PFAS Technical Group

August 19, 2022 (9-10:30)

Agenda

- Welcome and introductions
- Factors and Trends in State and Federal Guidelines for PFAS in Environmental Media - Gloria B. Post, Ph.D., NJDEP
- Updates on the EPA Multi-Industry Per- and Polyfluoroalkyl Substances (PFAS) Study – 2021 Preliminary Report - Doruntinë (Dori) Rexhepi, U.S. EPA
- Conclusions & next steps

Factors & Trends in State & Federal Guidelines for PFAS in Environmental Media

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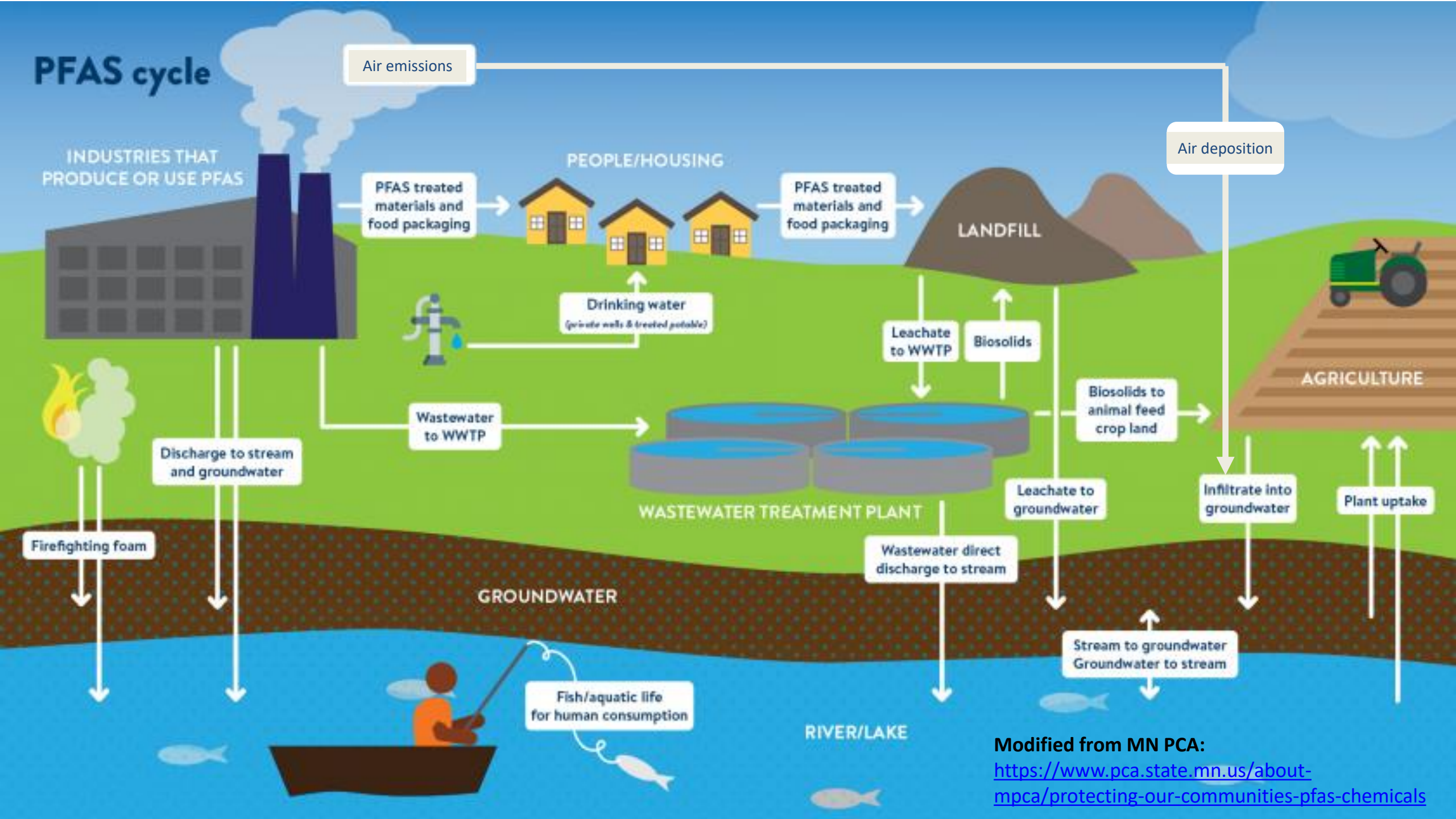
New Jersey Department of Environmental Protection

Wisconsin DNR PFAS Technical Group

August 19, 2022



Modified from MN PCA:
https://www.pca.state.mn.us/about-mpca/protecting-our-communities-pfas-chemicals

Overview - Human Health Criteria & Guidelines

- "Guidelines" refers here to standards and guidance values.
- Human health criteria are goals.
- Final regulatory standard may need to be set higher than human health criterion due to consideration of other factors such as:
  - *Analytical limitations, available treatment removal technology, and, in some cases, cost or cost-benefit.*
- Factors considered differ among types of guideline (e.g., drinking water, ground water, surface water, soil) and among states (e.g., cost-benefit).
- Guidelines can also be based on criteria other than for human health (e.g., protection of aquatic life).
  - *Not discussed in this presentation.*

State & Federal PFAS Guidelines

- "Guidelines" include standards (enforceable) and guidance values (non-enforceable).
- In general, state standards:
  - *May address contaminants with no federal standards.*
  - *May be **more stringent, but not less stringent,** than federal standards.*
- Example: State PFAS drinking water standards (Maximum Contaminant Levels; MCLs):
  - *Some states have developed their own MCLs for many years, including for PFAS.*
  - *Additional states that never previously developed MCLs have developed PFAS MCLs.*
  - *Due to **nationwide concerns** about PFAS in drinking water.*
- Other states are required to use EPA standards or do not currently plan to develop PFAS MCLs.
  - *Most of these states used the previous **2016 EPA Health Advisories** (not enforceable) for PFOA and PFOS as guidance.*

Overview - Basis of Human Health Criteria

Toxicity factors

- **Oral:**
  - Non-cancer effects - *Reference Dose (ng/kg/day).*
    - *Dose below which toxicity is not expected to occur (threshold assumption).*
  - Carcinogenic effects - *Cancer Slope (Potency) Factor* $(ng/kg/day)^{-1}$
    - *Assumes some risk at any dose (non-threshold assumption).*
    - *Must select cancer risk level (e.g., 1 in 1 million, 1 in 100,000).*
  - Same chemical-specific toxicity factor should be used for all guidelines based on oral exposure, unless there is a policy reason for a difference.
- **Inhalation:**
  - Non-cancer effects - *Reference Concentration* (ng/m^3).
  - Carcinogenic effects - *Unit Risk Factor* $(ng/m^3)^{-1}$.
  - Current PFAS inhalation toxicity factors are extrapolated from oral toxicity factors.

Exposure assumptions

- Specific to exposure pathways for each type of criterion.

Examples of Exposure Pathways for PFAS Human Health Criteria

Medium	Exposure Routes & Assumptions		Comments
Drinking Water; Ground Water* (ng/L)	**Drinking water ingestion** *L water/kg body wt/day*		*For ground water that is potentially potable
Surface Water (ng/L)	***Freshwater (if designated potable)***	**Drinking water + fish consumption**	Fish tissue concentration determined by bioaccumulation/ bioconcentration factor (BAF or BCF; *L water/kg fish*)
	Saline water (& fresh water not designated potable)	**Fish consumption** *grams fish/kg body wt/day*	
Soil (mg/kg)	***Residential: Child***	**Incidental soil ingestion** *mg soil/kg body wt/day*	
	Non-residential: Worker		
	Impact-to-Ground water	**Leaching from soil to ground water**	Soil conc. resulting in exceedance of GW guideline
Air (ng/m^3)	***Inhalation***	**Daily inhalation rate** *m^3/day*	Extrapolated from oral PFAS toxicity factors
Fish and Deer Consumption Advisories (meal frequency)	***Recreationally caught fish or deer***	**Consumption** *Meal size (grams/meal)*	Examples: once per week; once per month; once per year; do not eat

Examples: Human Health Water Criteria for Non-Carcinogens

Drinking Water Criterion (ng/L) =

$$\frac{\text{Reference Dose (ng/kg/day)} \times \text{Body Wt. (kg)} \times \text{Relative Source Contribution (\%)}}{\text{Water Ingestion Rate (L/day)}}$$

Freshwater Surface Water Criterion (ng/L) =

$$\frac{\text{Reference Dose (ng/kg/day)} \times \text{Body Wt. (kg)} \times \text{Relative Source Contribution (\%)}}{\text{Water Ingestion Rate (L/day)} + [\text{BCF or BAF (L/kg)} \times \text{Fish Consumption Rate (kg/day)}]}$$

Saline (or Non-potable) Water Surface Water Criterion (ng/L) =

$$\frac{\text{Reference Dose (ng/kg/day)} \times \text{Body Wt. (kg)} \times \text{Relative Source Contribution (\%)}}{\text{BCF or BAF (L/kg)} \times \text{Fish Consumption Rate (kg/day)}}$$

