The PFAS Emergence: Is it Summer Yet? Assessing and Managing Risk

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This presentation will explore the following topics

- How is risk assessment for PFAS different from other chemicals?
- What are the health effects associated with PFAS?
- How do those health effects translate to risk-based levels?
- Why are drinking water standards for PFAS so low?

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Risk assessment vs. Risk-based concentration vs. Drinking water standard

Risk Assessment

What is the risk associated with exposure?

Risk = Exposure x Media concentration x Toxicity

- Risk: Cancer risk, Hazard index
- Exposure: Receptor, Exposure pathway, Exposure scenario
- Toxicity: Reference dose or Slope factor

Risk-Based Concentration

What is the concentration associated with exposure and risk?

Concentration = Risk / Exposure x Toxicity

Drinking Water Standard

What is the legally enforceable allowable concentration in drinking water?

Considers a balance of:

- Risk-based concentration (MCL goal)
- Treatment technology
- Cost-benefit

Characteristics of PFAS and 'classic' contaminants

Major Characteristics of Compound Class							
	PFAS	PCBs	Dioxins	PAHs	CVOCs	Mercury	Lead
Industrial/manufacturing uses	X	X	X	X	X	X	X
Present in consumer products / biosolids	X						(x)
Adsorbs to soil and sediment		X	X	X		X	X
Readily leaches to water	X				X		
Migrates in water	X				X		
Does not degrade in environment	X	X	X			X	X
Anthropogenic background	X		X	X		X	(x)
Bioaccumulates in food chain	X	X	X			X	X
Risk-based thresholds within 10X analytical detection limit	X		X	X	X		
Half-life in humans	2 - 27 years	2 - 6 years	7 - 11 years	<1 day	<1 day	30 - 60 days	2 months (tissue) / 35 years (bone)

- *…if dioxins were water soluble, then would a 'PFAS-like' response have happened decades ago…?*

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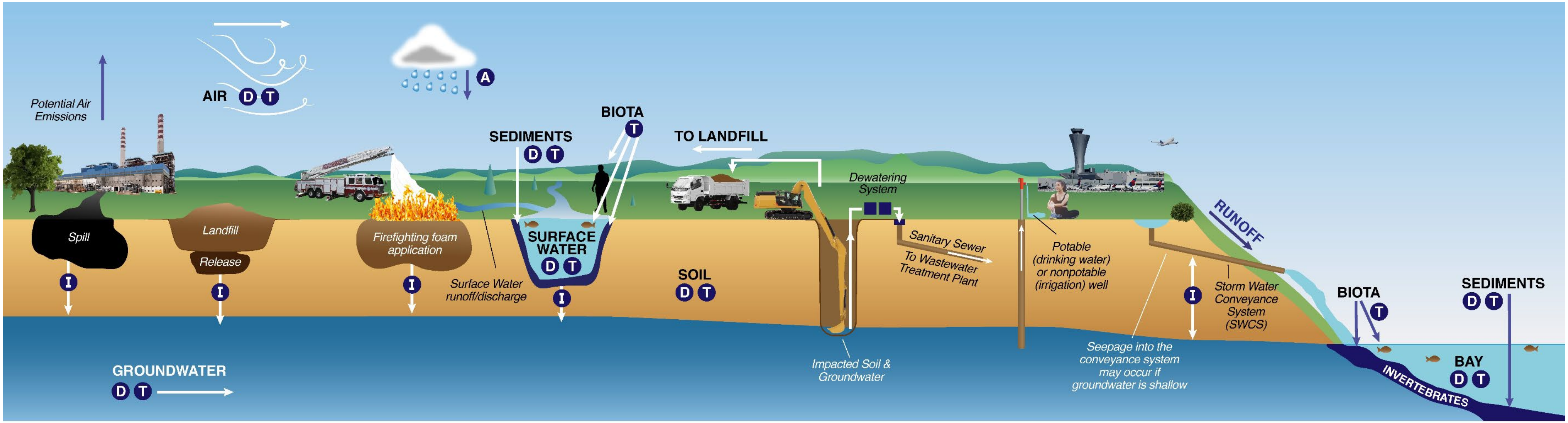
PFAS in our environment:
Sources, Migration pathways, and Receptors



KEY A **Atmospheric Deposition** D **Diffusion/Dispersion/Advection** I **Infiltration** T **Transformation of precursors (abiotic/biotic)**

- Soil → Leaching → Groundwater → Surface Water
- Landfills → Leaching to groundwater
- GWTP – NPDES – discharge to storm/sanitary
- Air → Deposition → Leaching → Groundwater
- WWTP → directly to surface water → biosolids → land application → crop uptake → food chain

Ultimate receiving media: groundwater, surface water, food chain

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Where are PFAS? Significant pathways and media

- Where do we find PFAS?
  - Worldwide (anthropogenic distribution)

