September 2017 DRAFT Per- and Poly-Fluorinated Alkyl Substances Chemical Action Plan (PFAS CAP)

The Washington State departments of Ecology and Health prepared a draft of several PFAS CAP chapters for external review. This document is one chapter to a planned multi-chapter PFAS CAP. This material may be modified in response to comments and the content re-organized for the final Action Plan.

The September 2017 Draft PFAS CAP includes: Health, Environment, Chemistry, Regulations, Uses/Sources, Intro/Scope. This draft may include cross-references to other sections/chapters in the Draft PFAS CAP or notes where additional information will be provided in a later draft.

An updated draft of the PFAS CAP will be provided in November/December 2017 for additional review and comment. The PFAS CAP Advisory Committee will discuss comments on these draft chapters at the November 1, 2017 meeting.

Ecology and Health are asking interested parties to provide feedback. Comments on these draft documents are due to Ecology by October 20, 2017.

Submit comments, suggestions, and questions to Kara Steward at kara.steward@ecv.wa.gov.

The Draft PFAS CAP documents are posted at https://www.ezview.wa.gov/?alias=1962&pageid=37105 (at the bottom of the webpage).

PFAS REGULATORY STATUS

PFAS chemicals have been in use in a variety of applications since the 1950s as ingredients, intermediates or surfactants and surface protectors. Several of these compounds are recognized as highly persistent, potentially bioaccumulative, and toxic (PBT). Several PFAS have been detected in the environment, biota, humans, and food around the globe.

This chapter provides an overview of international, federal and state regulations, guidance or advisories for PFAS chemicals. PFOS and PFOA receive the greatest attention.

Summary of PFAS Regulations, Guidance and Requirement

State, Country or	Regulation or Guidance	PFAS	Limit or Requirement
Organization			
Washington	Health advisory	PFOA, PFOS	Supports EPA health
			advisory level of 0.07 μg/L
	PBT List	PFOS and salts	None
	CSPA Reporting Rule	PFOS	Reporting
	Dangerous waste	Halogenated organic carbons	Persistent waste
Alabama	Fish consumption advisory	PFOS in fish from two	Consumption limits
		water bodies	
Alaska	Groundwater cleanup	PFOS	0.4 μg/L
	levels	PFOA	0.4 μg/L
	Soil cleanup levels	PFOA	1.6 mg/kg
		PFOS	1.6 mg/kg
California	Proposition 65; proposed	PFOS	Notification
	listing	PFOA	
Connecticut	Drinking water action level	Five PFAS	0.070 μg/L
Delaware	Groundwater reporting	PFOA	0.070 μg/L
	levels	PFOS	0.070 μg/L
Maine	Maximum exposure guideline drinking water	PFOA	0.1 μg/L
	Health advisory	PFOA, PFOS	0.070 μg/L
	Children's product reporting	PFOS	Reporting not required
Minnesota	Risk limits	PFOA	0.035 μg/L
		PFOS	0.027 μg/L
		PFBS	9 μg/L
		PFBA	7 μg/L
		PFHxS (use PFOS	0.027 μg/L
		value)	. 5.
	Fish consumption limits	PFOS	800 μg/kg do not eat
	,		40-800 μg/kg restrictions
			<40 μg/kg no limits

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State, Country or Organization	Regulation or Guidance	PFAS	Limit or Requirement
New Hampshire	Ambient groundwater	PFOA	0.07 μg/L, individually and
•	quality standards	PFOS	combined
New Jersey	Maximum contaminant	PNFA	0.013 μg/L
•	level (MCL) drinking water		
	MCL recommendation	PFOA	0.014 μg/L
	Hazardous substances	PFNA	Recommended addition
New York	Hazardous substances	PFOA, APFO, PFOS, K- PFOS	Storage, handling
North Carolina	Maximum allowable concentration	PFOA	1 μg/L
Oregon	Children's product reporting	PFOS	Reporting required
West Virginia	Screening levels	PFOA	150 μg/L drinking water
-			240 mg/kg soil
			1 μg/m³ air
Wisconsin	Fish consumption	PFOS in Mississippi	Consumption limits
	guidelines	River fish	
Vermont	Health advisory	PFOS	0.2 μg/L
		PFOA	0.2 μg/L
	Interim groundwater	PFOA	0.02 μg/L
	enforcement standard		
	Children's product	PFOS	Reporting required
	reporting		
Texas	Soil and groundwater	16 PFAS	
	cleanup standards		
US - TCSA	Notification, authorizes uses	PFOS, polymers, salts	
	Carpet and care only	LCPFAC	
US - SDWA	Health Advisories	PFOA	0.070 μg/L
		PFOS	
	UMCR3	Testing for 6 PFAS	
US - FD&C	Food contact substance	3 PFAS	
US - CERCLA	Soil screening level (site	PFOA	16 mg/kg
	specific)	PFOS	6 mg/kg
US - EPA	Voluntary phase-out	PFOA (2010-15) PFOS (2002)	
European Union (EU)	REACH	PFOS, POFA, PFNA	Restricted, limited allowed uses
	CLP	PFOA, APFO	Labelling
	EFSA Tolerable daily	PFOA	1.5 μg/kg bw/day
	intake	PFOS	0.15 μg/kg bw/day
	Water Framework	PFOS freshwater	0.00065 μg /L
	Directive	PFOS drinking water	0.1-0.5 μg/L
	Stockholm Convention	PFOS, salts, PFOSF	POP restrictions