- *In equations above, exposure from fish consumption is much greater than from drinking water for PFAS that are highly bioaccumulative in fish (e.g., PFOS and PFUnDA [C11]).*
- *Specific approaches are needed for BAF determination for PFAS.*
  - *PFAS bioaccumulation is associated with proteins, not lipids as for many other organic contaminants.*

EPA & State PFAS Drinking Water Guidelines (ng/L; ppt)

(includes standards and guidance values - proposed, recommended, and final)

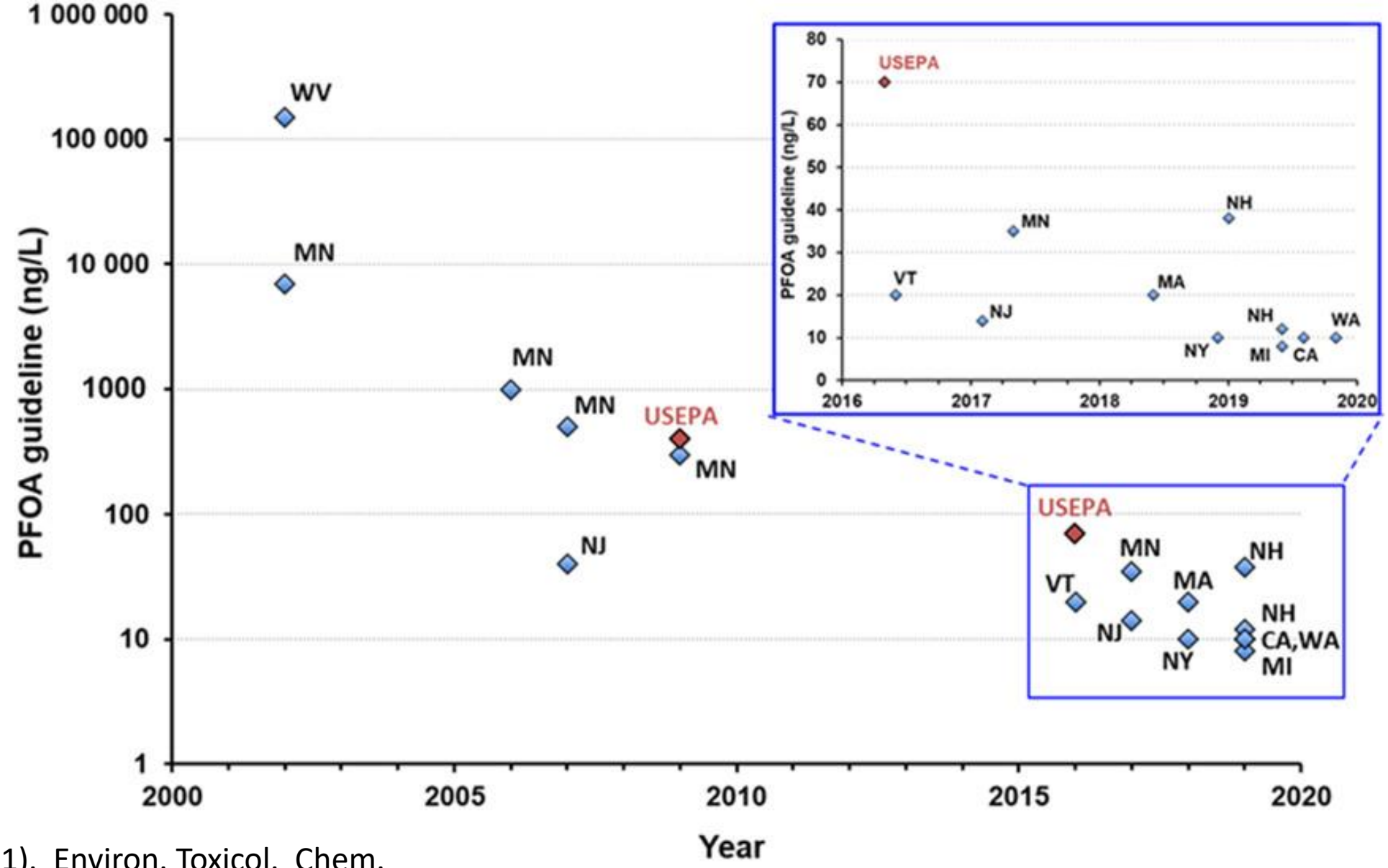
	PFOA	PFOS	PFNA	PFHxS	PFHpA	PFDA	*Total?*	PFBA	PFHxA	PFBS	GenX
EPA	~~70~~ 0.004*	~~70~~ 0.02*	---	---	---	---	***~~Yes (2)~~***	---	---	2000	10
CA	5.1/10** 0.007***	6.5/40** 1***	---	2****	---	---	*No*	---	---	500/5000**	---
CT	70	70	70	70	70	---	***Yes (5)***	---	---	---	---
DE	21	14	---	---	---	---	*No*	---	---	---	---
IL	2	14	21	140	---	---	*No*	---	560,000	2100	---
MA, ME, RI	20	20	20	20	20	20	***Yes (6)***	---	---	2000	---
MD	---	---	---	140	---	---	---	---	---	---	---
MI	8	16	6	51	---	---	*No*	---	400,000	420	370
MN	35	15	---	47	---	---	*No*	7000	200	100	---
NH	12	15	11	18	---	---	*No*	---	---	---	---
NJ	14	13	13	---	---	---	*No*	---	---	---	---
NY	10	10	---	---	---	---	*No*	---	---	---	---
NC	---	---	---	---	---	---	---	---	---	---	140
OH	70	70	21	140	---	---	***PFOA+PFOS***	---	---	2100	21
OR	30	30	30	30	---	---	***Yes (4)***	---	---	---	---
PA	14	18	---	---	---	---	***Total < 17***	---	---	---	---
VT	20	20	20	20	20	---	***Yes (5)***	---	---	---	---
WA	10	15	14	70	---	---	*No*	---	---	1300	---

Several states not listed use previous EPA PFOA/PFOS Health Advisories of 70 ng/L as guidance.

****Interim **Notification Level/Response Level ***Draft Public Health Goal ****Notification Level***

State & EPA PFOA Drinking Water Guidelines: 2002-2020

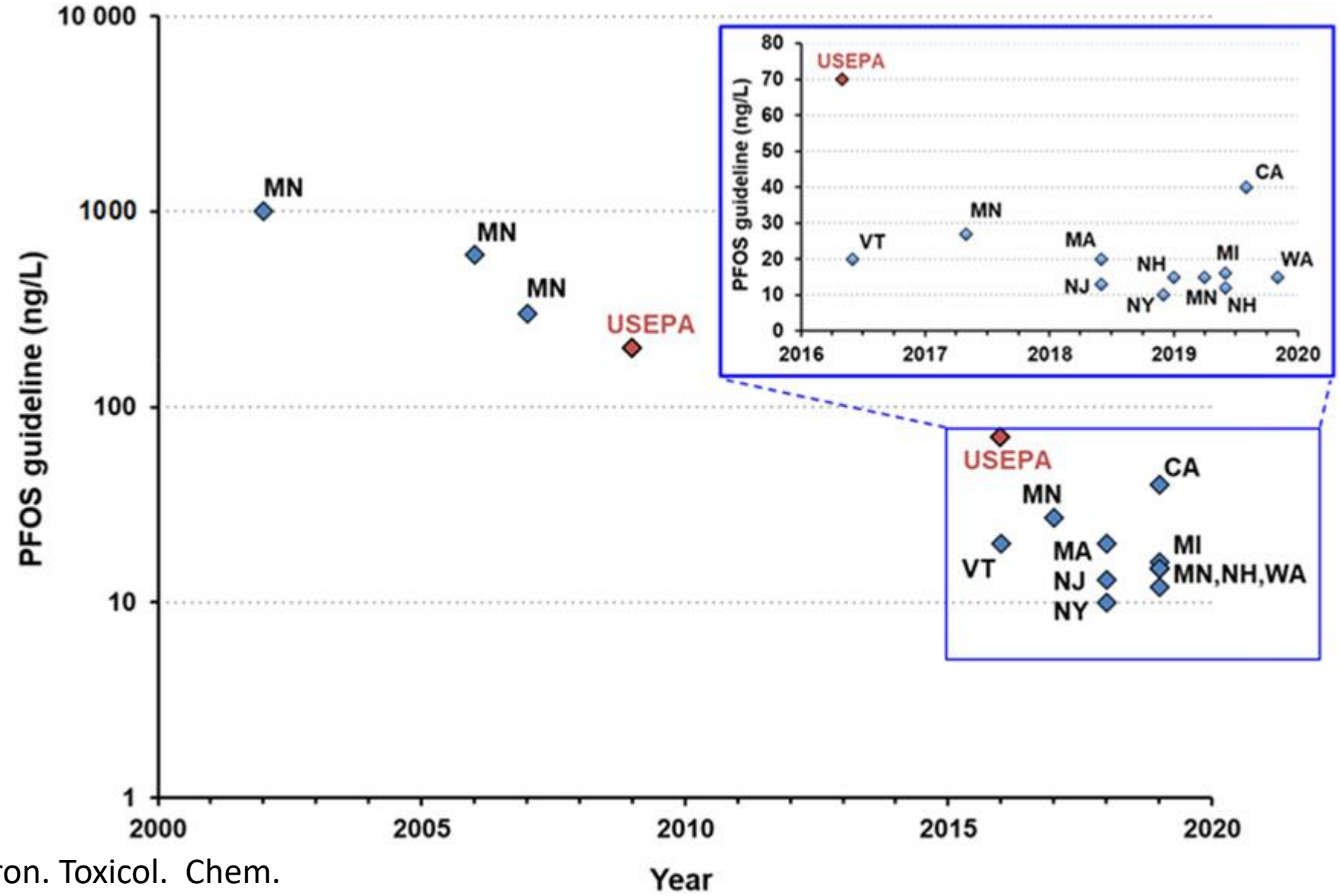
(Does not include more recent guidelines, including EPA & CA values several orders of magnitude below scale of graph)



Post (2021). Environ. Toxicol. Chem.

