

Drinking Water Health Advisories (HAs) for Per- and Polyfluoroalkyl Substances (PFAS)

Briefing for the National Drinking Water Advisory Council

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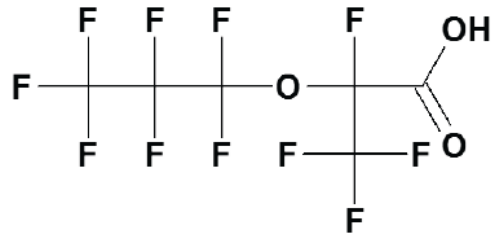
Background

- The Safe Drinking Water Act (SDWA) authorizes EPA to develop drinking water Health Advisories (HAs).
- HAs are *non-regulatory* concentrations of drinking water contaminants that are defined as a level of drinking water contaminant concentration for a specific exposure duration, at or below which exposure is not anticipated to lead to adverse human health effects.
- HAs can be developed more rapidly than SDWA regulations when concerns arise about drinking water quality.
- There are currently over 200 HAs that provide states/tribes and drinking water utilities technical information on health effects, analytical detection methods, and treatment technology.
- EPA is currently developing Final HAs for **GenX chemicals** and **PFBS**, which we expect to publish in Spring 2022, as stated in the PFAS Strategic Roadmap.
- In November 2021, EPA committed to updating the HAs for **PFOA** and **PFOS** as quickly as possible, in light of new data and the agency's draft health effects analyses developed to support the SDWA National Primary Drinking Water Regulation.

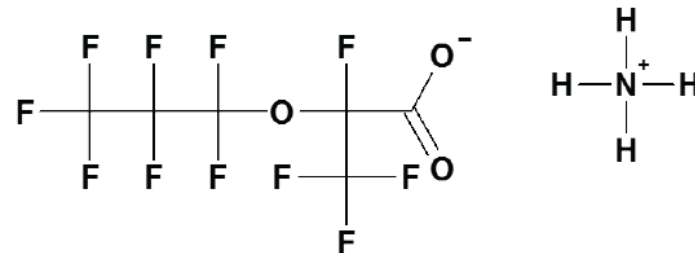
GenX Chemicals and PFBS

GenX Chemicals – Background

- GenX is a trade name for a processing aid technology used to make high-performance fluoropolymers without the use of PFOA. Hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt are the major chemicals associated with the GenX processing aid technology.
- Products that used to be made using PFOA may now rely on GenX chemicals. According to the Chemours Company, fluoropolymers have “countless” industrial applications, including in the medical, automotive, electronics, aerospace, energy, and semiconductor industries.
- GenX chemicals have been found in surface water, groundwater, drinking water, rainwater, and air emissions.



HFPO dimer acid
CASRN 13252-13-6



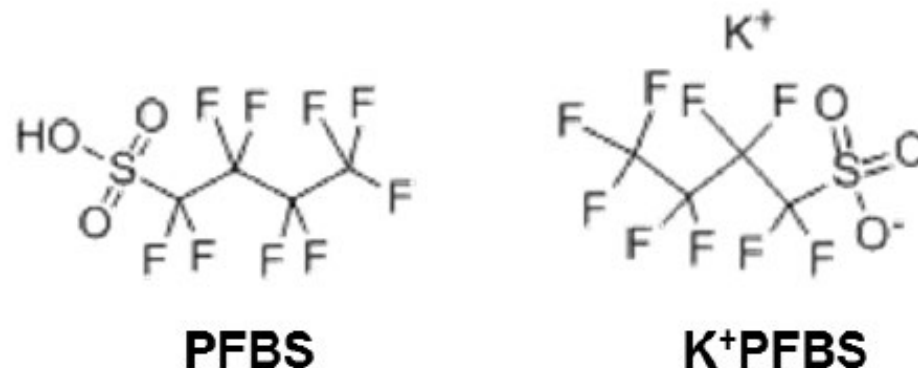
HFPO dimer acid ammonium salt
CASRN 62037-80-3

GenX Chemicals – Health Effects and HA

- Final HA will be based on EPA's 2021 final toxicity assessment for GenX chemicals:
 - Animal toxicity studies following oral exposure to GenX chemicals have found health effects on the liver, the kidney, the immune system, and developmental effects, as well as cancer.
 - The liver appears to be particularly sensitive after oral exposure to GenX chemicals.
 - Chronic **RfD is 3×10^{-6} mg/kg/day** based on critical liver effects (constellation of liver lesions as defined by the National Toxicology Program Pathology Working Group) in parental female mice exposed to HFPO dimer acid ammonium salt by gavage for 53–64 days.
 - Suggestive evidence of carcinogenic potential of oral exposure to GenX chemicals in humans.

