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Environmental Working Group Comments on the Agency for Toxic Substances and Disease Registry (ATSDR) Draft Toxicological Profile for Perfluoroalkyls

Submitted to docket ATSDR-2015-0004

The Environmental Working Group, a nonprofit research and policy organization with offices in San Francisco and Sacramento, Calif., Minneapolis, Minn., and Washington, DC., is pleased to provide comments on the ATSDR 2018 draft Toxicological Profile for perfluoroalkyls. We express our support for the ATSDR's in-depth assessment, and we urge the Agency to go further in establishing more health-protective guidelines. We support the derivations of Minimal Risk Levels, or MRLs, for PFNA and PFHxS and the further development of MRLs for additional chemicals, but to be health protective, the agency must consider exposure to the entire class of chemicals known as PFAS (per- and polyfluoroalkyl substances). In setting a safe exposure level, the agency should utilize human epidemiological evidence of health impact when available.[1]

After decades-long use and unchecked disposal of PFAS chemicals into the environment, this class of contaminants is now found in nearly all Americans' bodies, in the water supplies serving an estimated 110 million Americans, and in different foods and consumer products to which these chemicals are either intentionally added or unintentionally contaminated. Scientists and health advocates have sounded the alarm about this widespread contamination and a growing number of peer-reviewed scientific reports find that PFAS chemicals may cause health harm at levels found the bodies of people today.[2]

Since 2004, EWG has researched the health impacts of PFAS chemicals and advocated for strict limits for human exposure to these persistent contaminants. A map developed by EWG and the Social Science Environmental Health Research Institute at Northeastern University documents 172 known PFAS contamination sites in 40 states across the country, and the numbers keep growing, indicating that more and more communities will be seeking science-based guidance on health-protective limits for PFAS chemicals.[3]

We consider ATSDR's updated guidelines for perfluoroalkyls an essential step in the right direction, albeit a step that does not go far enough. These MRLs will provide vital information to government health and environmental agencies, public health professionals, and concerned individuals, improving their ability to assess environmental conditions and determine when pollution remediation may be necessary.

However, ATSDR has only proposed MRLs for 4 perfluoroalkyl substances: perfluorohexane sulfonic acid (PFHxS); perfluorooctanoic acid (PFOA); perfluorooctane

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sulfonic acid (PFOS); and perfluorononanoic acid (PFNA). Yet, as research shows, the long-chain PFAS chemicals have been replaced by shorter-chain PFAS chemicals, which in some areas are becoming the dominant type of PFAS exposure.[4] Therefore, establishing health guidance for the entire PFAS class is essential, and EWG comments present a framework for how such an approach can be developed.

1. Long-chain PFAS chemicals are demonstrated to cause health harm
2. Short-chain alternatives such as GenX present similar human health concerns
3. Only a class approach can tackle the health risks of PFAS

Details and rationale for our recommendations are provided below

1. Long-chain PFAS chemicals demonstrated to cause health harm

The extensive body of research documented by ATSDR and other agencies demonstrates adverse health effects of long-chain PFAS chemicals including developmental effects to fetuses during pregnancy and to breastfed infants, (low birthweight, accelerated puberty, skeletal variations), cancer (testicular, kidney), liver effects (tissue damage), immune effects, thyroid effects and changes to cholesterol levels. The latest research has shown that at exposure levels commonly found in humans, there is evidence of the reduced effectiveness of vaccines as well as effects on the human reproductive system and on the developing fetus.

ATSDR defines minimal risk levels as estimates of "the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure." When translated to drinking water-specific concentrations following the EPA's methodology, ATSDR's updated MRLs for PFOA and PFOS are an order of magnitude lower than the drinking water advisories published by the EPA in 2016.[5]

Recent studies on human tissue found PFAS in liver, thyroid and brain tissues, indicating long-term persistence in the body and possible bioaccumulation not previously evaluated by prior studies that focused only on blood serum levels. Recent research raises significant concern about variation in organ and tissue distribution of PFAS chemicals with shorter chain length chemicals accumulating to higher levels in some organs. Together, these findings highlight how little is known about possible biopersistence in organs and distribution of PFAS chemicals in humans and the ability of PFAS chemicals to persist in the body to levels that may cause harm even in their short-chain iterations.

2. **Replacement alternatives present human health concerns**

GenX, a PFOA alternative originally brought to market by DuPont in 2009, is one of the few examples of a shorter-chain chemical with disclosed safety information.[6] Based on implications that GenX molecules "will persist in the environment, could bioaccumulate, and be toxic to people," the EPA restricted GenX use pursuant to EPA Consent Order PMN P-08-509. EPA supported this assessment based on data on the substances, and analogy to other chemicals – including PFOA and PFOS – with concerning expectations of environmental persistence and bioaccumulation. Additionally, EPA stated a high expectation of human health concerns due to the structural similarities to PFOA and PFOS and likely absorption through "all routes of exposure."[7]

The consent order required the company to file chemical substantial risk notices under Section 8(e) of the Toxic Substances Control Act (TSCA). These notices, submitted to the EPA between April 2006 and January 2013, cite numerous health effects in animals including changes in the size and weight of animals' livers and kidneys, alterations to their immune responses and cholesterol levels, weight gain, reproductive problems and cancer. DuPont largely represented these risks as inapplicable to human exposure based on limited information on bioaccumulation rates and the high dosage levels utilized in the studies, however, independent evaluations counter the manufacture's conclusion.