State & EPA PFOS Drinking Water Guidelines: 2002-2020

(Does not include more recent guidelines, including EPA value several orders of magnitude below scale of graph)



Post (2021). Environ. Toxicol. Chem.

States Guidelines for PFAS of Local Concern

- States have developed guidelines for PFAS of local concern.
  - May later become of concern in other states or nationwide.
- Examples of guidelines in response to detections near industrial facilities where discharged:
  - PFNA (phased-out 9 carbon PFAS) - New Jersey:
    - *First state to evaluate its toxicity; established MCL and ground water standard.*
    - *MCLs later established by several other states; EPA IRIS assessment currently underway.*
  - GenX (PFOA replacement) - North Carolina:
    - *First state to establish drinking water guideline.*
    - *Guidelines later established by several other states; EPA drinking water Health Advisory now final.*
  - Chloroperfluoropolyether carboxylates (ClPFPECAs; alternative for PFNA) - New Jersey:
    - *Industrial user provided toxicity studies to NJDEP; also submitted human worker biomonitoring/health effects information to EPA TSCA.*
    - *Equally or more toxic and bioaccumulative than PFOA and PFNA.*
    - *Established interim ground water criterion and standard.*

Why do human health criteria developed by different agencies differ?

In general, states follow EPA risk assessment guidance. However….

- Risk assessment is not a "cookbook" – involves scientific judgement.
- Criteria are developed at different times, and new data constantly become available.
- Scientists reviewing the same data using same risk assessment guidelines may have different conclusions.

Toxicity factor:

- Animal or human data as primary basis.
- Non-carcinogenic effects (Reference Dose) or cancer risk (slope factor).
- Choice of critical study and endpoint.
- Choice of uncertainty factors (Reference Dose); cancer risk level (carcinogens).
- Human-to-animal extrapolation approach (e.g., measured versus modeled blood serum PFAS level).
  - *Humans and animals compared on basis of internal dose (serum PFAS level).*
  - *PFAS excreted much more slowly (i.e., longer half-life) in humans.*
  - *Same administered dose results in much higher blood serum level in humans.*

Exposure assumptions:

- Choice of target population.
  - *e.g., drinking water ingestion rate for default adult, lactating woman, breastfed infant, or child.*
- Relative Source Contribution (for water criteria based on non-cancer effects).
  - *Percent of Reference Dose assumed to come from other sources.*

*PFAS Reference Dose (RfD) Development Process**

<u>Serum Level</u> Point of Departure (POD) for critical toxicological effect from animal study *(ng/ml; BMDL, NOAEL, or LOAEL)*

↓

Apply Uncertainty Factors

Target Human Serum Level (ng/L)

↓

***Apply Clearance Factor** (relates serum level to human dose)*

Target Human Serum Level (ng/L) x Clearance Factor (L/kg/day)
= Reference Dose (ng/kg/day)

**CL (L/kg/day) =
Volume of Distribution (L) x (ln 2 ÷ $t_{1/2}$ [days])

↓

Reference Dose (ng/kg/day)

Order of application of Uncertainty Factors and Clearance Factors may be reversed to develop Human Equivalent Dose POD (POD_{HED}) before applying uncertainty factors.* ***Does not affect resulting Reference Dose.*

Examples of Differences in Basis of Reference Doses for PFOA

	Draft EPA (2021)	NJ	NH	NY	MI	WA/ATSDR*	MN	VT/EPA (2016)**	MA
Critical Effect	Decreased vaccine response	Increased liver weight			Developmental: Neurobehavioral; Skeletal*		Developmental: Accelerated puberty (males); Delayed ossification		
Species	Human	Mouse							
Study	Grandjean 2012, 2017	Loveless 2006		Macon 2011	Onishchenko 2011; Koskela 2006		Lau, 2006		
Serum PFOA Metric	Measured	Measured			Modeled average				
Point of Departure	BMDL				LOAEL				
Conversion of serum PFOA to human administered dose	Model accounting for prenatal & early life exposure	Clearance factor from EPA 2016 Health Advisory (to convert serum PFOA level to human administered dose)							
Intraspecies UF	10								
Interspecies UF	1	3							
LOAEL-NOAEL UF	1	1			3	10	3	10	
Database UF	1	10	3	3	3	1	3	1	3
TOTAL UF	*10*	*300*	*100*	*100*	*300*		*300*	*300*	*1000*
RfD (ng/kg/day)	0.0015	2	6.1	1.5	3.9	3	18	20*	5

*ATSDR (2021) Minimal Risk Level (MRL). **no longer supported by EPA.

Examples of Differences in Basis for Reference Doses for PFOS

	Draft USEPA (2021)	NJ/NY	MI	MN/NH/WA	MA	VT/EPA (2016)*	ATSDR**
Critical Effect	Decreased vaccine response	↓ antibody response to foreign antigen			Developmental: ↓ body weight in offspring		
Species	Human	Mouse			Rat		
Study	Grandjean 2012, 2017	Dong 2009		Dong 2011	Luebker 2005		
Serum PFOA Metric	Measured	Measured			Modeled average		
Point of Departure	BMDL	NOAEL					
Clearance Factor	Model accounting for prenatal & early life exposure	From EPA 2016 HA; based on $t_{1/2}$ of 5.4 years (Olsen 2007)	Based on $t_{1/2}$ of 3.4 years (Li et al., 2017)		From EPA 2016 HA; based on $t_{1/2}$ of 5.4 years (Olsen 2007)		
Intraspecies UF	10						
Interspecies UF	1	3					
Database UF	1	1		3		1	10
TOTAL UF	10	*30*		*100*		*30*	*300*
RfD (ng/kg/day)	0.0079	1.8 / 2***	2.9	3	5	20	2

*No longer supported by USEPA. **ATSDR (2021) MRL. ATSDR (2021) also developed candidate MRL based on immunotoxicity (Dong 2011) of 3 ng/kg/day. ***Difference due to rounding.

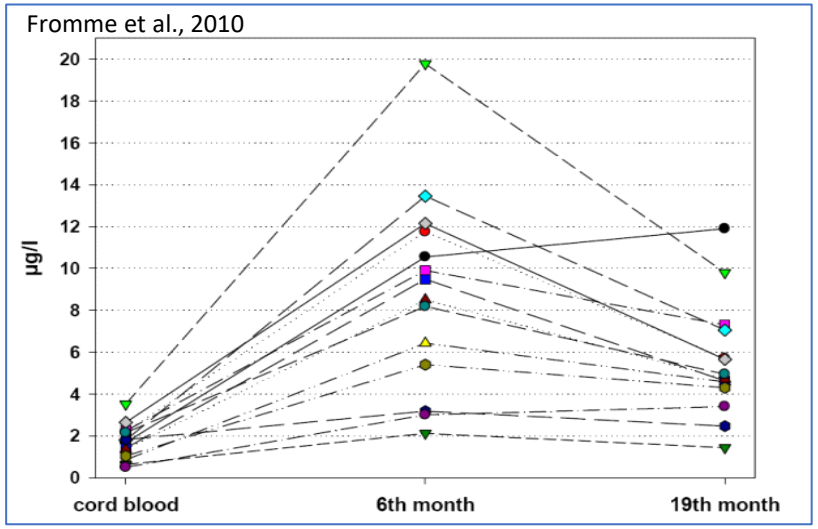
Exposure Assumptions: Drinking Water Ingestion