PFBS - Background

- Perfluorobutane sulfonic acid and its related compound potassium perfluorobutane sulfonate (PFBS) is a replacement chemical for PFOS, which was voluntarily phased out by the primary U.S. manufacturer by 2002.
- PFBS-based compounds are surfactants used primarily in the manufacture of paints, cleaning agents, and water- and stain-repellent products and coatings.
- PFBS has been identified surface water, wastewater, drinking water, dust, and a variety of consumer products.



PFBS – Health Effects and HA

- Final HA will be based on EPA’s 2021 final toxicity assessment for PFBS:
 - 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 thyroid appears to be particularly sensitive to oral PFBS exposure.
 - Chronic RfD is **3×10^{-4} mg/kg/day** based on critical effect of decreased serum total thyroxine (T4) in newborn (postnatal day (PND) 1) mice.
 - 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.

PFOA and PFOS

Previous and **Current Uses:** Industrial and Consumer Products

Perfluorooctanoic Acid (PFOA)

- Cooking surfaces
- **Fire fighting foams**
- Toothpaste, shampoos, cosmetics
- Semiconductor industry
- Polishes and waxes
- Electronics
- **Lubricants/surfactants/emulsifiers**
- Pesticide
- Plumbing tape
- Food containers and contact paper
- Textiles and leather
- Paints, varnishes, sealants
- Cleaning products
- And more...

