

PFAS — Technical Information and Supporting Documentation

Per- and polyfluoroalkyl substances (PFAS) are a group of manmade chemicals applied to consumer goods to make them waterproof, stain resistant, or nonstick. PFAS are used in numerous products including cosmetics, fast food packaging, and firefighting foam. PFAS have been used globally since the 1950s in manufacturing, firefighting, and common household products. PFAS are considered to be “contaminants of emerging concern”, meaning that research into the harm they may cause to human health is still ongoing.

While there are thousands of substances in the PFAS family, detection methods, toxicity studies, and toxicity determinations by government agencies are only available for a limited number. The Ohio Environmental Protection Agency (EPA) and Ohio Department of Health (ODH) took these limitations into account when developing the Action Levels in the *Ohio PFAS Action Plan for Drinking Water*. The purpose of this document is to present the technical information and supporting documentation that explain the decisions presented in the Ohio PFAS Action Plan for Drinking Water. Per Objective 6 of the plan, the agencies will ensure the plan is adapted as science and the national regulatory framework unfolds.

Selected PFAS

Ohio EPA and ODH have included six PFAS in the Ohio PFAS Action Plan. These compounds have been detected in Ohio drinking water during monitoring conducted for the third Unregulated Contaminant Monitoring Rule (UCMR) or during C8/perfluorooctanoic acid (PFOA) epidemiological testing conducted outside Parkersburg, West Virginia. Each of the six PFAS have also had robust toxicity determinations by authoritative government bodies, such as U.S. EPA, the Agency for Toxic Substances and Disease Registry (ATSDR), or in the case of hexafluoropropylene oxide dimer acid and its ammonium salt (commonly known as GenX), the state of North Carolina. The chemicals included in Ohio’s PFAS Action Plan are: PFOA, perfluorooctane sulfonate (PFOS), GenX, perfluorobutane sulfonic acid (PFBS), perfluorohexane sulfonic acid (PFHxS) and perfluorononanoic acid (PFNA).

Ohio’s PFAS Action Levels

The Ohio PFAS Action Levels are not boundaries between “safe” and “dangerous” levels of these six chemicals in drinking water. Rather, Ohio is establishing conservative action levels that represent the concentrations of these six PFAS at which no adverse, non-cancer health effects would be anticipated for the most sensitive populations. The toxicity data used to derive Ohio’s PFAS Action Levels consider noncarcinogenic toxic effects of the chemicals, including their developmental and reproductive toxicity; therefore, they do not include potential for genotoxic or carcinogenic effects due to lack of available toxicity determinations for cancer. The toxicity values for the specific PFAS are referred to as reference doses (RfDs) expressed in milligrams per kilogram body weight per day (mg/kg-day). Thresholds are based on these RfDs and were calculated using the equation below, resulting in the action level concentrations of PFAS in drinking water as nanogram/liter (ng/L) or parts per trillion (ppt).

$$\text{Action Level (ng/L)} = \frac{\text{RfD} \times \text{BW}}{\text{DWI}} \times \text{CF} \times \text{RSC}$$

RfD = reference dose (mg/kg-day)

BW = body weight (kg)

DWI = daily water intake (L/day)

CF = conversion factor (mg to ng)

RSC = relative source contribution (unitless)

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PFOA and PFOS Ohio Action Levels

The Ohio Action Levels for PFOA and PFOS are the U.S. EPA lifetime exposure duration health advisory levels (HALs) of 70 ng/L for each compound, or as a combined total when both are present. Because the toxic effects for PFOA and PFOS are based on similar developmental effects and are numerically identical, when these chemicals co-occur at the same time and location in a drinking water source, U.S. EPA recommends comparing the sum of the concentrations of PFOA and PFOS to the HAL (U.S. EPA, 2016a) (U.S. EPA, 2016b). U.S. EPA defines a lifetime HAL as the concentration in drinking water that is not expected to cause any adverse noncarcinogenic effects over a lifetime of exposure. U.S. EPA develops HALs to serve as technical information for unregulated drinking water contaminants to assist federal, state and local officials, and managers of public or community drinking water systems in protecting public health (U.S. EPA, 2018a). Toxicity and exposure parameters used to develop the U.S. EPA PFOA and PFOS HALs and the Ohio Action Levels were calculated using exposure parameters for lactating women, who drink more water than other populations and can pass these chemicals to the most sensitive populations. Table 1 below presents the parameters used in the Action Level Equation above for the U.S. EPA HALs for PFOA and PFOS and the Ohio Action Levels.