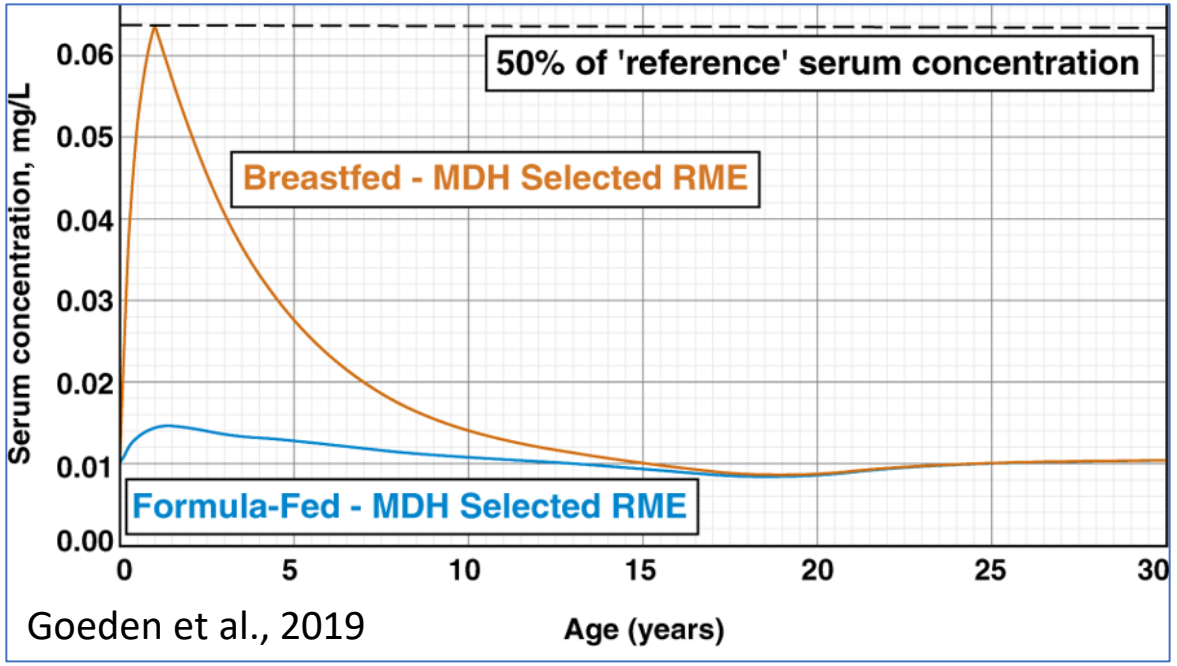
$$\text{Drinking Water Guideline (ng/L)} = \frac{\text{Reference Dose (ng/kg/day)} \times \text{Relative Source Contribution (\%)}}{\text{Water Ingestion Rate (L/kg/day)}}$$

- ↑ Ingestion rate (L/kg body wt./day) ⟶ ↓ Drinking water guideline.
- Target populations and approaches (constant ingestion rate or toxicokinetic model) that are used by one or more states:
  - *Default adult (upper percentile) - 0.029 L/kg/day.*
  - *Lactating woman (80th percentile) - 0.054 L/kg/day (EPA, 2016).*
  - *Infant, 0-1 years old (95th percentile) - 0.175 L/kg/day.*
  - *Higher exposure of breast-fed infant (MN Dept. of Health toxicokinetic model) used by several states, also considered in draft EPA (2021).*

Minnesota Department of Health Model for Early Life PFAS Exposure Example: PFOA

- Infant exposures higher than in older individuals.
- From breast milk or formula:
  - *Higher PFAS levels in breast milk than in mother's drinking water.*
  - *Infants ingest much more fluid per body weight.*
- Sensitive subpopulation for developmental & other short-term effects.
- Model considers:
  - *Prenatal exposure from maternal drinking water consumption.*
  - *Postnatal exposure from breast milk for 1 year.*
  - *Followed by lifetime drinking water exposure.*



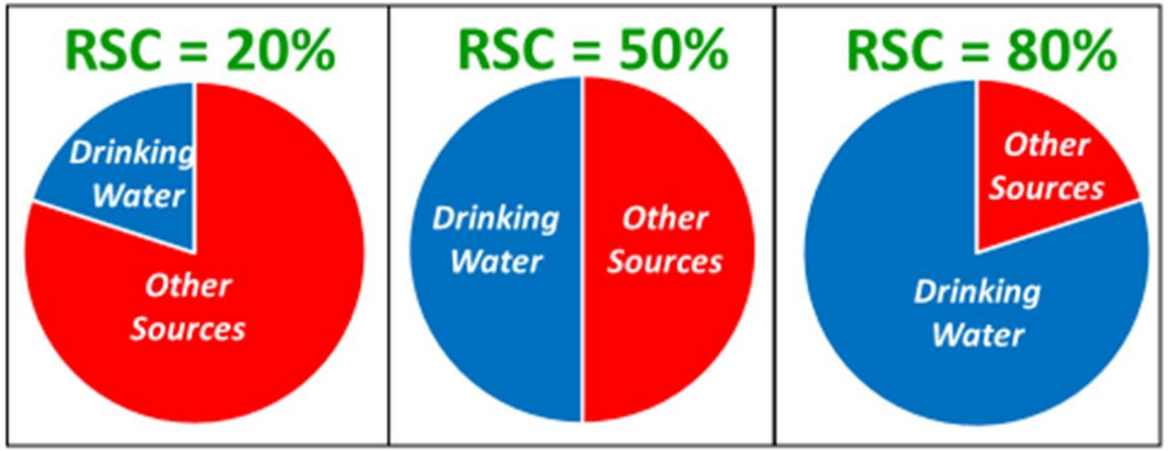


Exposure Assumptions in State Guidelines: Relative Source Contribution (RSC)

Drinking Water Guideline (ng/L) =

$$\frac{\text{Reference Dose (ng/kg/day)} \times \text{Relative Source Contribution (\%)}}{\text{Water Ingestion Rate (L/kg/day)}}$$

- Percent of total exposure assumed to come from drinking water.
  - Accounts for non-drinking water exposures (e.g., food, consumer products).
- Total exposure from drinking water + other sources should not exceed **Reference Dose**.
- ↑ RSC ⟶ ↑ drinking water guideline.
- **Default RSC:** ***20% (multiple states; EPA).***
- **Chemical-specific RSC:**
  - Can be developed if data are available.
  - 20% to 80% (per USEPA guidelines).
  - ***50% (for infants) or 60% - several other state..***



Examples of EPA & State Reference Doses, Exposure Assumptions & Drinking Water Guidelines for PFOA

	Interim EPA (2021)	EPA (2016)*	MA	VT	NJ	MN	MI	WA	NH	NY
Reference Dose (ng/kg/day)	0.0015	20	5	20	2	18	3.9	3	6.1	1.5
Ingestion Rate or Exposure Model	0.0701 L/kg/day *Child (0- <5 yr; 90th %)*	0.054 L/kg/day *Lactating woman (80th %)*		0.175 L/kg/day *Infant (0-1 yr; 95th %)*	0.029 L/kg/day *Default adult (upper %)*	Modeled: • *Prenatal exposure.* • *Breast milk - 1 yr.* • *Followed by lifetime drinking water exposure.*				Not specified *(0.029 - 0.175 L/kg/day considered)*
Relative Source Contribution	20%					50% (for infants)				60%
Guideline (ng/L)	0.004	70	20	20	14	35	8	10	12	10

*No longer supported by EPA.

Application of Guidelines to PFAS Mixtures

- Some states apply guidelines to long-chain PFAS **individually**.
- Other states apply guidelines to **total of 4 to 6 long-chain PFAS** based on:
  - *Similar structures, long human half-lives, generally similar toxic effects.*
- Draft EPA (2021) document recommends assumption of dose additivity for non-cancer effects of PFAS mixtures.

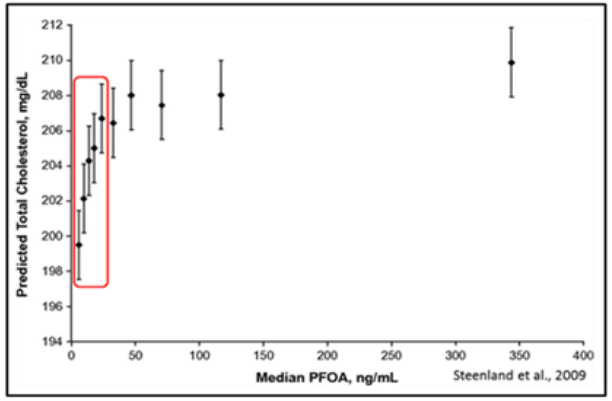
	PFOA	PFOS	PFNA	PFHxS	PFHpA	PFDA	*Total?*	PFBA	PFHxA	PFBS	GenX
EPA	~~70~~ 0.004*	~~70~~ 0.02*	---	---	---	---	***~~Yes (2)~~***	---	---	2000	10
CA	5.1/10** 0.007***	6.5/40** 1***	---	2****	---	---	*No*	---	---	500/5000**	---
CT	70	70	70	70	70	---	***Yes (5)***	---	---	---	---
DE	21	14	---	---	---	---	*No*	---	---	---	---
IL	2	14	21	140	---	---	*No*	---	560,000	2100	---
MA, ME, RI	20	20	20	20	20	20	***Yes (6)***	---	---	2000	---
MD	---	---	---	140	---	---	---	---	---	---	---
MI	8	16	6	51	---	---	*No*	---	400,000	420	370
MN	35	15	---	47	---	---	*No*	7000	200	100	---
NH	12	15	11	18	---	---	*No*	---	---	---	---
NJ	14	13	13	---	---	---	*No*	---	---	---	---
NY	10	10	---	---	---	---	*No*	---	---	---	---
NC	---	---	---	---	---	---	---	---	---	---	140
OH	70	70	21	140	---	---	***PFOA+PFOS***	---	---	2100	21
OR	30	30	30	30	---	---	***Yes (4)***	---	---	---	---
PA	14	18	---	---	---	---	***Total < 17***	---	---	---	---
VT	20	20	20	20	20	---	***Yes (5)***	---	---	---	---
WA	10	15	14	70	---	---	*No*	---	---	1300	---

