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ENVIRONMENTAL PROTECTION AGENCY

[FRL 9855-01-OW]

Lifetime Drinking Water Health Advisories for Four Perfluoroalkyl Substances (PFAS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) announces the release of health advisories for four perfluoroalkyl substances (PFAS), including interim updated lifetime drinking water health advisories for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), and final health advisories for hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt (together referred to as “GenX chemicals”) and perfluorobutane sulfonic acid and its related compound potassium perfluorobutane sulfonate (together referred to as “PFBS”). EPA’s health advisories, which identify the concentration of chemicals in drinking water at or below which adverse health effects are not anticipated to occur, are: 0.004 parts per trillion (ppt) for PFOA, 0.02 ppt for PFOS, 10 ppt for GenX chemicals, and 2,000 ppt for PFBS. Health advisories are non-regulatory and reflect EPA’s assessment of the best available peer-reviewed science. The interim updated health advisories for PFOA and PFOS supersede EPA’s 2016 health advisories for PFOA and PFOS.

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SUPPLEMENTARY INFORMATION:

I. What are PFAS, and specifically, what are PFOA, PFOS, GenX chemicals, and PFBS?

PFAS are a large and diverse structural family of compounds used in myriad commercial applications due to their unique properties, such as resistance to high and low temperatures, resistance to degradation, and nonstick characteristics. Although PFAS have been manufactured and used broadly in commerce since the 1940s, particular concern over potential adverse effects on human health grew in the early 2000s with the discovery of PFOA and PFOS in human blood. Since that time, hundreds of PFAS have been identified in water, soil, and air. Many PFAS are environmentally persistent, bioaccumulative, and have long half-lives in humans, particularly the longer-chained carbon species such as PFOA and PFOS. Most uses of PFOA and PFOS were phased out by U.S. manufacturers in the mid-2000s although there are a limited number of ongoing uses. In addition, some currently used PFAS break down into PFOA and PFOS in the environment. PFAS with fewer carbon atoms, such as GenX chemicals and PFBS, were subsequently developed to replace PFOA and PFOS, respectively, and integrated into various consumer products and industrial applications because they have the desired properties and characteristics associated with this class of compounds but are more quickly eliminated from the human body than PFOA and PFOS.

II. What health effects are associated with exposure to PFOA, PFOS, GenX chemicals, and PFBS?

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The interim updated health advisories for PFOA and PFOS are based on human epidemiology studies in populations exposed to these chemicals. Human studies have found associations between PFOA and/or PFOS exposure and effects on the immune system, the cardiovascular system, human development (e.g., decreased birth weight), and cancer. The most sensitive non-cancer effect and the basis for the interim updated health advisories for PFOA and PFOS is suppression of vaccine response (decreased serum antibody concentrations) in children. While there is evidence that PFOA is likely to be carcinogenic to humans, EPA has not derived a cancer risk concentration in water for PFOA at this time. There is suggestive evidence of carcinogenic potential of PFOS in humans. Cancer analyses are ongoing for both PFOA and PFOS.

EPA's final health advisories for GenX chemicals and PFBS are based on animal toxicity studies following oral exposure to these chemicals. GenX chemicals have been linked to health effects on the liver, the kidney, the immune system, and developmental effects, as well as cancer. The most sensitive non-cancer effect and the basis for the final health advisories for GenX chemicals is a liver effect (constellation of liver lesions). There is suggestive evidence of carcinogenic potential of oral exposure to GenX chemicals in humans, but data are insufficient to derive a cancer risk concentration in water for GenX chemicals at this time. Animal studies following oral exposure to PFBS have shown health effects on the thyroid, reproductive organs and tissues, developing fetus, and kidney following oral exposure. The most sensitive non-cancer effect and the basis for the final health advisory for PFBS is a thyroid effect (decreased serum total thyroxine). There are no known studies evaluating potential cancer effects of PFBS and so the potential for cancer effects after PFBS exposure could not be evaluated.

III. What are Drinking Water Health Advisories?

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Under the Safe Drinking Water Act, EPA may publish health advisories for contaminants that are not subject to any national primary drinking water regulation. 42 U.S.C. 300g-1(b)(1)(F)). EPA develops health advisories to provide information on the chemical and physical properties, occurrence and exposure, health effects, quantification of toxicological effects, other regulatory standards, analytical methods, and treatment technology for drinking water contaminants. Health advisories describe concentrations of drinking water contaminants at which adverse health effects are not anticipated to occur over specific exposure durations (e.g., one-day, ten-days, and a lifetime). Health advisories serve as technical information to assist Federal, state and local officials, as well as managers of public or community water systems in protecting public health. They are not regulations and should not be construed as legally enforceable Federal standards. Health advisories may change as new information becomes available.

IV. What are EPA’s Interim Health Advisories for PFOA and PFOS?

EPA is releasing interim updated health advisories for PFOA and PFOS based on data and draft analyses that indicate that the levels at which negative health effects could occur are much lower than previously understood when the agency issued its 2016 health advisories for PFOA and PFOS (70 parts per trillion or ppt). Human studies have found associations between PFOA and/or PFOS exposure and effects on the immune system, the cardiovascular system, development (e.g., decreased birth weight), and cancer. These data and draft analyses, which were released publicly in November 2021, are currently undergoing EPA Science Advisory Board (SAB) review. EPA is concerned about the public health implications of these preliminary findings and is therefore issuing interim updated health advisories for PFOA and PFOS. The interim updated health advisories for PFOA and PFOS are 0.004 ppt and 0.02 ppt, respectively. The interim updated health advisories replace the 2016 final health advisories for PFOA and

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PFOS which were both set at 70 ppt. EPA is reviewing and will respond to the SAB comments as the Agency moves forward to develop Maximum Contaminant Level Goals (MCLGs) to support the Safe Drinking Water Act National Primary Drinking Water Regulation for PFOA and PFOS, which is expected to be proposed later this year.

V. What are EPA’s Final Health Advisories for GenX Chemicals and PFBS?

EPA is also releasing final health advisories for GenX chemicals and PFBS for the first time, based on EPA’s 2021 final toxicity assessments for these PFAS. In chemical and product manufacturing, GenX chemicals are considered a replacement for PFOA, and PFBS is considered a replacement for PFOS. Animal toxicity studies following oral exposure to GenX chemicals have reported health effects in the liver, kidney, immune system, development, as well as cancer. For PFBS, animal studies have reported health effects on the thyroid, reproductive system, development, and kidney following oral exposure. The final health advisories for GenX chemicals and PFBS are 10 ppt and 2,000 ppt, respectively.

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