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Environmental Working Group Comments on the Environmental Protection Agency Human Health Toxicity Values for Hexafluoropropylene Oxide Dimer Acid and Its Ammonium Salt (GenX Chemicals) and Perfluorobutane Sulfonic Acid (PFBS) and Related Compound Potassium Perfluorobutane Sulfonate

Submitted to docket EPA-HQ-OW-2018-0614

The Environmental Working Group, a nonprofit research and policy organization with offices in San Francisco and Sacramento, Calif., Minneapolis, Minn., and Washington, D.C., welcomes the opportunity to provide comments to EPA on the proposed toxicity values for GenX chemicals and PFBS. We express our strong support for the EPA's continued efforts to assess the risks of per- and polyfluoroalkyl substances, or PFAS, and we urge the agency to adopt an expedited, comprehensive and action-based approach that would encompass the entire class of PFAS chemicals.

For 15 years EWG has researched the impact of PFAS chemicals on human health, communicated this information through public reports and the media, and advocated for more stringent measures to protect human health and the environment from PFAS pollution.

In the early 2000s, decades after the primary U.S. manufacturers of PFAS, 3M and DuPont, first learned about the toxicity concerns related to PFOA and PFOS, the EPA began assessing regulatory options for these chemicals. Now, two decades later, states, communities and elected officials are beginning to grasp the alarming extent of contamination by PFAS chemicals and their overall impact on health. Both academic and government-sponsored research on PFOA and PFOS have found these chemicals to be significantly more toxic than initially believed. In collaboration with scientists at Northeastern University, EWG has been educating the public on the extent of contamination by mapping known polluted sites across the country in an accessible online webpage.[1]

Initial findings about PFOA and PFOS are just the tip of the iceberg when it comes to PFAS contamination in drinking water. When Eurofins Eaton Analytical reanalyzed approximately 10,500 samples they previously tested from the third Unregulated Contaminant Monitoring Rule, but using a detection limit of 2.5 ng/L, they found PFOA or PFOS in nearly one out of every four samples. Additionally, PFBS was in nearly 12 percent of water samples, and a similar percentage of tested drinking water samples also had detectable PFHxS and PFHpA.

Extrapolating these results to the drinking water supply serving all Americans indicates that more than 100 million people may be consuming water containing PFAS.[2] This

estimated prevalence of PFAS in water confirms the biomonitoring data from the Centers for Disease Control and Prevention that finds PFAS chemicals in the bodies of nearly all Americans. Without their consent, Americans have been subject to decades of exposure to a wide array of PFAS chemicals and are effectively serving as test animals for the chemical industry.

The frequent co-occurrence of many PFAS contaminants indicates that a comprehensive toxicity assessment of PFAS risks to human health must evaluate exposure to PFAS mixtures. Treating the health risks of individual PFAS chemicals in isolation is inconsistent with the available science and fails to protect public health. For example, in blood testing of 345 participants in North Carolina, GenX was not detected above 2 parts per billion, or ppb, in any person, but three other PFAS compounds were detected in nearly all participants.[3] Thus, an absence of any specific PFAS chemical in the human body or an environmental medium is not an assurance of an absence of human and environmental health risk from PFAS pollution.

EWG provides the follow specific suggestions to the EPA:

1. Consider all PFAS chemicals together when assessing toxicity and risk, and commit to frequent and periodic updates of any evaluation.
2. Block any new PFAS chemicals from the market until complete toxicity testing information for these chemicals becomes available.
3. Use human exposure and epidemiological evidence and environmental co-occurrence data.
4. In assessing GenX and PFBS, use results from PFOA and PFOS to extrapolate uncertainty factors.
5. EPA should track use, occurrence and releases of PFAS and, with maps, make publicly available and accessible all information.

Our comments are provided in greater detail below.