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State, Country or Organization	Regulation or Guidance	PFAS	Limit or Requirement
Australia	Drinking Water	PFOS	0.07 μg/L
		PFOA	0.56 μg/L
		PFHxS	0.07 μg/L
Canada	Environmental Protection	PFOS, PFOS, LC-PFCA	Prohibited, limited
	Act		allowable uses
	Drinking Water Guidance	PFOA	0.7 μg/L
	Values	PFOS	0.3 μg/L
	Maximum acceptable	PFOA	0.2 μg/L
	concentration (proposed)		
China	Announcement	PFOS, salts, PFOSF	Prohibition
Denmark	List of Undesirable	PFOS, PFOA	Consider for substitution
	Substances		
	Soil screening level	12 PFAS	0.4 mg/kg
	Water screening level		0.1 μg/L
Italy	Freshwater Biota	PFOA	0.1 μg/L
	Drinking water	PFBA	7 μg/L
		PFPeA,	3 μg/L
		PFHxA	1 μg/L
		PFBS	3 μg/L
Japan	Chemical Substances Control law	PFOS and salts	Restricted substances
Netherlands		PFOS	0.53.44/1
Netherlands	Drinking water Fresh water	PFOS	0.53 μg/L
Nemus		PFOS	0.0065 µg/L
Norway	Priority substances	PFAS	Production restriction,
			monitoring, cleanup,
Danielia of Kanas	Davidout Overvie	DEOC salta DEOCE	discharge limits Restricted
Republic of Korea	Persistent Organic Pollutant list	PFOS, salts, PFOSF	Restricted
Sweden	Drinking water	11 PFAS	0.09 μg/L
United Kingdom	Persistent Organic	PFOS and derivatives	Restricted, limited allowed
	Pollutant list		uses
	Drinking Water	PFOS	0.3 μg/L Tier 2
		PFOA	1.0 μg/L Tier 3
			45 μg/L Tier 4

US States

In the absence of enforceable federal drinking water standards or soil cleanup standards for PFAS substances, some states - New Jersey, Maine, Minnesota, Vermont, North Carolina, and Michigan - have established state health advisory levels for drinking water. Some individual states have chosen to set health advisory levels lower than the EPA's 70 ppt. States with lower health advisory levels are New Jersey, 2016 (PFOA, 0.014 μ g/L), Minnesota, 2017 (PFOA, 0.035 μ g/L and PFOS, 0.027 μ g/L) and Vermont, 2016 (0.02 μ g/L).

Several states with localized surface water contamination (e.g., near manufacturing plants) have developed fish advisories for PFAS. Fish consumption advisories provide information about fish from water bodies such as lakes and rivers that may be contaminated with a particular chemical. Fish filets are tested to find the average amount of a chemical in the fish species and this information is used to determine a recommendation for how much fish is safe to eat or to avoid eating. Several states have fish advisory levels from PFOS contaminated water bodies. These states are Alabama, Michigan, Minnesota, and Wisconsin. Other states are considering fish advisories, including Washington State. Many more states do not have the funding for surveillance or PFAS analysis for recreational fish.

Washington State

<u>Health Advisory:</u> The Washington State Department of Health (DOH) supports EPA's May 2016 health advisory level for drinking water of 70 ppt (or $0.07~\mu g/L$) for PFOA and PFOS, or combined, because DOH is confident that the EPA's science is robust (based on the best available peer-reviewed science), and the health advisory is protective for pregnant women, nursing women, and children who may drink water during a short period of time or lifetime without harm. A lifetime HA does not represent a definitive level between safe and unsafe conditions. Confidence in the safety of the level decreases above this number. At this time, we don't know enough to predict the drinking water that will produce health effects in people.

When levels of PFOA and PFOS exceed the health advisory levels, DOH recommends that people follow the health advisory in order to reduce exposures. EPA advises not to drink the water and to use a different source for cooking and brushing teeth as well [302]. DOH is currently assessing data on other PFAS to determine whether they should be included in the health advisory for drinking water.

<u>PBT List:</u> In 2006, Washington State's Persistent, Bioaccumulative, and Toxic Rule (Chapter 173-333-310 Washington Administrative Code (WAC)) identified PFOS and its salts as PBT chemicals. This rule details the process for developing a Chemical Action Plan to reduce and phase-out PBT uses, releases and exposures in Washington. Washington State's Executive Order (EO) 04-01 requires state agencies to reduce the use and purchase of products that contain PBT compounds (Washington 2004).

<u>CSPA Rule:</u> In 2011, the Children's Safe Products Reporting Rule requires manufacturers to annually report to Ecology the presence of chemicals of high concern used or present in children's products. The Reporting Rule identifies 66 chemicals of concern to children required to be reported when present in children's products either intentionally or as a contaminant. PFOS is included in the list of 66 chemicals of concern to children (WAC 173-334-130). The reporting for PFOS in children's products has been required since 2012. Rulemaking to add PFOA to the list of chemicals under the rule is ongoing and when adopted will require reporting in children's products in January 2019.

<u>Dangerous Waste:</u> Washington State's Dangerous Waste Regulations (WAC 173-303-100) meet the requirements of the Federal Resource Conservation and Recovery Act (RCRA) and the Department of Ecology is authorized by the US EPA to implement RCRA within the state. Washington State also has specific requirements that pertain to toxicity and persistent criteria. Halogenated organic compounds like PFAS are considered persistent in dangerous waste regulations as defined under WAC 173-303-040.

Alabama

The Alabama Department of Environmental Conservation published an interim technical memorandum for cleanup levels for PFOA and PFOS in groundwater and soil. The cleanup levels are 0.4 μ g/L for groundwater and 1.6 mg/kg for soil for both PFOA and PFOS (ADEC 2016).

Alaska

The Alaska Department of Public Health released its 2017 fish consumption advisories which included advisories for PFOS. The Alaska Department of Public Health advises 1 meal consisting of 8 ounces of raw fish per month for the Baker's Creek and Wheeler Reservoir waterbodies with PFOS contamination (ADPH 2017).

California

In 2016, the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment issued a notice of intent to list PFOA and PFOS as known to the state to cause reproductive toxicity under Proposition 65 (OEHHA 2017). Proposition 65 requires businesses to notify the state about significant amounts of chemicals in the products they purchase, in their homes or workplaces, or that are released into the environment (Safe Drinking Water and Toxic Enforcement Act Health and Safety Code section 25249.5 *et seq*).

