

Fact Sheet: Draft Toxicity Assessments for GenX Chemicals and PFBS

Federal, state, tribal, and local governments are working together to address per- and polyfluoroalkyl substances (PFAS) in the environment. PFAS are man-made chemicals used in a wide range of products because of their ability to repel water, grease, and oil. While PFOA and PFOS are the two most extensively produced and studied chemicals in the group, EPA is asking for public comment on draft toxicity assessments for GenX chemicals and perfluorobutane sulfonic acid (PFBS) to increase the amount of information the public has on other PFAS. When issued, the toxicity assessments can be used along with exposure information and other important considerations to assess potential health risks to determine if, and when, it is appropriate to action to address these chemicals.

Questions and Answers

What are PFAS, including PFBS and GenX chemicals?

PFAS: Per- and polyfluoroalkyl substances (PFAS) are a group of man-made chemicals that have been in use since the 1940s, and are (or have been) found in many consumer products like cookware, food packaging, and stain repellants. PFAS manufacturing and processing facilities, airports, and military installations that use firefighting foams are some of the main sources of PFAS. PFAS may be released into the air, soil, and water, including sources of drinking water. PFOA and PFOS are the most studied PFAS chemicals and have been voluntarily phased out by industry, though they are still persistent in the environment. There are many other PFAS, including GenX chemicals and PFBS in use throughout our economy.

Gen X Chemicals: GenX is a trade name for a technology that is used to make high-performance fluoropolymers (e.g., some non-stick coatings) without the use of perfluorooctanoic acid (PFOA). HFPO dimer acid and its ammonium salt are the major chemicals associated with the GenX technology. GenX chemicals have been found in surface water, groundwater, finished drinking water, rainwater, and air emissions in some areas.

PFBS: PFBS is a replacement chemical for PFOS, a chemical that was voluntarily phased out by its U.S. manufacturers. PFBS has been identified in the environment and consumer products, including surface water, wastewater, drinking water, dust, carpeting and carpet cleaners, floor wax, and food packaging.

How are people exposed to GenX chemicals and PFBS?

People can be potentially exposed to GenX chemicals and PFBS through a number of different pathways, including drinking water, inhaling air, and consuming food wrapped in PFAS containing products. (Note: The Food and Drug Administration is responsible for food packaging.) While EPA is continuing to work with state, tribal, and local partners to gather additional information, the agency believes that exposure to GenX chemicals through the ambient air and drinking water is likely localized or regional in nature. EPA will continue to work collaboratively with partners to increase the amount national data on the occurrence of GenX chemicals in water.

EPA recognizes that humans have the potential to be exposed to PFAS through drinking water and other exposure sources. 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.

What health effects are associated with GenX chemicals and PFBS?

Overall, the available oral toxicity studies show that the liver is sensitive to GenX chemicals, and the kidney and thyroid are sensitive to PFBS. EPA has requested public comment on these complex relationships.

GenX Chemicals: Animal studies have shown health effects in the kidney, blood, immune system, developing fetus, and especially in the liver following oral exposure. The data are suggestive of cancer.

PFBS: Animal studies have shown health effects on the thyroid, reproductive organs and tissues, developing fetus, and kidney following oral exposure. Overall, the thyroid and kidney are particularly sensitive to PFBS. The data are inadequate to evaluate cancer.

What is an EPA toxicity assessment?

As public officials work to protect public health, they first must assess the risks before they can identify a plan to manage them. A toxicity assessment is part of the risk assessment process and is a written summary of the potential health effects associated with a chemical that identifies the levels at which those health effects may occur. Specifically, the draft GenX chemicals and PFBS toxicity assessments cover the first two steps (Step 1. Hazard Identification and Step 2. Dose-Response) of the four-step risk assessment process developed by the National Academy of Sciences. Risk characterization, which is not done in these toxicity assessments, requires additional consideration of exposure. For more details about this process: <https://www.epa.gov/risk/conducting-human-health-risk-assessment>.

When issued, the toxicity values from the GenX chemicals and PFBS assessments can be combined with specific exposure information (Step 3. Exposure Assessment) to help characterize the potential public health risks associated with exposure to these chemicals (Step 4. Risk Characterization).

EPA will continue to work with our state, tribal, and local partners to provide technical assistance, including information about appropriate regulations and statutes, as they begin considering the public comments and revised toxicity values along with relevant exposure scenarios.

After the full risk assessment process is completed, public officials can work to identify how to manage the identified risk. It is through this process that the supporting science, as well as statutory and other legal considerations, risk management options, public health considerations, cost/benefit considerations, economic factors, social factors, and other considerations are weighed.

What are the draft reference doses for PFBS and GenX chemicals?

As part of EPA’s draft toxicity assessment, the agency has developed draft oral reference doses (RfDs) for GenX chemicals and PFBS. A reference dose is an estimate of the amount of a chemical a person can ingest daily over a lifetime (chronic RfD) or less (subchronic RfD) that is unlikely to lead to adverse health effects. EPA will continue to work with state, tribal, and local partners to provide technical assistance should they wish to use the final values with relevant exposure scenarios to develop risk assessments to support risk management decisions.

