of the paradigm. The draft toxicity assessments for GenX chemicals and PFBS address the first two steps (Step 1. Hazard Identification and Step 2. Dose-Response) of the four-step risk assessment process described by the National Academy of Science in 1983 as "the characterization of the potential adverse health effects of human exposures to environmental hazards." Characterizing risk involves integrating information on hazard, dose-response, and exposure. For further details about risk assessments see: <https://www.epa.gov/risk/conducting-human-health-risk-assessment>.

When issued, the toxicity values for GenX chemicals and PFBS can be combined with specific exposure information (Step 3. Exposure Assessment) by government and private entities to help characterize (Step 4. Risk Characterization) potential public health risks associated with exposure to these chemicals. Thus, once the GenX chemicals and PFBS assessments are issued, the EPA will work with our state, tribal, and local partners to provide technical assistance, including information about appropriate regulations and statutes, as they begin considering the final values in relevant exposure scenarios. It is the risk management part of the risk assessment/risk management paradigm where the supporting science, as well as statutory and legal considerations, risk management options, public health considerations, cost/benefit considerations, economic factors, social factors, and other considerations are weighed.

The EPA recognizes that humans have the potential to be exposed to complex mixtures of PFAS and other chemicals and pathogens through drinking water and other exposure sources. The EPA's draft assessments for GenX chemicals and PFBS focus solely on the potential human health effects associated with oral exposure to each chemical; they do not consider potential cumulative (mixture) effects of GenX chemicals and PFBS or their possible interactions with other PFAS and/or other chemicals. This would involve a more complex assessment that would need to consider and evaluate mechanisms of action and endpoints of concern for each of the chemicals in the mixture.

IV. Why is the EPA Releasing Draft Toxicity Assessments for these Chemicals?

The EPA is issuing the draft toxicity assessments for PFBS and GenX chemicals for public comment to give interested stakeholders and the public an opportunity to provide input to the Agency. The public will have 60 days after publication in the *Federal Register* to provide input. At the end of the comment period, the EPA will evaluate the input, make appropriate

revisions, and finalize the toxicity assessments. Once the toxicity assessments are issued, the EPA will work with our state, tribal, and local partners to provide technical assistance, as they begin using the final values in relevant exposure scenarios to generate risk assessments to support risk management decisions.

V. Solicitation of Public Comment

During the 60-day comment period, the EPA is soliciting public comments regarding the science and technical approaches used in the derivation of the draft toxicity assessments for GenX chemicals and PFBS.

In the PFBS assessment, due to the lack of epidemiological studies demonstrating adverse effects in humans, the EPA derived candidate subchronic RfDs (see Section 6.1.1 of the toxicity assessment) and candidate chronic RfDs (see Section 6.1.2 of the toxicity assessment) for both thyroid effects and kidney effects in rodent toxicity studies. In light of the consistent observation of the thyroid effects across life stages and the greater dose-response sensitivity, relative to the kidney effects, the EPA is proposing to base the overall subchronic and chronic RfDs on the thyroid effects and is requesting public review and comment on this proposal in addition to the approaches and conclusions in the PFBS assessment. Additionally, as described in Section 6.1 of the PFBS toxicity assessment, decreased serum total T4 (thyroxine) in newborn mice was used as the basis for the thyroid-related candidate RfDs. Peer reviewers provided comments on thyroid effects and this choice of endpoint. See pages 15-25 and 31-32 in the *Response to Peer Review Comments on the Draft Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3)* for the array of peer review comments on these topics and the EPA's responses. These supporting documents are available in the public docket

for this ICR (under Docket ID number **EPA-HQ-OW-2018-0614**. Comments from the public are requested on the thyroid effects, this choice of endpoint, as well as the discussion on thyroid hormone economy in humans and animals (see Section 6.1 of the PFBS toxicity assessment).

These draft assessments are not final as described in the EPA's information quality guidelines, and do not represent Agency policy or views. The EPA will consider all public comments submitted in response to this notice when revising these documents.

Dated: _____.

David P. Ross,
Assistant Administrator, Office of Water.