Connecticut

In 2016, the Connecticut Department of Public Health established a drinking water action level of 0.070 μ g/L for the sum five PFAS compounds in private wells: PFOS, PFOA, perfluorononanoic acid (PFNA), perfluorohexanesulfonate (PFHxS), and perfluoroheptanoic acid (PFHpA) (CTDH 2016). Drinking water action levels that are protective of the public health and also feasible based upon analytical detection and treatment technology. If well contamination exceeds the level, the Connecticut Department of Energy and Environmental Protection is authorized to take further action in addressing groundwater contamination at the site.

Delaware

In 2016, the Delaware Department of Natural Resources and Environmental Control updated the reporting level tables used by owners and operators to notify the state of contamination.

When PFOS and PFOA are detected in groundwater at 0.07 μ g/L, the combined concentrations should be compared to the EPA Health Advisory Level (DNREC 2016).

Iowa

lowa Department of Natural Resources prescribes statewide standards for soil and groundwater (IDNR 2016). The standards are PFOA at 0.07 μ g/L in groundwater and 1.2 mg/kg in soil and PFOS at 0.07 μ g/L in groundwater and 1.8 mg/kg in soil.

Maine

In 2014, Maine Center for Disease Control and Prevention developed a health-based Maximum Exposure Guideline for PFOA of 0.1 μ g/L in drinking water [304]. Maximum exposure guidelines are recommendations for concentrations of chemicals in drinking water below which there are minimal risks of adverse health effects from a lifetime of ingestion. In 2016, the Maine Center for Disease Control adopted the US EPA 2016 drinking water health advisory of 0.07 μ g/L for PFOA and PFOS, individually or when combined, as maximum exposure guidelines for these compounds (MECDC 2017).

In 2008, Maine adopted the Toxic Chemicals in Children's Products Act (Chapter 38-16D Maine Revised Statutes) which requires manufactures to report the presence of eight priority chemicals or groups of priority chemicals in children's products to Maine Department of Environmental Protection. PFOS is included in the list of 36 chemicals of high concern but not listed as a priority chemical and therefore not required to be reported when present in a children's product. (MDEP 2017)

Michigan

In 2016, the Michigan Department of Environmental Quality published water quality values for PFOA and PFOS (MDEQ 2016). These values are used to assess point source discharges to surface and groundwater used or not used for drinking purposes.

Minnesota

<u>Drinking Water:</u> The Minnesota Department of Health set health risk limits for four PFAS: PFOA of $0.035~\mu g/L$, PFOS of $0.027~\mu g/L$, PFBS of $9~\mu g/L$, PFBA of $7~\mu g/L$ (307, 308, 310). MDH has not established a health risk limit for PFHxS, but recommends using the health based value for PFOS ($0.027~\mu g/L$) as a surrogate for PFHxS until more toxicological research on PFHxS is available. The basis for this rational is that PFHxS remains in the body longer than PFOS and appears to be similar in toxicity. (MNDOH 2017).

Fish Consumption: The Minnesota Department of Health provides advice on consumption of fish (MNDOH 2008). Fish with more than 800 μg/kg PFOS in edible parts are listed as do not eat,

fish with 40-800 μ g/kg have various recommended consumption restrictions, and fish with less than 40 μ g/kg have no suggested consumption limits. The 2016 fish guidelines have set "do not eat" recommendation for fish in three waterbodies: Allen Lake, Au Sable River, and Clark's Marsh.

New Hampshire

In 2016, the New Hampshire Department of Environmental Services filed an emergency rule to establish ambient groundwater quality standards of 0.07 μ g/L for PFOA, 0.07 μ g/L for PFOS and 0.07 μ g/L for PFOA and PFOS combined until formally adopted through rulemaking process. These standards give New Hampshire the authority to direct site remediation activities related to these contaminants, and also require public water systems to comply with these standards if found in their sources of drinking water (NHDES 2016).

New Jersey

In 2015, the New Jersey Drinking Water Quality Institute recommended 0.013 μ g/L as health-based maximum contaminant level (MCL) for PFNA in drinking water (NJDWQI 2015). Department of Environmental Protection recently accepted this proposal and initiated rulemaking to adopt this as a state standard (NJDEP 2017a).

In 2017, the same New Jersey panel recommended a health-based MCL for PFOA of 0.014 μ g/L (NJDWQI 2017). This recommendation has not been accepted by the NJ Department of Environmental Protection for rulemaking.

New Jersey DEP proposed regulations in April 2017 to include a proposed amendment to the Discharges of Petroleum and Other Hazardous Substances rules for the addition of perfluorononanoic acid (PFNA) to the List of Hazardous Substances (NJDEP 2017b). This rule lists all the substances, in addition to petroleum and petroleum products, which are considered hazardous substances under the Spill Compensation and Control Act.

New York

In 2016, New York State Department of Environmental Conservation adopted an emergency rule that listed four PFAS chemicals on the hazardous substances list that may be found in Class B firefighting foam (New York Code, Rules and Regulations Title 6, Part 597). The regulations address the storage, handling, and release of firefighting foams that contain the fluorinated hazardous substances: PFOA, Ammonium Perfluorooctanoate (APFO), PFOS, and a PFOS salt (K-PFOS).

Under New York regulations, storage of Class B foam with more than 1% by volume of one of the listed hazardous substances stored in above ground storage tanks (>185 gallons) or below ground tanks must be registered with DEC. The release of these hazardous substances of one pound or more is prohibited and if released must be reported. The use of Class B firefighting

foam containing these chemicals for fighting fires was allowed until April 25, 2017. (NYDEC 2016)

North Carolina

In 2012, the North Carolina Science Advisory Board on Toxic Air Pollutants recommended an Interim Maximum Allowable Concentration for PFOA in groundwater of 1 μ g/L [305].