Recent Use of Human Epidemiology Data in PFAS Risk Assessment

- In general, human data are preferred for risk assessment, if suitable.
- Multiple human health effects are associated with low (e.g., general population) exposures to long-chain PFAS.
  - *Generally consistent with toxicological effects in animals.*
- Generally agreed that strongest evidence for:

  ↑ *cholesterol* ↑ *liver enzymes* ↑ *kidney cancer (PFOA)*
  ↓ *birth weight* ↓ *response to vaccines*
- Until recently, all federal & state PFAS guidelines based on animal data.
  - *Previously concluded that limitations precluded human data as primary basis.*
- Recent draft EPA PFOA and PFOS risk assessments (November 2021) and interim Health Advisories (June 2022) based on human data.
- Human data also basis for other recent PFAS assessments:
  - *European Food Safety Authority (2021) - Tolerable Daily Intake for total of PFOA, PFOS, PFNA, PFHxS.*
  - *Draft California EPA (2021) - Drinking water Public Health Goals for PFOA and PFOS.*
  - *National Academies of Sciences, Engineering, and Medicine (July 2022) - recommendations for clinicians.*
- PFAS guidelines based on human data are usually lower than those based on animal data.
  - *Because human health effects occur at PFAS exposure levels far below doses used in animal studies.*

Steep Dose-Response at Low Exposure Levels – Increased Cholesterol and PFOA



Other associations at low serum levels include ↑ liver enzymes, ↓ vaccine response, and ↓ birth weight.

***Draft* EPA (2021) PFOA and PFOS Assessments**

- Draft basis for Maximum Contaminant Level Goals (MCLGs) for National Primary Drinking Water Regulation (NPDWR; MCLs or Treatment Technique).
  - *EPA plans to propose NPDWR in Fall 2022 and finalize in Fall 2023.*
- Non-cancer effects – **PFOA and PFOS**:
  - *Draft Reference Doses based on human data for ↓ antibody response to vaccines in children.*
  - *Several orders of magnitude below previous (2016) Reference Doses based on animal data.*
- Carcinogenic effects:
  - **PFOA**: *"Likely to be carcinogenic to humans." Revision from previous "suggestive evidence."*
    - *Draft cancer slope factor based on National Cancer Institute study of PFOA and kidney cancer in U.S. general population.*
    - *Much more stringent than previous slope factor based on rat tumor data.*
    - *USEPA policy for "likely carcinogens" has traditionally been MCLG of "zero" (aspirational goal).*
  - **PFOS**: *Remains as "suggestive evidence of carcinogenicity." No cancer slope factor developed.*
- Draft EPA (2021) documents were reviewed by EPA Science Advisory Board (SAB).
  - *SAB report will be finalized soon.*
  - *EPA has stated that toxicity factors (Reference Doses, PFOA cancer slope factor) will change in response to SAB comments.*

***Interim* EPA (2022) PFOA/PFOS Health Advisories**

- Interim Health Advisories (June 2022) of 0.004 ng/L for PFOA and 0.02 ng/L for PFOS.
  - *Several orders of magnitude below EPA analytical Reporting Levels of 4 ng/L.*
- Based on draft USEPA (2021) Reference Doses for decreased vaccine response in children.
  - *Consider only non-cancer effects, not cancer risk.*
- Protective for lifetime exposure, but also apply to **short-term** exposure.
  - *Effects of short-term exposure in children identified as most sensitive – more sensitive than chronic effects.*
- EPA has stated that:
  - *Interim Health Advisories **replace/supersede** 2016 Health Advisories of 70 ng/L for PFOA and PFOS.*
    - https://www.epa.gov/sdwa/drinking-water-health-advisories-pfoa-and-pfos
    - https://www.govinfo.gov/content/pkg/FR-2022-06-21/pdf/2022-13158.pdf
  - *Final Health Advisories will differ from Interim Health Advisories, in response to SAB comments (previous slide), but are likely to remain below Reporting Levels of 4 ng/L.*

National Academies of Sciences, Engineering, and Medicine (NASEM, 2022) PFAS Report

- NASEM expert panel report - "*Guidance on PFAS exposure, testing, and clinical follow-up*" - written at request of ATSDR and NIEHS.
- Some conclusions are relevant to development of health-based guidelines for PFAS.
- Conclusions on PFAS human health effects:
  - *"Sufficient evidence" for ↓ antibody response to vaccination/infection; ↑cholesterol; ↓ infant/fetal growth; ↑risk of kidney cancer.*
  - *"Suggestive/limited evidence" for ↑liver enzymes; ↑risk of pregnancy-induced hypertension, ulcerative colitis, thyroid disease/dysfunction, testicular and breast cancer.*
- NASEM conclusions on blood serum PFAS levels of potential concern:
  - *"Potential for adverse effects, especially in sensitive populations," if total serum concentration of seven PFAS* is 2 - 20 ng/mL (includes 89% of U.S. population).*
  - *"Increased risk of adverse effects" if total serum concentration of the seven PFAS is > 20 ng/mL (includes 9% of U.S. population).*
- NASEM recommendation:
  - *If total serum concentration of the seven PFAS >2 ng/L, encourage exposure reduction if source (e.g., drinking water) is identified, especially for pregnant individuals.*

*PFOA, PFOS, PFNA, PFHxS, PFDA, PFUnDA, MeFOSAA

Information Sources for PFAS Guidelines

- **Environmental Council of the States (ECOS) White Paper: Processes & Considerations for Setting State PFAS Standards**
  https://www.ecos.org/wp-content/uploads/2022/03/Standards-White-Paper_Updated_V3_2022_Final.pdf
  - Updated annually; latest update was June 2022.
  - Provides information on state efforts and considerations for future regulatory activities on PFAS.
  - Includes tables of information on state PFAS standards, advisories, and guidance values for numerous environmental media.
- **Interstate Technical & Regulatory Council (ITRC) PFAS Water and Soil Values Table Excel file**
  - Updated ~monthly.
  - Includes soil and water values established by EPA, states, and other nations.

Thank you!

For questions or additional information:

Contact me at gloria.post@dep.nj.gov

NJDEP Division of Science & Research PFAS website:
https://www.nj.gov/dep/dsr/pfas.htm

NJDEP Division of Science & Research Peer-reviewed PFAS Publications

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EPA's Effluent Limitations Guidelines and Standards (ELG) Program Update