1. **Consider all PFAS chemicals together when assessing toxicity and risk, and commit to frequent and periodic updates of this evaluation.**

EPA has already set a precedent for the class approach to PFAS but has been unnecessarily restrictive in defining the class. The criteria for defining the class should be expanded. In many instances, EPA has recognized a subset of PFAS to be a class of chemicals. Examples of EPA's class approach are found within the Significant New Use Rules for PFOS and PFOA and related compounds, which together include hundreds of specifically listed compounds as well as general formulaic specifications that define which other unlisted compounds would be considered in the group.[4] The 2016 EPA Health Advisory for PFOA and PFOS set a limit for the combined concentration based on

the biological systems they had the potential to impact. This approach should be applied across an expanded set of PFAS chemicals.

With the proposed toxicity assessments of GenX and PFBS, the EPA has now provided some public assessment of toxicity for four different PFAS compounds. According to a recent EPA report, 1,013 PFAS chemicals listed on the TSCA inventory are in active use.[5] Assuming no new PFAS chemicals have reached the market, that would mean just 1,009 toxicity assessments of active chemicals remain.

The single-chemical-by-single-chemical approach to assessing toxicity and setting regulations is untenable for PFAS compounds. All PFAS chemicals have a shared environmental persistence that create a legacy of contamination and will continue to complicate toxicity assessments in the future.[6] All humans across the globe are exposed to a mixture of PFAS from water, food and foodwares, dust, textiles, consumer products and various other sources. Developing toxicity assessments of and exposure regulations about this class of chemicals will more efficiently and effectively protect public health.[7] Independent scientists and other government agencies also advocate expanding the class approach to include shorter-chain PFAS.[8] A class-based approach that relies on extrapolating toxicity information from the most concerning member will also ensure that the chemical industry stop transitioning from one concerning chemical to another without providing substantiating data.

The body of scientific research on PFAS toxicity and exposure is growing on an annual basis, and a toxicity assessment without periodic reassessments will likely be out of date before the government review and publication are complete. EWG believes that it is imperative for the EPA to establish and follow a periodic review of the science and make appropriate adjustments to any toxicity assessment or risk management action.

2. **Block any new PFAS chemicals from the market until complete toxicity testing information for these chemicals becomes available.**

The EPA's draft GenX toxicity assessment reinforces a major concern of scientists – namely, the fact that a PFAS chemical that is *not* either PFOA or PFOS does not indicate that such a chemical is non-toxic or safe.[9] Specifically, for GenX, the EPA found that its internal toxicity is increased relative to PFOA, even though the bioaccumulation potential of GenX is lower. This finding calls into question the robustness of the earlier toxicity reviews of new PFAS chemicals allowed onto the market.

EPA has allowed hundreds of PFAS chemicals onto the market since 2004, and there is inadequate public information about their potential toxicity. In the absence of detailed testing results, the EPA should assume that any new PFAS has the potential to be as toxic as the most potent PFAS studied to date. New PFAS compounds without complete datasets should be barred from the market pending adequate testing.

3. **Use human exposure and epidemiological evidence and environmental co-occurrence data.**

Water testing in North Carolina completed by EPA and academic researchers found GenX, along with PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFBS, PFHS and PFOS. And at levels 100 times higher, PFMOAA, along with PFMOPrA, PFMOBA, PRO2HxA, PFO3OA, and PFO4DA, were also detected in the finished drinking water.[10] Subsequent human testing of more than 300 people in the area did not reveal GenX in blood but did find other PFAS compounds. When assessing human epidemiology studies of PFOA, the EPA stated that human studies had much greater uncertainties and could not be used to set a safe exposure level, in part because of discovering the presence of many different PFAS chemicals.

> *In addition, most of the subjects of the epidemiology studies have many PFASs and/or other contaminants in their blood. Although the study designs adjust for other potential toxicants as confounding factors, their presence constitutes a level of uncertainty that is usually absent in the animal studies.*[11]

By this same logic, it is unclear how a toxicity assessment of GenX alone can address the human health impacts of GenX and the related compounds that are released from production, or use when it is just one of many PFAS chemicals found in the environment, drinking water and people.