Pathway	Exposure Media
Leaching to groundwater	Groundwater
Migration and discharge to surface water	Surface water and fish
Biosolids application / irrigation with contaminated groundwater	Food crops
Air dispersion, deposition, and subsequent leaching	Groundwater
Direct contact with soil	Soil

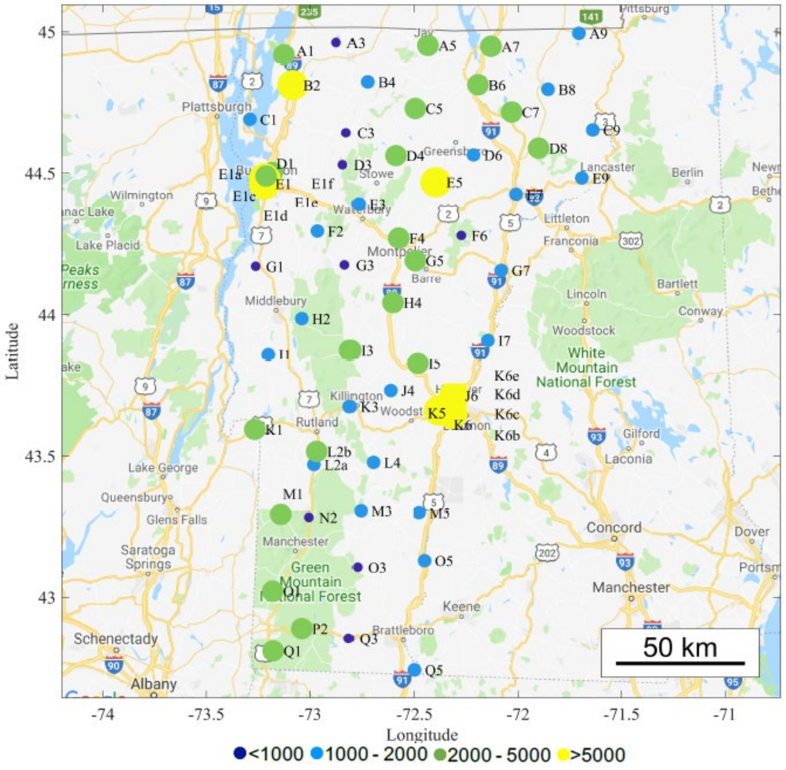

Figure 5.1. Spatial distribution of ΣPFAS.

- Identified in these media because:
  - No degradation
  - Analytical detection limits are very low (less than 2 parts per trillion)

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How is risk assessment for PFAS different from other chemicals?

- More exposure media and receptors
  - Migration long distances in water, persistence, bioaccumulation
  - Surface water systems, fish consumption, game hunting
  - Food crops, dairy, meat

Maine dairy farm plagued by chemical contaminants may be 'tip iceberg'

Jill Brady | York Coun

Fred Stone, owner of Stoneridge Farms, Inc., holds his six-month-old cow Lida Rose on Tuesday. Stone said his dairy been ruined by chemicals in sludge the state approved for spreading.

'Do Not Eat' deer advisory issued after PFAS contamination

By LESTER GRAHAM • OCT 19, 2018

PROGRAM The Environment Report

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Clark's Marsh near the closed Wurtsmith Air Force Base is contaminated with PFAS chemicals.

CREDIT LESTER GRAHAM / MICHIGAN RADIO

State agencies in Michigan have issued a 'Do Not Eat' advisory for deer in Oscoda Township near the closed Wurtsmith Air Force Base.

The state tested deer tissue from areas across the state known to have PFAS chemical contamination, including places such as Grayling, Rockford, and Oscoda Township.

NEWS

Michiganders warned not to eat PFAS-contaminated freshwater fish

The chemical bonds don't degrade or do so only slowly in the environment and remain in a person's bloodstream indefinitely

Angela Mulka, Staff writer

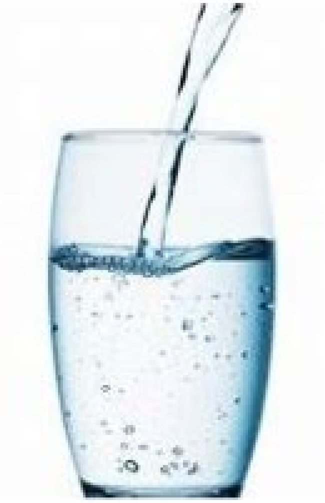
May 6, 2022

Risk assessment for PFAS differs from other chemicals: *Exposure*

- In addition to drinking water, food web exposures may need to be considered
- Even if an aquifer is not used for drinking water, use of water for livestock or food crops, migration to surface water, and subsequent food web exposure may need to be considered
- Generally, direct contact with soil is not a significant exposure pathway

PFAS and human health effects

- Epidemiology studies:
  - Occupational exposure studies
  - Residential drinking water studies
  - General population/background exposure studies



- Evidence suggest link between PFAS exposure and:
  - Pregnancy-induced hypertension/pre-eclampsia
  - Elevated liver enzymes
  - Increased cholesterol and serum lipids
  - Decreased antibody response to vaccines
  - Small decreases in birth weight
  - Carcinogenicity – increase in testicular and kidney cancers in highly exposed populations