Oregon

In 2015, the Oregon Toxic-Free Kids Act requires manufacturers of children's products to report products that contain high priority chemicals of concern for children's health to the Oregon Health Authority (Chapter 431A.250 Oregon Revised Statute). The law identifies 66 chemicals required to be reported to Oregon Health Authority starting in January of 2018. The law requires manufacturers of children's product to remove or make a substitution for the chemical by the third biennial reporting or to seek a waiver. PFOS is included in the list of 66 chemicals and will require reporting starting in 2018. (OHA 2017)

Texas

The Texas Commission on Environmental Quality provides information on cleanup standards for the Texas Risk Reduction Program (TCEQ 2017). There are protective concentration levels for 16 PFAS in the March 2017 Tier 1 levels for soil and groundwater. The 16 PFAS are:

- Perfluorooctanoic sulfonic acid (1-Octanesulfonic acid, heptadecafluoro-1-)
- Perfluoroundecanoic acid (Undecanoic acid, uncosafluoro-)
- Perfluoropentanoic acid (Pentanoic acid, nonafluoro-)
- Perfluorohexanoic acid (Hexanoic acid, undecafluoro-)
- Perfluorododecanoic acid (Dodecanoic acid, tricosafluoro-)
- Perfluorooctanoic acid (Octanoic acid, pentadecafluoro-)
- Perfluorodecanoic acid (Decanoic acid, nonadecafluoro-)
- Perfluorodecane sulfonic acid (1-Decanesulfonic acid, heneicosafluoro-)
- Perfluorohexane sulfonic acid (1-Hexanesulfonic acid, triddecafluoro-)
- Perfluorobutyric acid (Butanoic acid, heptafluoro-)
- Perfluorobutane sulfonic acid (1-Butanesulfonic acid, nonafluoro-)
- Perfluoroheptanoic acid (Heptanoic acid, tridecafluoro-)
- Perfluorononanoic acid (Nonanoic acid, heptadecafluoro-)
- Perfluorotetradecanoic acid (Tetradecanoic acid, heptacosafluoro-)
- Perfluorotridecanoic acid (Tridecanoic acid, pentacosafluoro-)
- Perfluorooctane sulfonamide (1-Octanesulfonamide, hetpadecafluoro-)

Vermont

In 2016, the Vermont Department of Health's set a drinking water health advisory level for the sum of PFOA and PFOS of 0.02 μ g/L (VDH 2016a). Vermont also set an Interim Ground Water Enforcement Standard for PFOA of 0.02 μ g/L (VDH 2016b).

Beginning January 2017, manufacturers who use chemicals designated by the State of Vermont as Chemicals of High Concern to Children to report to the Vermont Department of Health (Vermont Statutes Title 18, Chapter 38A). The 2015 Chemicals of High Concern in Children's Products reporting rule identified 66 chemicals of high concern based on WA State's Chemicals of High Concern to Children list. The reporting rule requires children's products reported to contain the chemicals to be identified by brand name and product model. PFOS is included in the list of 66 chemicals and has been required to be reported since 2016 (VDH 2016c).

West Virginia

In 2002, the West Virginia Environmental Protection and the ammonium perfluorooctanoate (C8) Assessment of Toxicity Team developed risk-based human health protective screening levels for PFOA of 150 μ g/L in drinking water, 240 mg/kg for soil and 1 μ g/m³ for air [306].

Wisconsin

Wisconsin Department of Natural Resources released its 2016 fish consumption guidelines which included guidance on fish consumption for PFOS contamination in Mississippi River (WIDNR 2016). In 2 species of fish, a guidance of 1 meal per week is provided and the meal is based on serving size according to the consumer's body weight. This guidance is based on the reference dose set by Minnesota of 0.08 $\mu g/kg$ -day (WIDNR 2011).

FEDERAL

PFAS regulations, guidance values, and actions set by the U.S. federal government come under the authority of the Toxic Substances Control Act (EPA), Clean Water Act (EPA), and Food, Drug and Cosmetics Act (FDA). Additionally, manufacturers have worked with the EPA on voluntary phase-outs, enforced consent agreements, and memorandum of understandings.

Toxic Substances Control Act

Under the Toxic Substances Control Act the EPA reviews new chemical notifications and if it finds an "unreasonable risk to human health or the environment," it may regulate the substance from limiting uses or production volume to outright banning it. Several Significant New Use Rules, called SNURs, have been adopted that require notice to EPA before specific PFAS are used. Since 2002, five new rules were published and one proposed for PFAS

compounds. These rules were adopted into EPAs rules on Significant New Uses of Chemical Substances (Chapter 40 Code of Federal Regulations (CFR) Part 721).

PFAS Si	gnificant	New	Use	Rule
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Year	PFAS substances		Uses allowed	
40 CFR	40 CFR 721.9582 - Certain perfluoroalkyl sulfonates			
2002	13	PFOS and polymers	Photographic, semiconductor, aviation,	
2002	75	PFOS and salts, POSF, polymers	intermediates	
2007	183	PFAS chemicals	Photographic, semiconductor, aviation,	
2013	7	PFAS chemicals	intermediates, etching, metal plating/finishing	
40 CFR 721.10536 Long-chain perfluoroalkyl carboxylate chemical substances.				
2013	2	LCPFAC	Carpet and carpet treatment	
2015	20	LCPFAC	Carpet and carpet treatment	

In 2000, EPA adopted a new rule requiring manufacturers and importers to notify at least 90 days before commencing the manufacture or import using 13 PFAS (40 CFR 721.9582). These chemicals include polymers derived from PFOS and its higher and lower homologues. This rule was amended in 2002 to add 75 substances including PFOS and certain salts, perfluorooctanesulfonyl fluoride (POSF), certain higher and lower homologues of PFOS and POSF, and certain other chemical substances, including polymers, that are derived from PFOS and its homologues. This restricted the return of 88 PFOS-related chemicals phased out by 3M (refer to sources/uses chapter) to the US market.