Wisconsin DNR – PFAS Technical Group

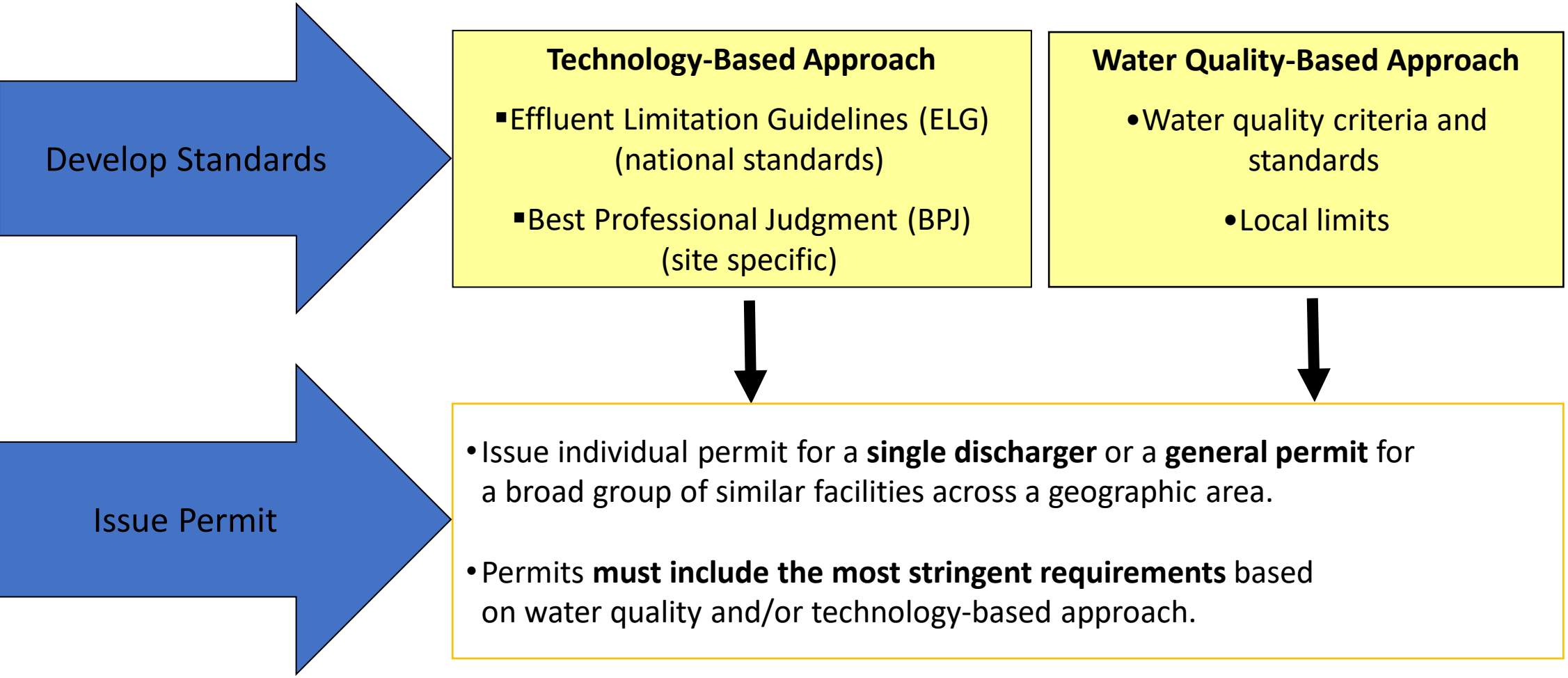
August 19th, 2022

Doruntinë (Dori) Rexhepi
ELG Planning Project

Outline

- Overview of ELG Program & Planning Process
- Preliminary ELG Program Plan 15
  - Results of 2021 annual review
  - Results from industry studies
    - Focus: Multi-Industry PFAS Study
  - Announcements of rulemakings
- Clean Water Act (CWA) Analytical Methods

Regulation of Point Source Discharges



Effluent Limitation Guidelines and Standards (ELGs)

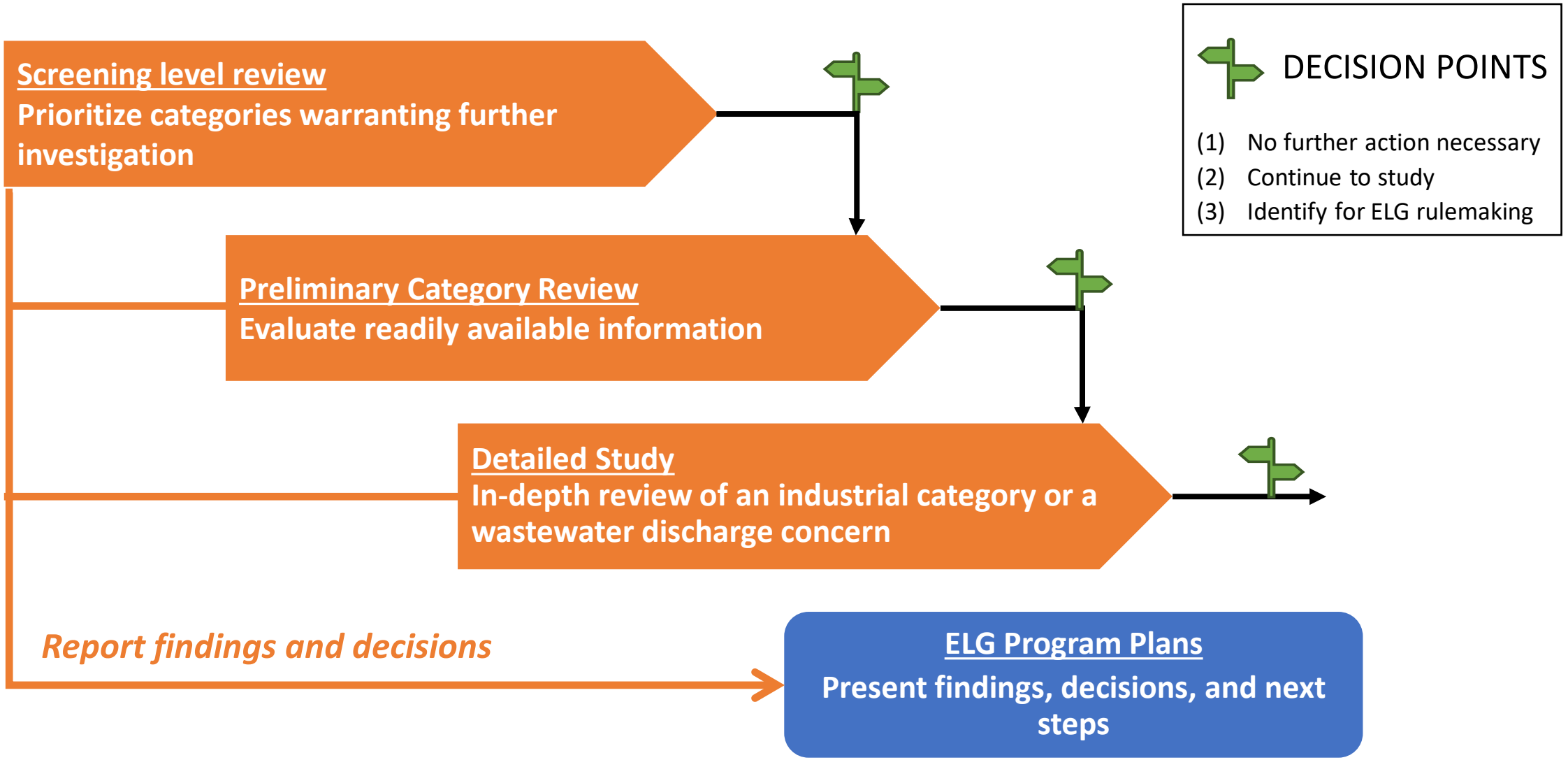
- Effluent Guidelines are:
  - National wastewater discharge standards.
  - Technology-based regulations developed for a specific industry.
  - Represent the greatest pollutant reductions that are economically achievable for an industry.
  - For sources discharging directly to surface waters and indirectly to publicly owned treatment plants (POTWs).
- The CWA requires EPA to review and, if appropriate, develop new or revise existing Effluent Guidelines.

Effluent Guidelines Planning

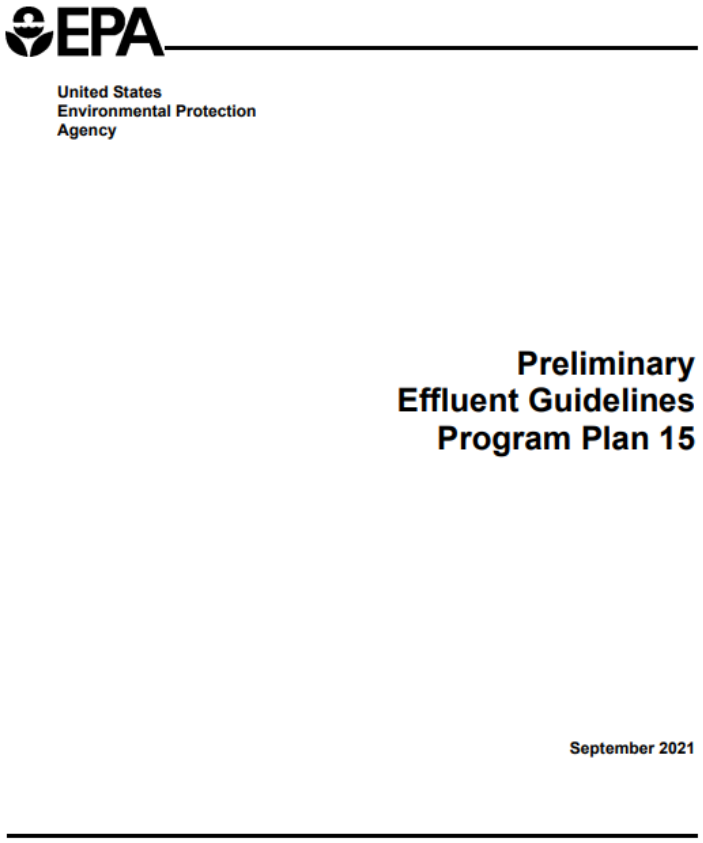
- The 1987 CWA Amendments added Section 304(m), which re-enforced Congress' intent that effluent guidelines keep pace with pollution prevention and treatment technology.
- EPA must review all promulgated effluent guidelines annually.
- EPA publishes a plan every other year, after proposal and public comment, for the guidelines program which:
  - Establishes a schedule for any effluent guidelines revisions that have been identified.
  - Identifies any industries not currently subject to effluent guidelines that discharge nontrivial amounts of toxics and establishes a schedule to take final action.