Table 1. Toxicity and Exposure Parameters used to Develop Ohio Action Levels for PFOA and PFOS

Parameters*	PFOA	PFOS
Toxicity Reference Dose (Rfd) (mg/kg/day)	0.00002	0.00002
Adult Body Weight (BW) (kg)	70	70
Daily Water Intake for Lactating Women (DWI) (L/day)	4	4
Conversion Factor (CF) (mg/L to ng/L)	1,000,000	1,000,000
Relative Source Contribution** (RSC)	0.2	0.2
Ohio Action Levels (ng/L (ppt))	70	70

* All toxicity and exposure parameters for PFOA and PFOS are obtained from U.S. EPA Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA) (U.S. EPA, 2016b) and U.S. EPA Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS) (U.S. EPA, 2016a).

**Relative Source Contribution (RSC) is an estimate that drinking water contributes 20% of total exposure to PFOA and PFOS. Other sources contributing 80% of exposure to PFOA and PFOS include but are not limited to air, foods, incidental soil/dust ingestion, and consumer products (U.S. EPA, 2016b) (U.S. EPA, 2016a).

GenX, PFBS, PFHxS and PFNA Ohio Action Levels

In the absence of established U.S. EPA regulatory limits for PFAS, the Ohio Action Levels for GenX, PFBS, PFHxS and PFNA were calculated using Ohio EPA and ODH recommended toxicity RfDs and exposure parameters in Table 2. The RfDs were selected following the Ohio EPA toxicity hierarchy (Ohio EPA, 2010) that ranks which resources should be followed for contaminants without formally developed toxicity values. The action level for PFBS is based on the U.S. EPA, Office of Research and Development (ORD) Provisional Peer Reviewed Toxicity Values (PPRTV), which establishes a provisional RfD that is likely to be without deleterious effects over a lifetime of exposure (U.S. EPA, 2014). The action levels for PFHxS and PFNA are based on the peer-reviewed, provisional minimal risk levels (MRLs) from the ATSDR Toxicological Profile for Perfluoroalkyls Draft for Public Comment (2018). MRLs are RfD estimates of the amount of a chemical a person can eat, drink, or breathe each day without a detectable risk to health. In this case, the Ohio Action Levels for PFHxA and PFNA are based on concentrations that are safe for sensitive populations to drink for up to one (1) year (intermediate exposures) (ATSDR, 2018). For GenX, the threshold value was calculated to protect against a lifetime of exposures based on the State of North Carolina's Updated Risk Assessment for GenX (North Carolina Department of Health and Human Services, 2017).

The Ohio Action Levels for GenX, PFBS, PFHxS and PFNA were calculated using the U.S. EPA Drinking Water Equivalent Level (DWEL) approach. The main distinction between a HAL calculation and a DWEL calculation is the use of different relative source contribution (RSC) factors. U.S. EPA assumes a RSC of 20% (0.2) for HALs, which takes into account exposures to the contaminant from sources other than drinking water, and assumes 100% (1) for DWEL calculations, which considers all of the exposure to the contaminant is from drinking water (ATSDR, 2005). The DWEL equation was used because there is a lack of established U.S. EPA regulatory limits for these compounds. The DWEL calculation is equivalent to an ATSDR Environmental Media Evaluation Guide (EMEG) calculation (ATSDR, 2005).

The Ohio Action Levels for GenX, PFBS, PFHxS, and PFNA use conservative exposure parameters (i.e., body weight and drinking water intake for an infant). Ohio EPA and ODH considered using the HAL approach with an adult default body weight (70 kg adult) and default daily drinking water intake (2 L/day) and a relative source contribution (RSC) of 20%

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per the U.S. EPA Office of Water Drinking Water Standards and Health Advisories Tables (U.S. EPA, 2018a) when developing these Action Levels. However, the HAL calculation using the adult default exposure parameters and the 20% RSC was essentially equal to the DWEL calculation using infant exposure parameters. Therefore, Ohio EPA and ODH used the infant, 0 to 1 year old, exposure parameters and DWEL equation to calculate Ohio Action Levels to characterize and communicate very conservative estimates of risk to children’s health for GenX, PFBS, PFHxS and PFNA. Table 2 below presents the toxicity and exposure parameters used in Action Level Equation for the Ohio PFAS Action Levels in drinking water.