This rule provided EPA with the opportunity to evaluate an intended new use and associated activities and, if necessary, to prohibit or limit that activity before it occurs. The rule allowed only three specific, technically essential low volume, low exposure, and low release uses to continue in the photographic/imaging industry, semiconductor industry, and aviation industry. A fourth exception allowed intermediates solely to produce other chemical substances for the other three specific uses.

In 2007, the rule was updated to add 183 PFSA chemicals that were on the public TSCA Inventory and not covered by the previous rule updates. In addition to the four excepted uses, two new exclusions are allowed for ongoing use which include seven chemicals for use as an etchant and one chemical for use in metal plating and finishing. In 2013, another seven PFAS were added to the list of chemicals requiring notification. These seven PFSA chemicals completed the TSCA new chemical review process but the manufacture had not yet started production or import. This designated processing as a significant new use for all listed PFAS.

In 2013, another new rule was adopted regarding the manufacture, import, and processing of long-chain perfluoroalkyl carboxylate (LCPFAC) substances for use as part of carpets or for treating carpet (e.g., for use in the carpet aftercare market) (40 CFR 721.10536). Two LCPFAC chemical substances used as surfactants in carpet cleaning products are exceptions. Import or processing of the LCPFAC chemical substances as part of the article are not exempt. In 2015, an

amendment to the LCPFAC rule was proposed to add a list of 20 LCPFAC compounds to the notice requirements. This rule amendment has not been adopted.

Safe Drinking Water Act

The Safe Drinking Water Act (SDWA) is the federal law that protects public drinking water in the U.S. Under SWDA, EPA sets regulatory limits for the amounts of certain contaminants in water provided by public water systems. There is currently no regulatory limit for PFAS compounds under the SWDA. Under the SWDA, EPA issues "health advisories" for some contaminants, including some that have not been regulated, and requires drinking water testing of public water supply systems.

EPA health advisories provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. EPA's health advisories are non-enforceable and non-regulatory and provide technical information to states agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination.

EPA established health advisories for PFOA and PFOS based on the agency's assessment of the latest peer-reviewed science to provide drinking water system operators, and state, tribal and local officials who have the primary responsibility for overseeing these systems, with information on the health risks of these chemicals, so they can take the appropriate actions to protect their residents. EPA's health advisory levels for PFOA and PFOS offers a margin of protection for all Americans throughout their life from adverse health effects resulting from exposure to PFOA and PFOS in drinking water.

In 2009, drinking water health advisories were set at 0.4 μ g/L (or 400 part per trillion (ppt)) for PFOA and 0.2 μ g/L for PFOS. In May 2016, EPA announced lifetime health advisories for PFOA and PFAS in drinking water to supersede the 2009 provisional health advisories. The health advisories levels for PFOA and PFAS are at 0.07 μ g/L individually or when both found in drinking water then a combined concentration of 0.07 μ g/L. The new levels are based on the evaluation of latest peer-reviewed scientific evidence and calculated to offer a margin of protection against adverse health effects, including the most sensitive populations (fetuses during pregnancy and breastfed infants), from a lifetime of exposure to drinking water [19].

EPA collects data for contaminants that are suspected to be present in drinking water under the Unregulated Contaminant Monitoring Rule (UCMR - 40 CFR 141.35 and 40 CFR 141.40). In 2012, EPA published the third UMCR (UMCR3) which required monitoring of 30 contaminants between January 2013 to December 2015. Monitoring occurred at large public water systems and a representative selection of smaller water supply systems. UMCR monitoring includes contaminants not regulated, known or anticipated to occur, and may warrant regulation under SWDA.

Monitoring under UMCR 3 required testing for 6 PFAS chemicals: PFOS at 0.04 μ g/L, PFOA at 0.02 μ g/L, PFNA at 0.02 μ g/L, PFHxS at 0.03 μ g/L, PFHpA at 0.01 μ g/L, and PFBS at 0.09 μ g/L. Between January 2013 and December 2015, 132 public water systems in Washington participated in UCMR3 (EPA 2017). Refer to Health Chapter for a discussion of these results.

Federal Food, Drug and Cosmetic Act

The U.S. Food and Drug Administration (FDA) oversees the safety of food, drugs and cosmetics under the Federal Food, Drug and Cosmetic Act. Among the responsibilities of the FDA is regulation of components of food contact materials, including packaging – the FDA refers to these materials as food contact substances (food additive regulations: 21 CFR 174-179) (FDA 2017).

The FDA authorized the use of PFAS for specific food-contact uses such as coatings on fast-food wrappers, to-go boxes, and pizza boxes. In 2010, the FDA identified safety concerns through a comprehensive review of available literature. These safety concerns included systemic and developmental toxicity in combination with bio-persistence. The FDA worked with industry to stop distribution of the long-chain PFAS most commonly used in food packaging at that time, which are authorized under food contact notifications. By 2011 the manufacturers assured the FDA that they had voluntarily stopped distributing these long-chain PFAS.

In 2016, in response to a petition filed on behalf of the 3M Corporation, the FDA amended a food additive regulation to no longer authorize the use of three PFAS compounds in "grease-proof" food packaging (FDA 2016). The petition provided evidence that the use of these compounds, for which 3M stated it was the sole domestic and international manufacturer, has been completely and permanently abandoned by industry in the U.S. market. FDA's action in amending this regulation is not based on a safety evaluation; rather, it is based on the abandonment of these uses. Although manufacturers had voluntarily stopped using these products, FDA's action means that any food additive use of the PFAS covered by the regulations is no longer authorized. The three restricted PFAS are:

- Diethanolamine salts of mono- and bis (1 H, 1 H, 2 H, 2 H perfluoroalkyl) phosphates.
- Pentanoic acid, 4,4-bis [(gamma-omega-perfluoro-C8-20-alkyl)thio] derivatives, compounds with diethanolamine.
- Perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[([gamma], [omega]-perfluoro C4-20 alkylthio) methyl]-1,3propanediol, polyphosphoric acid and ammonium hydroxide.