Chemical	Draft Subchronic RfD (mg/kg-day)	Draft Chronic RfD (mg/kg-day)
PFBS*	0.04 (candidate based on thyroid effects)	0.01 (candidate based on thyroid effects)
	0.1 (candidate based on kidney effects)	0.01 (candidate based on kidney effects)
GenX Chemicals	0.0002	0.00008
*The EPA developed candidate values based on thyroid and kidney effects and is requesting public review and comment on these candidate values for PFBS.		

To learn more about EPA’s toxicity values, please visit: <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system>

How does the toxicity of PFBS and GenX chemicals compare to PFOA and PFOS?

The draft RfD for PFBS suggests it is less toxic than GenX chemicals, PFOA, and PFOS. The draft RfD for GenX chemicals suggests that they are less toxic than PFOA and PFOS. However, these draft values may change in response to public comment.

Toxicity is only one piece of information that public officials consider when determining whether there is a risk to public health. Other factors, such as exposure, must also be considered.

Chemical	Chronic RfD (mg/kg-day)
PFBS	0.01*
GENX chemicals	0.00008*
PFOA	0.00002
PFOS	0.00002
*indicates draft value	

How might GenX chemicals or PFBS impact my drinking water?

EPA recommends that you contact your local water utility to learn more about your drinking water and to see whether they have provided any specific recommendations for your community. GenX chemicals and PFBS typically come from manufacturing processes and industrial releases. These compounds can migrate in the environment and impact the quality of surface water and groundwater which may be used as sources of drinking water. If you own a private well, EPA recommends learning more about how to protect and maintain your well for all contaminants of concern. For information on private wells visit: www.epa.gov/privatewells

Should states, tribes, or local communities use EPA's draft toxicity values now?

No, these draft toxicity values are not final and may change following the public comment period. EPA is issuing the draft toxicity assessments for PFBS and GenX chemicals for public comment to give interested stakeholders 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, EPA will consider the input and issue the assessments.

Does EPA plan to issue a regulation for these chemicals?

Not at this time. EPA is making the draft toxicity assessments available to provide states, tribes and local governments with the tools they need to better understand PFBS and GenX chemicals. Once the assessments are issued, state, tribal, and local partners can use this information to help inform whether local actions are needed to protect public health.

How can I comment on the draft toxicity assessments?

Public input plays a critical role in EPA's process for issuing the draft toxicity assessments. The agency is accepting public comments for 60 days following publication in the Federal Register. Submit your comments, identified by Docket ID No. EPA-HQ-OW-2018-0614, to the public docket at: <http://www.regulations.gov>. To view the draft toxicity assessments and other related information on GenX chemicals and PFBS, visit www.epa.gov/pfas/genx-pfbs.

Engagement and Peer Review

EPA is following through on its commitment to work in close collaboration with our federal and state partners to develop draft toxicity assessments for GenX chemicals and PFBS. EPA has engaged with federal, tribal, and state partners throughout the development of the draft toxicity assessments, including both before and after an external peer review.

Federal and tribal partners included:

- U.S. Department of Defense (DoD)
- U.S. Department of Energy (DOE)
- U.S. Geological Survey (USGS)
- U.S. Department of Health and Human Services (HHS), including the Food and Drug Administration (FDA), Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute of Environmental Health Science (NIEHS) including the National Toxicology Program, and other offices
- U.S. Department of Veterans Affairs (VA)
- National Aeronautics and Space Administration (NASA)
- National Toxic Tribal Council (NTTC)
- Office of Management and Budget (OMB)

EPA also engaged extensively with the Association of State Drinking Water Administrators (ASDWA) and five state partners recommended by the Environmental Council of the States (ECOS): Colorado, Michigan, Minnesota, New Hampshire, and Ohio.

Review Process

EPA discussed the assessment process, available data, and methods to be used to derive toxicity values (in this case, reference doses) for GenX chemicals and PFBS with the federal, tribal, and state partners. After external peer review, EPA also discussed the comments received and how EPA planned to address those comments with the partners.

EPA held additional detailed discussions with North Carolina's Department of Health and Human Services (DHHS) and Department of Environmental Quality (DEQ) to continue the agency's efforts to provide technical assistance as the state develops its own technical assessment for GenX chemicals for its Science Advisory Board (SAB) review. EPA also presented its available data and approaches to North Carolina's SAB.

Independent Peer Review

In June and July 2018, EPA conducted a contractor-led independent, external peer review of the initial draft assessments. The peer review panel included five experts in the areas of general risk assessment; benchmark dose modeling; liver, kidney, hematological, thyroid, immune, and reproductive and developmental toxicity; PFAS chemistry; and toxicity. In general, the peer reviews were favorable and

in each case the reviewers provided important feedback that is reflected in the draft toxicity assessments.

Next Steps

Following closure of the 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 the toxicity assessments.