Table 2. Toxicity and Exposure Parameters used to Develop Ohio Action Levels for GenX, PFBS, PFHxS and PFNA

Parameters	GenX****	PFBS****	PFHxS	PFNA
Toxicity Reference Dose (RfD) (mg/kg/day)*	0.0001	0.02	0.00002	0.000003
Infant Body Weight, 0 – 1 year (BW) (kg)**	7.8	7.8	7.8	7.8
Daily Water Intake for Infants (DWI) (L/day)**	1.113	1.113	1.113	1.113
Conversion Factor (CF) (mg/L to ng/L)	1,000,000	1,000,000	1,000,000	1,000,000
Ohio Action Level (ng/L (ppt))	700	140,000	140	21

*Toxicity values were selected following the Ohio EPA toxicity hierarchy (Ohio EPA, 2010). U.S. EPA Office of Research and Development Provisional Peer-Reviewed Toxicity Values (PPRTV) was used for PFBS (U.S. EPA, 2014) and ATSDR provisional MRLs were used for PFHxS and PFNA (ATSDR, 2018). For GenX, toxicity information from the state of North Carolina was utilized (North Carolina Department of Health and Human Services, 2017) (Staley & Moore, 2017).

**Infant (0-1 year) body weight (BW) of 7.8 kg (U.S. EPA, 2011b).

***Infant drinking water intake (DWI) of 1.113 L/day (U.S. EPA, 2011a).

****U.S. EPA published draft RfDs for GenX and PFBS in November 2018. Once the draft RfDs are finalized, Ohio may consider incorporating the updated RfD from U.S. EPA in the GenX and PFBS Ohio Action Level calculation (U.S. EPA, 2018b) (U.S. EPA, 2018c).

PFAS Mixtures

Current human exposures to PFAS involve complex mixtures, not individual chemicals. Comprehensively identifying PFAS in samples is challenging due to thousands of PFAS in existence, of which, only a limited number have standards available for quantification. U.S. EPA has approved methodology for measuring up to 25 PFAS in drinking water. Therefore, being able to discern the human health implications with limited knowledge of the occurrence and the toxicity of PFAS, especially as mixtures, is challenging for federal and state agencies. While U.S. EPA recommends comparing the sum of the concentrations of PFOA and PFOS to the HAL based on similar effects, effect levels, and common co-occurrence, U.S. EPA has not made a determination as to whether the health effects, effect levels, and co-occurrence of other PFAS are sufficiently similar to warrant considering the combined effects of other PFAS to themselves or PFOA and PFOS. Ohio will continue to consider peer reviewed data and federal guidance to make determinations with respect to exposures to PFAS mixtures.

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List of Acronyms

ATSDR	Agency for Toxic Substances and Disease Registry
BW	body weight
CF	conversion factor
DWEL	drinking water equivalent level
DWI	daily water intake
GenX	Gen X chemicals (i.e., HFPO dimer acid and its ammonium salt), also known as (2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy) propanoic acid (CASRN 13252-13-6) or hexafluoropropylene oxide (HFPO) dimer acid and 2,3,3,3-tetrafluoro-2(1,1,2,2,3,3,3-heptafluoropropoxy) propanoate (CASRN 62037-80-3) or HFPO dimer acid ammonium salt)
HAL	health advisory level
mg/kg-day	milligrams per kilogram body weight per day
MRL	minimal risk level
ODH	Ohio Department of Health
PFAS	Per- and polyfluoroalkyl substances
PFBS	Perfluorobutane sulfonic acid
PFHxS	Perfluorohexane sulfonic acid
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonate
PFNA	Perfluorononanoic acid
ppm (mg/L)	parts per million (milligram per liter)
ppt (ng/L)	parts per trillion (nanogram per liter)
RfD	reference dose
RSC	relative source contribution
UCMR	Unregulated Contaminant Monitoring Rule
U.S. EPA	United States Environmental Protection Agency

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