Interim Reference Dose and Soil Screening Levels

After PFOA and PFOS were found at two Superfund sites in EPA Region 4, in surface soils and groundwater, EPA established toxicity values (EPA 2009). The recommended interim oral non-cancer reference dose values for PFOA and PFOS were 0.0002 mg/kg-day and 0.00008 mg/kg-

day, respectively. Using these reference doses in the Superfund risk-based regional screening level calculator established surface soil screening levels of 16 mg/kg for PFOA and 6 mg/kg for PFOS. The exposure assumptions are protective of children over a six-year exposure period. These screening levels do not account for several uncertainties, including lack of long-term exposure for PFOS and PFOA and lack of sub-chronic or lifetime exposure for other PFAS chemicals.

U.S. EPA Negotiations

In 2000, EPA and 3M, the sole manufacturer of products based on PFOS chemistry in the US, negotiated a voluntary phase out for the production of PFOS and a commitment to finding substitutes (EPA 2000). Production of PFOS in 3M's manufacturing of a range of consumer and industrial products (firefighting foams, coatings from fabrics, leather and some paper products, and surfactants) was reduced by 90% at the end of 2000. By 2002, 3M had ceased all production of PFOS globally.

In 2003, EPA initiated enforceable consent agreements, which were finalized on July 8, 2005, with four companies to collect testing data on incineration of two formulated composites of fluorotelomer-based polymer chemicals (EPA 2005a) and four formulated composites of fluoropolymer chemicals (EPA 2005b). The testing data would help determine whether the incineration of fluorotelomer-based polymer and fluoropolymers are a source and/or pathway for environmental and human exposure to PFOA for a PFOA risk assessment.

In 2006, a Voluntary 2010/2015 PFOA Stewardship Program was established between the US EPA and eight major fluoropolymer and flurotelomer manufacturers: Arkema, Asahi Glass, Ciba (now BASF), Clariant (now Archroma), Daikin, DuPont, 3M/Dyneon, and Solvay Solexis (ref). Participating companies agreed to reduce PFOA, precursor chemicals that can break down into PFOA, and related higher homologue chemicals by 95% no later than 2010 and to work toward eliminating these chemicals from facility emissions and in product content entirely by 2015. Progress towards meeting the goals was measured by companies submitting annual reports to EPA on their data from emissions and product content compared to the baseline data in 2000, or the nearest year available.

INTERNATIONAL

PFAS is an emerging issue in many countries. The European Union, through the Stockholm Convention addresses PFAS. Member states may provide additional guidance or regulations: drinking water, recreational water, air, soil, consumer products, firefighting foam, food (sources and contact paper), dust etc. Recent OECD reports indicate that most member states rely on EU regulations to address PFAS.

Some countries have adopted a range of drinking water guidance levels to guide their decisions in protecting public health. Differences among these guidance levels come from sources of uncertainties, the use of pharmacokinetic models to derive human equivalent doses

calculations for PFAS, different species, less stringent reference doses, uncertainty factors, relevance of epidemiological studies, and other reasons.

European Union

<u>European Chemicals Agency</u> – The European Restriction, Authorisation, and Registration of Chemicals (REACH) regulation identifies Substances of Very High Concern (SVHC), restrictions and authorizations for specific chemicals.

In June 2017, PFOA, its salts and related substances were added to the REACH restricted substances list. These substances shall not be manufactured or placed on the market as substances after July 4, 2020. The restriction details concentration limits and exceptions (ECHA 2017).

PFOS was originally included in the list of restricted substances under REACH. In 2010, PFOS was removed from the REACH restriction list and added to the Stockholm Convention list of persistent organic pollutants.

C11-C14 PFAS are listed as SVHC under REACH, requiring registration, notification, and duty to communicate on articles that contain these PFASs with the ultimate aim to substitute the substances completely. PFNA and its sodium and ammonium salts are identified as SVHC because they are toxic for reproduction and Persistent, Bioaccumulative and Toxic (PBT) substances.

REACH allows the continued use of eight carbon perfluorinated substances in certain applications (DEPA 2015). Permitted uses include:

- Use as an anti-erosion additive in fire-resistant phosphate ester aviation hydraulic fluids.
- Use in photomicrolithography processes to produce semiconductors or similar components of electronic or other miniaturized devices.
- Use in coating for surface tension, static discharge, and adhesion control for analog and digital imaging films, papers, and printing plates.
- Use as a fume/mist suppressant in metal finishing and plating baths.

<u>Classification</u>, <u>Labelling and Packaging (CLP)</u> – PFOA and AFPO are required to be classified, labelled, and packaged under the CLP regulation. A comparable classification and labelling is proposed for PFNA, and PFDA by Sweden.

European Food Safety Authority - In 2008, EFSA reviewed and evaluated the available PFOA and PFOS toxicity studies and derived a tolerable daily intake (TDI) for both chemicals. TDIs are expressed on a per body weight basis and represent levels of a substance that can be ingested over a lifetime without appreciable health risk (EFSA, 2008). EFSA calculated a TDI value of 0.15 μ g/kg body weight per day for PFOS and a TDI of 1.5 μ g/kg-b.w. per day for PFOA [21].

<u>Water Framework Directive</u> – The Water Framework Directive sets environmental standards for priority substances in surface and ground waters in the EU. PFOS is proposed to be included as a priority substance under this EU Directive (EC 2012).

In 2013, the Directive on "Environmental Quality Standards" listed PFOS and its derivatives. This Directive sets an annual average environmental quality standard for PFOS in surface freshwater at 0.00065 μ g/l, based on the potential for secondary poisoning in humans due to fish consumption [325]. Provisional drinking water standards for PFOS range from 0.1 to 0.5 μ g/L.