By disregarding relevant human epidemiological data, the health advisories for PFOA and PFOS published by the EPA in 2016 have presented a concerning precedent. EWG firmly believes that such human data should be used both to update those assessments with respect to setting a health-protective reference dose and drinking-water limits, and to fill data gaps within the assessments of GenX and PFBS.

The state of New Jersey reviewed and summarized 54 epidemiology studies about PFOA and 124 studies about PFOS[12] and associations between exposure and human health effects.[13] EPA also evaluated a significant number of epidemiology studies but, concerningly, the EPA determined that every human epidemiology study was inadequate for use in setting a safe exposure level.

Numerous studies on humans have found health impacts at levels detected both in contaminated communities and in the general population.[14] Yet the EPA set a health advisory level at 70 parts per trillion, or ppt, for PFOA and PFOS, a level that is three to five times more than the U.S. 95th percentile for exposure.[15] The reliance on animal testing for setting a safe exposure level for PFAS compounds is not adequately protective of health.

4. **In assessing GenX and PFBS, the results from PFOA and PFOS should be used to extrapolate uncertainty factors.**

An uncertainty factor of 3 in the draft GenX and PFBS toxicity assessments was added because of the lack of safety testing or "database deficiencies," but this factor of 3 does not sufficiently capture the full extent of PFAS toxicity as has been demonstrated for chemically related compounds, nor is it protective of human health. The EPA has asserted in the draft report that a single uncertainty factor of 3 could account for the absence of human epidemiological studies, the lack of testing of developmental and immunological toxicity, and the lack of a chronic mouse study and a full two-generation reproductive toxicity study, as well as other testing deficiencies identified by the agency. EWG disagrees with such a position and believes that a much greater safety/uncertainty factor should be applied for the risk assessment of PFAS chemicals.

As an illustration, PFOA and PFOS are more comprehensively studied than GenX, and in the past decade, research filling critical data gaps about toxicity has supported a reduction in guideline values of tenfold to a hundredfold or greater. The changes in relative reference dose levels calculated from recent studies on PFOA and PFOS as compared to studies from decades ago should be used to set uncertainty factors for data gaps in the GenX, PFBS and other PFAS assessments.

EWG urges the EPA to use, at a minimum, a safety factor of 10 for GenX and PFBS, and recommends the agency review what we have learned from PFOA and PFOS in recent studies in comparison with previously assumed safety factors. The agency should also revaluate the use of these safety factors if future scientific research supports a need for an even greater safety factor, especially for children's health protection from this family of toxic chemicals.

5. **EPA should track use, occurrence and releases of all PFAS and make publicly available and accessible all information with maps.**

The public is clamoring for information about the extent of PFAS toxicity, use and contamination, and the EPA has the capacity to collect and disseminate information about where these chemicals have and are being used and are known or suspected to have been released, and all contamination detected in both ground and drinking water. This information should be publicly accessible and, when possible, available in map form. A national resource on PFAS toxicity, use and occurrence in the environment would give states, academic researchers and the public the opportunity to access their impacts, conduct research and make more informed decisions. This process should be initiated by listing and mapping all locations that have used or potentially released as a byproduct GenX or PFBS, and all monitoring samples that have detected these contaminants.

Conclusion

PFAS contamination is a national crisis that is continuing to expand in size as more water systems and communities test positive for these chemicals. PFAS chemicals are ubiquitous in people, the environment and products found around the home, yet the full health consequences of exposure to this cocktail are not understood. What we do know is that a few of these compounds have the capacity to harm health at the low part per trillion level, and EPA must take action now to safeguard health. EPA has taken on the important task of assessing the specific toxicity of GenX and PFBS but should expand its assessment to include the entire class of PFAS chemicals.

Submitted on behalf of the Environmental Working Group

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