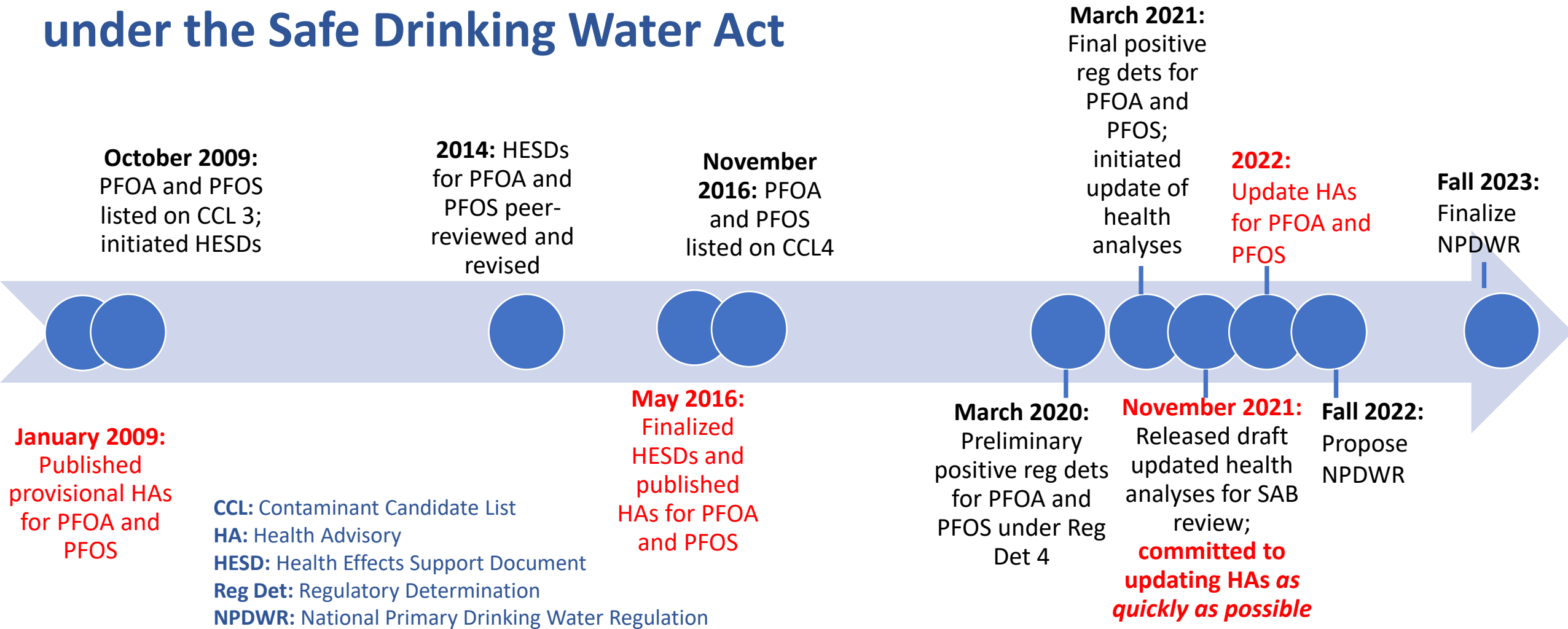
NOTE: GenX chemicals replaced PFOA

Perfluorooctane Sulfonic Acid (PFOS)

- **Metal plating and finishing**
- **Fire fighting foams**
- **Photograph development**
- Semiconductor industry
- **Aviation fluids**
- Flame repellants
- Packaging papers
- Oil and mining
- Stain repellants on carpets and upholstery
- Cleaning products
- Paints, varnishes, sealants
- Leathers, textiles
- And more...

NOTE: PFBS replaced PFOS

EPA's Assessment of PFOA and PFOS under the Safe Drinking Water Act



Draft Health Effects Analyses for PFOA and PFOS

- EPA is conducting extensive evaluations of human epidemiological and experimental animal study data to support the SDWA National Primary Drinking Water Regulation for PFOA and PFOS.
- In November 2021, EPA released draft updated health effects analyses for Science Advisory Board review.
 - EPA evaluated over 400 studies published since 2016 and used new approaches, tools, and models.

	PFOA	PFOS
# of new animal tox studies	25 relevant studies	29 relevant studies
# of new human epi studies	350 relevant studies	338 relevant studies
# of new cancer studies – epi; tox	13 (8 medium or high quality); 1	11 (8 medium or high quality); 0
Health effects observed	immune, developmental, cardiovascular, hepatic, reproductive, nervous, endocrine, and metabolic effects and cancer	immune, developmental, cardiovascular, reproductive, endocrine, metabolic, and hepatic effects and cancer
# of new PK or PBPK studies	44 relevant studies	37 relevant studies

Draft Health Effects Analyses for PFOA and PFOS

- EPA's November 2021 draft analyses indicate that the levels at which negative health effects could occur are likely **much lower** than previously understood when EPA issued the EPA's 2016 HAs for PFOA and PFOS (70 parts per trillion or ppt) – including near zero for certain health effects.
 - EPA's 2021 draft noncancer reference doses (RfDs) based on human epidemiology studies for various effects (e.g., developmental/growth, cardiovascular health outcomes, immune health) range from $\sim 10^{-7}$ to 10^{-9} mg/kg/day, **two to four orders of magnitude lower** than the 2016 RfDs of 2×10^{-5} mg/kg/day.
 - In addition, PFOA is a likely carcinogen (cancer-causing agent) and PFOS is a suggestive carcinogen.

Additional PFAS

PFAS IRIS Assessments

- EPA will prioritize HA development for PFAS with IRIS assessments under development:

Chemical	Public Product(s)/Activity	Projected Date
Perfluorobutanoic Acid (PFBA)	External Peer Review	February 22-23, 2022
Perfluorodecanoic Acid (PFDA)	Public Comment Draft Release External Peer Review	FY23 Q1 FY23 Q2
Perfluorohexanoic Acid (PFHxA)	External Peer Review	FY22 Q3
Perfluorohexanesulfonic Acid (PFHxS)	Public Comment Draft Release External Peer Review	FY23 Q2 FY23 Q2
Perfluorononanoic Acid (PFNA)	Public Comment Draft Release External Peer Review	FY23 Q2 FY23 Q3

Source: EPA IRIS Program Outlook (February 2022)



QUESTIONS ?