<u>Stockholm</u> – In 2001, the Stockholm Convention adopted the international treaty to protect human health and the environment from the harmful effects of Persistent Organic Pollutants (POP). The treaty requires that developed countries provide new and additional financial resources and measures to eliminate production and use of intentionally produced POPs, eliminate unintentionally produced POPs where feasible, and manage and dispose of POPs wastes in an environmentally sound manner. Precaution is exercised throughout the Stockholm Convention, with specific references in the preamble, the objective, and the provision on identifying new POPs.

In 2009, PFOS and its salts¹ and perfluorooctane sulfonyl fluoride (PFOSF) were added as restricted POPs to the Stockholm Convention. In 2011, production, supply and use of firefighting foam with PFOS is banned. PFOS-containing foam stocks must be managed as hazardous waste (Sontake 2014). Acceptable uses of PFOS, its salts and PFOSF include (Stockholm 2017b):

- Photo imaging
- Photo resist and anti-reflective coatings for semi-conductors
- Etching agent for compound semi-conductors and ceramic filters
- Aviation hydraulic fluids
- Metal plating (hard metal plating) only in closed-loop systems
- Certain medical devices (such as ethylene tetrafluoroethylene copolymer (ETFE) layers and radio-opaque ETFE production, in vitro diagnostic medical devices, and CCD colour filters)
- Firefighting foam
- Insect baits for control of leaf-cutting ants from Atta spp. and Acromyrmex spp.

The Stockholm Convention provides guidance for best available techniques and best environmental practices for the use of PFOS and related chemicals (Stockholm 2017a).

¹ PFOS Salts: potassium perfluorooctane sulfonate (CAS no. 2795-39-3); lithium perfluorooctane sulfonate (CAS no. 29457-72-5); ammonium perfluorooctane sulfonate (CAS no. 29081-56-9); diethanolammonium perfluorooctane sulfonate (CAS no. 70225-14-8); tetraethylammonium perfluorooctane sulfonate (CAS no. 56773-42-3); didecyldimethylammonium perfluorooctane sulfonate (CAS no. 251099-16-8).

Australia

In 2008, Australia adopted the 2008 health reference values set by the European Food Safety Authority (EFSA) [319]. In 2017, Australia reduced the recommended tolerable daily intake values for people potentially exposed to PFOS and PFOA. Those reduced values are 20 ng/Kg/day for PFOS, and 160 ng/kg/day for PFOA. The Australian drinking water quality values are 0.07 μ g/L for PFOS and 0.56 μ g/L for PFOA (Australia 2017).

Canada

The Canadian Environmental Protection Act lists perfluorooctanoic acid, its salts, and its precursors (PFOA); perfluorocarboxylic acids, their salts, and their precursors (LC-PFCAs); and perfluorooctane sulfonate, its salts and its precursors (PFOS) on the list of prohibited substances (Canada 2012). In general, the manufacture, use, sale, offer for sale, or import of these compounds are prohibited unless the substances are present in manufactured items before the regulation was enacted. Allowed uses include:

- The import, manufacture, use, sale and offer for sale of a product, if PFOA, LC-PFCAs, and/or PFOS are incidentally present.
- The import, manufacture, use, sale and offer for sale of PFOS or a product containing it
 if it is designed for use in photoresists or anti-reflective coatings for photolithography
 process or photographic films, papers and printing plates.
- The use and import of PFOS in aqueous film forming foam present in a military vessel or military fire-fighting vehicle contaminated during a foreign military operation.
- The import, use, sale and offer for sale of aqueous film forming foam for fire-fighting operations that contain PFOA and/or LC-PFCAs.
- The import, use, sale or offer for sale of manufactured items containing PFOA and/or LC-PFCAs.
- The use of PFOS in aqueous film forming foam at a concentration less than or equal to 10 ppm.
- The use or import of products containing PFOA and/or LC-PFCAs, if the product is for personal use.
- The use, sale or offer for sale of:
 - Products containing PFOA, LC-PFCAs and/or PFOS if manufactured or imported before the Regulations come into force.
 - PFOA and/or LC-PFCAs or products containing them if they were manufactured or imported in accordance with a permit.

In 2006, Health Canada developed Drinking Water Guidance Values for PFOS and PFOA. The drinking water guidance values are 0.3 μ g/L for PFOS and 0.7 μ g/L for PFOA [315]. More recently, the Federal-Provincial-Territorial Committee on Drinking Water assessed PFOA in drinking water and proposed a maximum acceptable concentration of 0.2 μ g/L for PFOA in drinking water [112].

China

In 2014, the Ministry of Environmental Protection issued an announcement banning "production, transportation, application, imports and exports of PFOS, its salts, and perfluorooctane sulfonyl fluoride (PFOSF), except for specific exemptions and acceptable use" (OECD 2015).

Denmark

PFOA and PFAS are on the Danish List of Undesirable Substances to encourage industry to phase out production and use (DEPA 2009). This list reflects the principles of REACH and other substances that are a particular focus in Denmark. The list is not legally binding, but provides a guide to industry to which substances the Danish EPA considers should be prioritized for substitution.

Denmark established screening levels for the combined concentration of 12 PFAS in water and soil. Those 12 compounds are PFBS, PFHxS, PFOS, PFOSA, 6:2 FTS, PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, and PFDA. The screening level for the combined PFAS in drinking water or groundwater is set at 0.1 μ g/L. The screening level for the combined PFAS compounds in soil is 0.4 mg/kg (DEPA 2015).

Germany

In 2003, the German Federal Environment Agency established a health-based precautionary value of 0.1 μ g/L for PFOA, PFOS and other perfluorocarbons. In 2006, the German Drinking Water Commission established three additional guidance levels for PFOS and PFOA in drinking water. A precautionary action value of 5.0 μ g/L for PFOA and PFOS in drinking water for adults. This value is used to indicate when immediate action is required to reduce exposure to PFOA and PFOS via drinking water. For pregnant women and infants a maximum value of 0.5 μ g/L is considered safe. A health based guide of 0.3 μ g/L was set for safe lifelong exposure [305, 316].