We call these Effluent Guidelines Program Plans

Review of Existing Effluent Guidelines



Preliminary ELG Program Plan 15

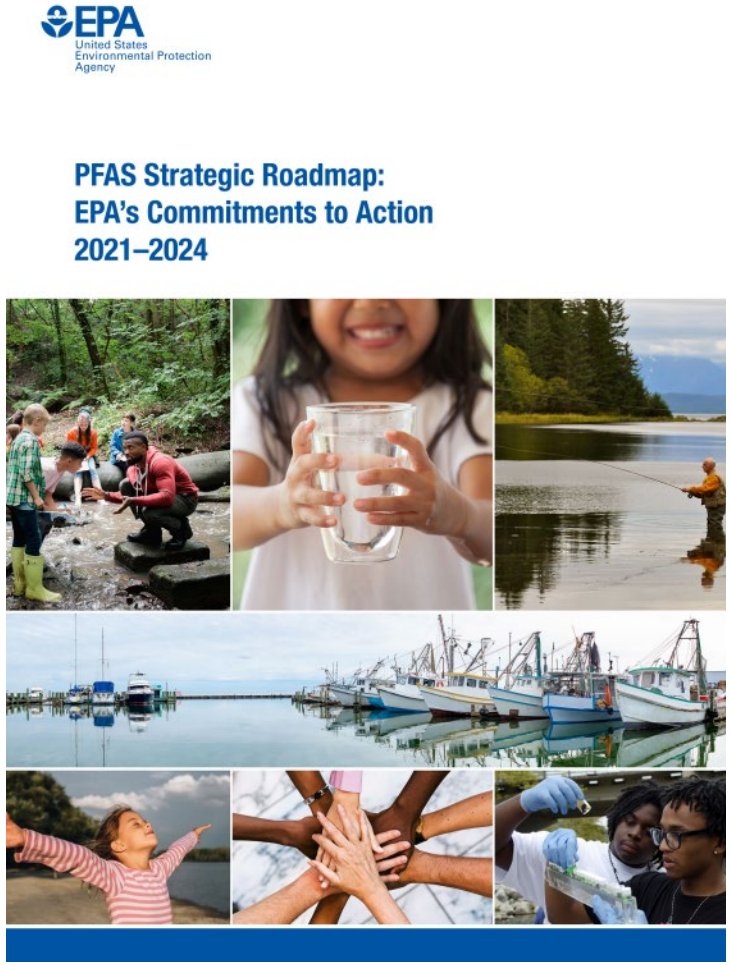


- Signed on September 8th, 2021
  - Public comments period closed on October 14th, 2021.
  - EPA is currently reviewing and assessing comments received and will address them accordingly in Program Plan 15.
- The Preliminary Plan 15 discusses:
  - Results of 2021 preliminary category reviews.
  - Concluding, continuing and new detailed studies:
    - Study of Electrical and Electronic Components Category
    - Study of Meat and Poultry Products Point Source Category
    - Study of Oil and Gas Extraction Wastewater Management
  - New rulemakings.
  - Other updates and announcements of new initiatives.

2021 Preliminary Category Review: Landfills Review

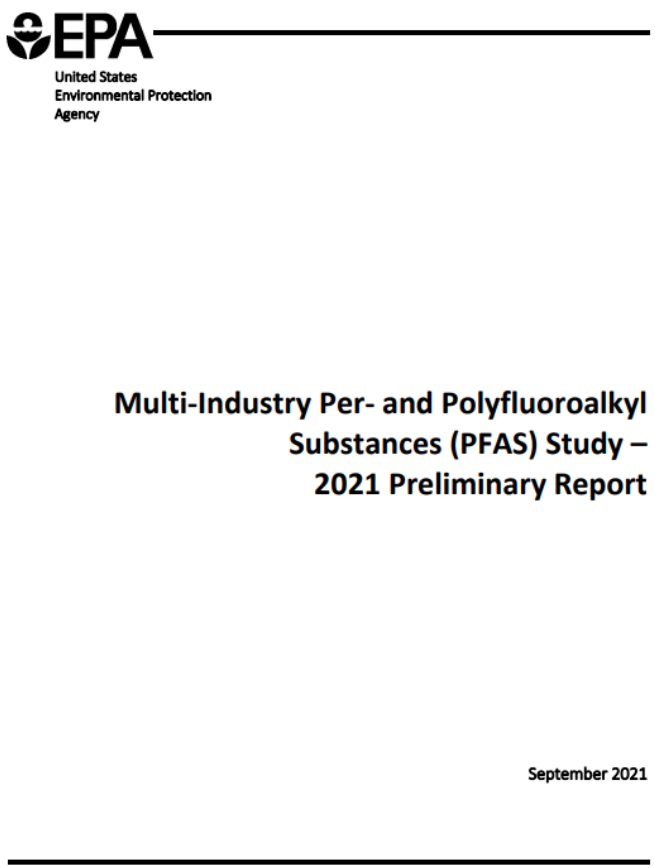
- EPA initiated a preliminary review of the Landfills PSC based on public comments received on Plan 14, identifying landfill leachate as a source of PFAS to surface water, groundwater, and POTWs.
  - EPA's review included but was not limited to PFAS.
- Areas of land or excavations in which hazardous and non-hazardous waste are placed for permanent disposal.
  - RCRA regulations require landfill operators to collect the leachate.
- Uses or Sources of PFAS
  - Receive many types of wastestreams containing PFAS, including:
    - Sludge from wastewater treatment plants.
    - Consumer Waste (e.g., treated paper & textiles, electronics).
    - Construction & Demolition Waste (e.g., carpets, building materials).
    - Industrial Waste (e.g., PFAS manufacturing waste).
  - Degradation and weathering cause PFAS to leach from solid waste to a wastewater stream.
- **Key Findings - Profile**
  - EPA identified more 1,000+ landfills in the U.S. that are generating and discharging landfill leachate.
  - Non-hazardous landfills are more likely to indirectly discharge landfill leachate to POTWs than hazardous landfills.
- **Key Findings – Wastewater Characterization**
  - Documented PFAS present in all landfill leachate samples collected from 100 facilities. Large variance in PFAS concentrations.
  - Factors affecting leachate PFAS concentrations include landfill type, climate, and age.
- **Key Findings – Control**
  - Landfill leachate presents a challenge for PFAS removal due to the presence of competing pollutants and varied PFAS concentrations.

2022 Preliminary Category Reviews



- As announced in the EPA's PFAS Strategic Roadmap, EPA has initiated data reviews for industrial categories for which there is little known information on PFAS discharges:
  - Plastics Molding and Forming (40 CFR 463)
  - Paint Formulating (40 CFR 446)
  - Leather Tanning (40 CFR 425)
- Once data review is complete, EPA will decide whether there are sufficient data to initiate a potential rulemaking or further review.

ELG Studies: Multi-Industry PFAS Study



- **Multi-Industry PFAS Study** – 2021 Preliminary Report
  - EPA reviewed information and data collected on PFAS manufacture, use, treatment, and discharge to surface water and POTWs by categories that EPA determined were likely to be discharging PFAS in their wastewater, and this includes commercial airports, pulp and paper, metal finishing, textile mills, and PFAS manufacturing facilities.
- Objectives:
  - Examine specific industrial categories manufacturing or using PFAS.
  - Identify specific facilities discharging PFAS in their wastewater.
  - Collect, compile, and review information on PFAS in discharges.
  - Determine types and concentrations of PFAS in wastewater discharges.
  - Assess availability of technologies capable of reducing or eliminating PFAS in wastewater discharges.

Multi-Industry PFAS Study – OCPSF Review

- Industrial facilities that manufacture organic chemicals, plastics, synthetic fibers or resin products.
- EPA focused its review on the subset of facilities that manufacture PFAS or process PFAS in production of other products.
- Uses or Sources of PFAS
  - Manufacture PFAS feedstocks.
  - Blend, convert, or integrate with other materials to produce new commercial or immediate products (e.g., plastic, rubber, resin).
  - Polymerization processing aids.
  - Manufacture PFAS-based commercial chemical products (e.g., carpet cleaning sprays, cleaning agents, protective coatings).
- **Key Findings - Profile**
  - Identified 6+ PFAS manufacturers and 7+ PFAS processors/formulators that potentially discharge PFAS-containing wastewater.
  - Long-chain PFAS that have been phased out in the U.S. were replaced with short-chain homologues manufactured by the same companies.
- **Key Findings – Wastewater Characterization**
  - Documented presence of 25+ PFAS in wastewater discharges.
  - PFAS manufacturer concentrations > PFAS processors/formulator concentrations.
- **Key Findings – Control**
  - Few permits include PFAS monitoring or control requirements.
  - Some facilities controlling PFAS using GAC, IX, RO, or thermal systems.