3. EWG urges ATSDR to develop a class approach for PFAS chemicals

Considering that exposure to perfluoroalkyls comes from multiple sources including food, water, materials that contact food, textiles and additional consumer products and that we are exposed to more than one type of PFAS chemicals from these sources, assessments should reflect the impacts of exposure to this entire class of chemicals. Developing MRLs for a class of chemicals with similar persistence and functionality will more efficiently protect public health.

Current public information regarding bioaccumulation of PFAS chemicals gives an incomplete picture because these compounds do not completely degrade and new PFAS chemicals continue to enter the market. 'Safe levels' indicated by individual manufacturing practices and end products do not accurately account for the potential cumulative and aggregate impact of total exposures. As described by one recent study:

> Even those fluorinated alternatives that are considered safe because of low acute toxicity and bioaccumulation…short-chain PFCA and PFSA homologues such as PFHxA and PFBS are persistent in the environment as the long chain homologues...[t]hus…these chemicals and their potential precursors will lead to increasing widespread environmental and human exposure that will last for the foreseeable future.[8]

Even though some PFAS chemicals may partially degrade in the environment over time, they will all ultimately transform into highly stable end products, typified by persistent perfluoroalkyl or perfluoroalkyl(poly)ether acids that pollute people's bodies.

Industry continues to replace the phased-out long-chain PFAS chemicals with other structurally similar PFAS chemicals. There are an estimated 3000 to 5000 PFAS chemicals on the global market, many unidentified in products. Collectively, these chemicals have very little publicly available safety information.[9,10] Using government resources to test and regulate each individual compound would be extremely inefficient and likely ineffective given current market practices. Scientists are increasingly calling for a class approach in regulating PFAS chemicals.[11]

Government agencies are also acknowledging the need to assess and manage PFAS chemicals as a class. The Swedish Chemicals Agency (KEMI) concluded in 2016, "The lack of knowledge on how PFASs are used and their toxicity makes it difficult to estimate the degree of exposure and the risks that PFASs pose to humans and the environment. Therefore, it is our opinion that PFASs should be assessed and managed broadly as a group."[12] The Danish Ministry of Environment released a report on a comprehensive review of human health and environmental fate of the class of short-chain PFAS chemicals. The goal of the report was to fill data gaps on the class of short-chain alternatives and to support the Danish EPA's strategy for the substance group to provide documentation for possible regulations.[13]

In summary, these considerations support assessment of PFAS chemicals as a group – including the shorter chain alternatives – due to their extensive use, under-evaluated risks, nearly universal human exposure, and lack of reasonable certainty that these substances are not harmful under their current conditions of use.

Conclusion

EWG supports the Agency's inclusion of recent emerging science on perfluoroalkyls in the draft Toxicological Profile and in the derivation of MRLs. The agency should be more protective of public health by utilizing human evidence of harm at 'background levels' and by expanding the scope of the PFAS assessment to include the whole chemical class. The science of PFAS exposure and toxicity is rapidly progressing and showing human health impacts at levels commonly detected in people's bodies. As more research emerges about the toxicity of this entire class of chemicals, ATSDR and other government agencies should amend standards according to the most up-to-date information to ensure standards are adequately protective of health.

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[1] P. Grandjean. Delayed discovery, dissemination, and decisions on intervention in environmental health: a case study on immunotoxicity of perfluorinated alkylate substances. Environmental Health 2018, 17:62.
[2] P. Grandjean and R. Clapp. Perfluorinated Alkyl Substances: Emerging Insights into Health Risks. NEW SOLUTIONS: A Journal of Environmental and Occupational Health Policy 2015, 25(2): 147-63.
[3] B. Walker. Update: Mapping the Expanding PFAS Crisis. Available at www.ewg.org/research/update-mapping-expanding-pfas-crisis
[4] M. Sun, E. Arevalo, M. Strynar, A. Lindstrom, M. Richardson, B. Kearns, A. Pickett, C. Smith, and D.R.U. Knappe. Legacy and Emerging Perfluoroalkyl Substances Are Important Drinking Water Contaminants in the Cape Fear River Watershed of North Carolina. Environmental Science & Technology Letters 2016, 3 (12): 415-419
[5] www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos
[6] www.documentcloud.org/documents/2746960-GenX8eFilings.html
[7] www.documentcloud.org/documents/2746607-Sanitized-Consent-Order-P08-0508-and-P08-0509.html
[8] Z. Wang, I.T Cousins, M. Scheringer, and K. Hungerbuhler. Fluorinated alternatives to long-chain perfluoroalkyl carboxylic acids (PFCAs), perfluoroalklane sulfonic

acids (PFSAs) and their potential precursors. Environment International 2013, 60:242-248.

[9] Wang et al, *A never ending story of per-and polyfluoroalkyl substances (PFASs)?,* Environ. Sci. Technol. 2017, 51, 2508-2518

[10] Organization for Economic Co-operation and Development. (2018) Toward a New Comprehensive Global Database of Per-and Polyfluoroalkyl Substances (PFASs): Summary Report on Updating the OECD 2007 List of Per- and Polyfluoroalkyl Substances (PFASs). Series on Risk Management, No. 39. ENV/JM/MONO(2018)7

[11] Blum et al. The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs) Environ. Health Perspectives 2015. ehp.niehs.nih.gov/1509934/

[12] Swedish Chemicals Agency KEMI. Strategy for reducing the use of highly fluorinated substances PFASs. 2016. www.kemi.se/global/rapporter/2016/report-11-16-strategy-for-reducing-the-use-of-higly-fluorinated-substances-pfas.pdf

[13] Danish Ministry of the Environment. Short-chain Polyfluoroalkyl Substances (PFAS) 2015. www2.mst.dk/Udgiv/publications/2015/05/978-87-93352-15-5.pdf