Recently, the German Human Biomonitoring Commission established a level for PFOA and PFOS in blood plasma at 2 ng/ml for PFOA and 5 ng/ml for PFOS. Germany used human data that shows that PFOA can cause problems in humans with pregnancy, hormones and thyroid, and reduced the effectiveness of vaccines. The blood level standard set by the German scientists would correspond to a limit for PFOA in drinking water of 0.0019 μ g/L – 36 times lower than the EPA lifetime health advisory [317].

Italy

The Italian government included PFAA in the Working Group on Environmental Quality Standard monitoring surface water pollutants. The freshwater standard adopted for PFOA is 0.1 μ g/L. Drinking water standards are 7 μ g/L PFBA, 3 μ g/L PFPeA, 1 μ g/L PFHxA, and 3 μ g/L PFBS.

Japan

Japan has listed PFOS and its salts as a Class I Specified Chemical Substance under the Chemical Substances Control Law (CSCL) and PFOS is subject to export restriction under the country's Foreign Exchange and Foreign Trade Law. The Class I listing occurred in response to the new listing of PFOS under the Stockholm Convention after the government evaluated if PFOS and its salts were persistent, bioaccumulative, and have long-term toxicity for humans and animals. (OECD 2015)

Netherlands

In 2011, the Netherlands developed a maximum tolerable level of PFOS in drinking water of 0.53 μ g/L, based on the EFSA 2008 health reference values. A negligible level of 0.0053 μ g/L of PFOS was derived by the further use of a factor of 100 [321].

The Netherlands National Institute for Public Health and the Environment has calculated a maximum permissible concentration for PFOS of 0.65 ng/L (0.00065 μ g/L) for fresh water (based on consumption of fish by humans as the most critical route). This value is based on a consumption of 115 grams of fish per day [324].

Norway

Norway listed several long-chain PFASs on its national list of priority substances starting in 2003, based on monitoring data that showed high levels of these substances in the environment as well as their toxicological profiles. Regulatory measures include monitoring and clean-up of PFAS-polluted soil at airport fire drill sites, waste treatment plant (WTP) discharge permits for select PFASs, analysis of PFAS in consumer products, and a national ban on the manufacture, production, import, and placing on the market of consumer products containing PFOA. (OECD 2015)

Republic of Korea

The Republic of Korea addresses PFOS, its salts and PFOS-F as restricted substances under the Persistent Organic Pollutants Control Act. Under the Act, any manufacture, import, export and use of PFOS, its salts and PFOS-F are restricted except for specific exemptions and acceptable use in the Stockholm Convention. (OECD 2015)

Sweden

In 2014, the Sweden's National Food Agency set a maximum tolerable level of 0.09 μg/L for drinking water (NFA 2016). This limit applies to the sum of eleven PFAS substances in drinking water: perfluorobutane sulfonate (PFBS), perfluorohexane sulfonate (PFHxS), PFOS, 6:2 fluorotelomer sulfonic acid (6:2 FTSA), perfluorobutanoic acid (PFBA), perfluoro-n-pentanoic acid (PFPeA), perfluorohexanoic acid (PFHxA), perfluorohexanoic acid (PFHpA), PFOA,

perfluorononanoic acid (PFNA), and perfluorodecanoic acid (PFDA) [318]. This action limit is based on a potential risk for human health coming from PFAS in drinking water. If concentrations of these 11 compounds are higher than the action limit, measures need to be taken in order to reduce them.

United Kingdom

PFOS and PFOS derivatives are on the United Kingdom list of POPs. POP allowed uses include research, reference standards or unintentional traced contaminants in substances, preparations, or articles. Unintentional trace levels for PFOS and PFOS derivatives²:

- textiles or other coated materials at a concentration below 1 μ g (0.000001 grams) per square meter of the coated material.
- semi-finished products, or parts of semi-finished products, at a concentration below 0.1% by weight of the parts of the product that contain PFOS (for example, if a 100kg semi-finished product includes a 1kg component that contains PFOS, the PFOS is considered an unintentional trace element if it weighs less than 1g). Semi-finished products are products partially assembled or manufactured in one country and completed in another country where they're sold.

Exceptions to the UK ban include use of PFOS or PFOS derivatives in the following products and processes:

- photoresists or anti-reflective coatings for photolithography processes
- photographic coatings applied to films papers, or printing plates
- mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems
- hydraulic fluids for aviation

The UK allows the use of 'articles' (such as manufactured products) that contain PFOS or PFOS derivatives, if the products were in use in the EU before 25 August 2010.

For waste that contains less than 50 mg/kg PFOS or PFOS derivatives, the UK Environment Agency will approve the application to send the waste to a hazardous waste landfill site. For waste that contains more than 50 mg/kg PFOS or PFOS derivatives material must be incinerated or chemically destroyed (United Kingdom 2015).

In 2007, the United Kingdom Drinking Water Inspectorate issued guidance for concentrations of PFOA and PFOS in drinking water and revised the guidance in 2009. The United Kingdom Tier 2 health guidance value is 0.3 μ g/L for PFOA and PFOS. The Tier 2 value was considered adequate to protect against potential effects such as cancer. A Tier 3 value of 1.0 μ g/L for PFOA and PFOS in drinking water will be protective for the whole range of consumers. A Tier 4 level of 45 μ g/L

² List of PFOS and related compounds: https://www.gov.uk/government/publications/perfluorooctane-sulfonates-pfos-and-related-compounds

for PFOA requires notification by water companies. This Tier 4 level was is based on a Total Daily Intake of 0.15 μ g/kg/day of PFOA assuming a 60 Kg adult consumes 2 liters a day of drinking water [305].



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