Multi-Industry PFAS Study – Metal Finishing Review

- Industrial facilities that change the surface of an object to improve its appearance or durability.
- Includes electroplating, electroless plating, anodizing, coating, printed circuit board manufacturing, and chemical etching and milling.
- EPA determined chromium electroplating and chromium anodizing is a significant source of PFAS in metal finishing wastewater; therefore, EPA focused its review on the subset of facilities that perform these operations.
- Uses or Sources of PFAS
  - Wetting agents.
  - Mist and fume suppressants to prevent air emissions of toxic fumes.
  - Reduce mechanical wear.
  - Surface coatings to reduce corrosion or enhance appearance.
- **Key Findings - Profile**
  - Potentially half of 1,300+ chromium electroplating facilities in the U.S apply PFAS-based mist and fume suppressant to control Cr VI fumes.
  - Mist and fume suppressants with > 1% PFOS no longer used in the U.S., but modern suppressants contain other PFAS (e.g., 6:2 FTSA, F-53B).
- **Key Findings – Wastewater Characterization**
  - Documented presence of 16+ PFAS in discharges.
  - Average 6:2 FTSA concentration > 100x any other detected PFAS.
  - PFOS still present despite 2015 phase out of PFOS-based suppressants.
- **Key Findings – Control**
  - Few permits include PFAS monitoring or control requirements.
  - Alternative controls for hexavalent chromium fumes are available.
  - Some facilities controlling PFAS using GAC.

Multi-Industry PFAS Study – Pulp and Paper Review

- Mills that convert wood or recycled fibers into pulp, paper, paperboard, and other cellulose-based products.
- Converting facilities that cut, fold, or otherwise convert pulp and paper into commercial products.
- Uses or Sources of PFAS
  - Additives or coatings to provide products with water and grease repellency.
  - Certain PFAS are approved by the Food and Drug Administration for use in food contact substances (i.e., food packaging and tableware).
  - Recycling of paper and paperboard products treated with PFAS.
- **Key Findings - Profile**
  - Documented approximately 10 facilities operated by 6 companies which have used PFAS in pulp or paper manufacture since 2020.
  - PFAS-containing product production represents less than 10% of total facility production and less than 1% of total industry production.
- **Key Findings – Wastewater Characterization**
  - Documented presence of 16+ PFAS in discharges.
  - 6:2 FTSA & short-chain PFCAs concentrations (degradation products of FDA-approved PFAS) > other PFAS concentrations.
- **Key Findings – Control**
  - Few permits include PFAS monitoring or control requirements.
  - Companies using PFAS indicated plans to eliminate PFAS use by end of 2024.

Multi-Industry PFAS Study – Textile Mills Review

- Textile mills receive and prepare fibers; transform fibers into yarn, thread, or webbing; convert yarn and webbing into fabric or related products; or finish these materials.
- Many facilities produce a final consumer product (e.g., thread, yarn, fabric) while the rest produce an intermediate product for use by other establishments in the industry.
- Uses or Sources of PFAS
  - Additives or coatings to provide products with water, oil, soil, and/or heat resistance.
  - Improve cleanability of oil- and water-based stains.
  - Wetting or antifoaming agents in dyeing and bleaching.
  - Breathable moisture barrier to wind and rain in outdoor gear
- **Key Findings - Profile**
  - EPA did not receive information or data from textile mills industry.
  - EPA does not have information to identify specific facilities using PFAS.
  - Majority of textile mills are concentrated in southeastern U.S.
- **Key Findings – Wastewater Characterization**
  - Documented presence of PFOA and PFOS in discharges.
  - EPA has limited concentration data on PFAS discharges by textile mills.
- **Key Findings – Control**
  - No final permits include PFAS monitoring or control requirements.
  - EPA does not have information on PFAS control at textile mills.

Multi-Industry PFAS Study – Commercial Airports Review

- Facilities associated with commercial air transport or aircraft flight operations.
- Military installations and other U.S. Department of Defense facilities are not considered commercial airports; therefore, PFAS use and discharge by these facilities are outside the scope of this study.
- Uses or Sources of PFAS
  - Component of aqueous film-forming foam (AFFF) used for exterminating hydrocarbon fuel fires, firefighting equipment testing, and firefighting training.
  - 14 CFR 139 contains the regulations pertaining to certification of airports and requires use of firefighting foams that conform to Mil-Spec MIL-PRF-24385. As of June 2021, all firefighting foams that meet MIL-PRF-24385 contain PFAS (concentrations <800 parts-per-billion).
- **Key Findings - Profile**
  - As of April 2021, FAA has certified 519 commercial airports which are required to use PFAS-based AFFF.
- **Key Findings – Wastewater Characterization**
  - Airports historically generated PFAS-containing wastewater during periodic testing and rinsing of equipment, live-fire firefighting training, emergency response activities, and accidental leaks.
- **Key Findings – Control**
  - FAA dropped mandate to use firefighting foams contain PFAS.
  - FAA approved and funds technologies and procedures that do not require dispensing AFFF during periodic equipment testing and training.
  - Developing fluorine-free alternatives that are environmentally friendly and provide same level of safety offered by Mil-Spec MIL-PRF-24385.

CWA Analytical Methods

- EPA published **Draft Method 1633**
  - A single-laboratory validated method to test for ***40 PFAS compounds*** in wastewater, surface water, groundwater, soil, biosolids, sediment, landfill leachate, and fish tissue.
- This draft method can be used in various applications, including National Pollutant Discharge Elimination System (NPDES) permits.
  - The method will support NPDES implementation by providing a consistent PFAS method that has been tested in a wide variety of wastewaters and contains all the required quality control elements in CWA method.
  - While the method is not nationally required for CWA compliance monitoring until EPA has promulgated it through rulemaking, ***it is recommended now for use in individual permits***.
- EPA published **Draft Method 1621 for Adsorbable Organic Fluorine (AOF)**
  - A single-laboratory validated method to screen for organofluorines in wastewaters and surface waters by Combustion Ion Chromatography (CIC).

Summary of PFAS efforts within ELG Program

- **Organic Chemicals, Plastics & Synthetics Fibers (OCPSF - 40 CFR Part 414)**
  - After completing the Multi-Industry PFAS Study, EPA is ***preparing a rulemaking to revise this regulation*** to address PFAS dischargers from facilities that manufacture PFAS.
- **Metal Finishing (40 CFR 433) & Electroplating (40 CFR Part 413)**
  - After completing the Multi-Industry PFAS Study, EPA is ***preparing a rulemaking to revise this regulation*** to address PFAS dischargers from metal finishing and electroplating facilities.
- **Textile Mills Detailed Study (40 CFR part 410)**
  - Detailed study of wastewater discharges from the Textile Mills point source to continue collecting and reviewing information and data on wastewater discharges of PFAS from textile mills that historically or currently use PFAS
- **Landfills Detailed Study (40 CFR 445)**
  - The goals of this study were to understand the total number and location of landfills discharging leachate across the US, characterize PFAS in leachate effluent from regulated landfills, and identify
- **Preliminary Category Reviews:**
  - Leather Tanning and Finishing (40 CFR part 425)
  - Paint Formulating (40 CFR part 446)
  - Plastics Molding and Forming (40 CFR part 463)
- **CWA Analytical Methods**

Other ELG Reviews, Studies & Rulemakings

- **2021 Preliminary Category Reviews**
  - Metal Products and Machinery (40 CFR Part 438), Explosives Manufacturing (30 CFR Part 457), Canned and Preserved Seafood (40 CFR 408), Sugar Processing (40 CFR Part 409), Soap and Detergent Manufacturing (40 CFR Part 417)
- **Study of Electrical and Electronic Components Category**
  - EPA is in the process of finalizing a study report to document this review and will ***evaluate next steps*** after the report is complete. EPA will provide an update on this study in the ELG Program Plan 15.
- **Study of Meat and Poultry Products Point Source Category**
  - EPA has completed the detailed study and data reviewed indicated that a revision of the ELG may be appropriate. As such, EPA ***initiated a rulemaking to revise*** the ELG for the Meat and Poultry Products category to address nutrient discharges.
- **Study of Oil and Gas Extraction Wastewater Management**
  - After further consideration, EPA ***decided to not move forward with revisions*** to the Oil and Gas Extraction ELGs at this time. EPA determined that the existing regulations provide sufficient flexibility for managing produced waters at the national level at this time. EPA will continue to monitor and evaluate activities being done at the state level and may re-visit regulatory changes in the future to address produced water discharges if industry practices change.
- **Steam Electric (40 CFR part 423) rulemaking**
  - EPA promulgated revisions to the Steam Electric ELGs in November 2015; which were revised in 2020.
  - On July 2021, EPA announced that it is initiating a rulemaking process to strengthen certain wastewater pollution discharge limits for coal power plants that use steam to generate electricity.
  - EPA intends to publish a proposed rule in late 2022.
- **Meat and Poultry Products (40 CFR 432) rulemaking**
  - EPA submitted a new Information Collection Request to OMB in March 2022 to obtain approval for two industry questionnaires to support the current rulemaking.
  - Public comment period for draft questionnaire ended on April 15, 2022.

Questions?

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DNR Updates, Conclusions & Next Steps