

Commonwealth of Pennsylvania



DEPARTMENT OF
ENVIRONMENTAL PROTECTION

DEPARTMENT OF
HEALTH

January 18, 2019

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Office of Water
1200 Pennsylvania Avenue, N.W.
Mail Stop 4101M
Washington, DC 20460

Attention: Docket No. EPA-HQ-OW-2018-0614

Re: Human Health Toxicity Values for GenX Chemicals and PFBSs
83 FR 58768 (November 21, 2018)

Assistant Administrator Ross:

The Pennsylvania Departments of Environmental Protection (PADEP) and Health (PADOH) appreciate the opportunity to comment on the United States Environmental Protection Agency's (USEPA) 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 published on November 21, 2018 (83 FR 58768).

PADEP oversees and regulates more than 8,500 public water systems across Pennsylvania that serve drinking water to 11.3 million people. PADEP also oversees and regulates the cleanup of contaminated land in Pennsylvania. PADOH promotes healthy lifestyles, prevents injury and disease, and assures the safe delivery of quality health care of nearly 13 million residents.

PADEP and PADOH appreciate EPA's solicitation of comments as we continue to have serious concerns with per- and polyfluoroalkyl substances (PFAS). PADEP and PADOH are working in coordination with other members of Pennsylvania's PFAS Action Team to thoroughly identify, remediate, and mitigate the sources and environmental and health effects of PFAS contamination in the Commonwealth.

The Departments offer the following comments and recommendations:

1. In general, the draft toxicity assessment documents are clearly written. The documents have consolidated study results and integrated suitable evidence to support judgements of health hazards.
2. PADOH generally agrees with USEPA's decisions regarding the choices of critical studies, critical health effects, determination of a human equivalent dose using body weight scaling, benchmark dose modeling, and application of uncertainty factors. However, we do have the following comments about the adequacy of the uncertainty factor chosen:
 - a. Agencies apply uncertainty factors to account for any uncertainties encountered during the development of health threshold values. The greater the uncertainty factor applied, the lower and more protective the health threshold outcomes. In the development of chronic oral reference dose (RfD) for GenX chemicals, USEPA applied an uncertainty factor of 3 for database deficiencies, including immune effects and additional developmental studies. PADOH's opinion is that an uncertainty factor of 3 is not adequate to protect human health. PADOH recommends that an uncertainty factor/modifying factor of 10 be applied for database limitations/deficiencies (e.g., lack of data on known sensitive health effects such as the immune system). In fact, the Agency for Toxic Substances and Disease Registry (ATSDR) recently applied an uncertainty factor/modifying factor of 10 for the development of oral intermediate duration (15 to 364 days) Minimum Risk Levels (MRLs) for perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), and perfluorononanoic acid (PFNA) because of data limitations, but not for perfluorooctanoic acid (PFOA). For the development of intermediate oral MRLs, ATSDR considered immune effects as a more sensitive health effect. Also, recently ATSDR could not develop oral chronic MRLs for any of the PFAS chemicals such as PFOA, PFOS, PFHxS, and PFNA stating that "there are insufficient data for derivation of a chronic oral MRL."
 - b. GenX and PFBS are often found as a mixture with other PFAS in the environment. Based on the Nation Health and Nutrition Examination Survey data, the U.S. population is exposed to a variety of PFAS compounds. Many of the PFAS compounds have similar targets of toxicity. They are also generally associated with similar health effects but the degree of toxicity may be different. Therefore, it is possible that effects could be additive. Currently, USEPA has developed chronic oral RfDs for PFOA, PFOS, PFBS, and GenX chemicals but not for some other PFAS compounds which are present in the environment. Focusing on these chemicals without considering other PFAS is not adequate to protect drinking water supplies and the environment. A recent PADOH biomonitoring effort in Bucks and Montgomery counties supports the concept that populations are exposed to a variety of PFAS compounds simultaneously.

As such, we recommend that USEPA prioritize PFAS efforts that address multiple PFAS compounds holistically. We recommend that USEPA consider focusing on groups of PFAS compounds, rather than one compound at a time. This includes all efforts to develop toxicity values, reference doses, health advisory levels (HALs), or

regulatory maximum contaminant levels, as well as efforts to develop risk communication messaging.

3. USEPA should work collaboratively with ATSDR to:
 - a. Assess and determine if the current HAL for PFOA and PFOS is still adequate, or if the numerical value of the HAL needs to be revised.
 - b. Develop and deliver a clear and consistent public message regarding risks from PFAS, including consideration of messaging for special populations such as pregnant women, infants, breastfeeding mothers, children, immunocompromised and the elderly.
 - c. Develop consensus standards that can be used to support a regulatory determination for PFAS.
 - d. Develop guidance for state drinking water programs, public water systems, and the public regarding HALs, MRLs, toxicity values, and RfDs so that the public understands how the values are used. In the meantime, develop interim chronic oral MRLs for at least PFOA and PFOS until further studies become available.

Thank you for your consideration of these comments and recommendation. If you have questions, please feel free to contact Brian Chalfant, Deputy Policy Director in the PADEP Policy Office, by email at bchalfant@pa.gov or by telephone at 717-783-8073.

Sincerely,



Patrick McDonnell
Secretary
Pennsylvania Department of Environmental Protection



Dr. Rachel Levine
Secretary
Pennsylvania Department of Health