Source: ATSDR Toxicological Profile for Perfluoroalkyls (2020)

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Comparing toxicological effects in humans and animals

Toxicological effect	Human	Animal
Pre-eclampsia	X	
Liver – enzymes and cholesterol	X	X
Liver - enlargement		X
Immune – decreased antibody response	X	X
Developmental		X
Carcinogenicity	X (kidney/testicular)	X (liver/pancreas)

- Mechanism of toxicity: fairly well understood in animals / developing understanding in humans
  - Adds to the challenge of correlating PFAS with health effects
  - Especially when effects are subtle and there is a need to differentiate baseline PFAS in serum from elevated PFAS in serum

Challenges in establishing toxicity values

- Human epidemiology studies not sufficient to establish a statistically significant relationship between PFAS intake and adverse effect
  - However, as blood PFAS levels increase, so does correlation with prevalence of health effects
- Challenges correlating PFAS intake, blood levels, and health effects
  - Must use laboratory animal studies to derive toxicity values
  - PFAS half-life in humans in years versus days for laboratory rodents
  - Modeling used to translate effects in laboratory animal to exposure in humans
  - Lots of unknowns

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Example development of toxicity value for PFOA (ATSDR)

Identify threshold dose in animal study (mg/kg/day)	modeling →	Estimate plasma PFAS in animal (ug/mL)	modeling →	Calculate equivalent dose in human corresponding to plasma level (mg/kg/day)	Apply uncertainty factors	Toxicity value (mg/kg/day)
0.3 mg/kg/day		8.29 ug/mL		8.2×10^{-4} mg/kg/day	300	2.7×10^{-6} mg/kg/day

- Net result: toxicity values are very low
  - Reflects modeling, half-life

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Comparison of PFAS toxicity value development with 'classic' contaminants

	Variables in Toxity Value Development			
Compound class:	PFAS	PCBs	PAHs	CVOCs
Example compound:	PFOA	Aroclor-1254	Benzo(a)pyrene	TCE
Animal study LOAEL or NOAEL (mg/kg/day)	0.30	0.005	0.21	0.35
Human equivalent concentration (mg/kg/day)	8.2E-04	--	9.2E-02	4.8E-02
Uncertainty factor	300	300	300	100
Toxicity value (reference dose; mg/kg/day)	2.7E-06	2.0E-05	3.0E-04	5.0E-04

~350X

~2X

~7X

- Modeling of animal to human exposure accounts for difference in PFAS values

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Toxicity value development has been led by states

Location	PFOA	PFOS	PFNA	PFBA	PFBS	PFHxS	PFHpS	PFHxA	PFPeA	PFHpA	PFOSA	PFDA	PFDS	PFUnDA	PFDoDA	PFTrDA	PFTeDA	6:2 FTS	8:2 FTS	Gen-X	NEtFOSAA, NMeFOSAA, PFTA, PFUnA
USEPA - Office of Water (2016)	X	X																			
California (CA)	X	X																			
Hawaii (HI)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				
Massachusetts (MA)	X	X	X			X				X		X									
Michigan (MI)	X	X	X		X	X		X												X	
Minnesota (MN)	X	X		X	X	X															
New Hampshire (NH)	X	X	X			X															
New Jersey (NJ)	X	X																			
New York (NY)	X	X																			
North Carolina (NC)	X																			X	
Texas (TX)	X	X	X	X	X	X		X	X	X	X	X		X	X	X	X				
Vermont (VT)	X	X	X			X				X											
ATSDR (2020)	X	X	X			X															
USEPA - Office of Water (2022)	(X)	(X)																			
USEPA - IRIS (2022 ->)			(X)	X	[X]	X		X				(X)									

(X) - draft value
[X] - PPRTV

- 2016: EPA office of water (PFOA, PFOS only)
- 2017 – 2020: Several states (several PFAS – different approach = lower values
- 2020: EPA ATSDR (several PFAS)
- 2022: EPA IRIS (several PFAS – in development)
- 2022: EPA office of water (PFOA, PFOS revision - draft)

Variability in toxicity values – PFOA as an example

- RfDs for same compound span 10-fold
- RfDs based on the same critical effect / study differ
- None of the toxicity values align with principal effects observed in epidemiology studies

Jurisdiction	Critical Effect Key Study Refence	Toxicity Value RfD (mg/kg-day)	Toxicity Value CSF $(mg/kg\text{-}day)^{-1}$
Federal			
USEPA	Developmental (reduced ossification, accelerated puberty) (Lau et al. 2006)	2.0E-05	NA
ATSDR	Neurodevelopmental and skeletal effects in mice (Koskela et al. 2016; Onishchenko et al. 2011).	2.0E-06	NA
State			
California	Hepatocellular adenoma/carcinoma and pancreatic acinar cell adenoma/carcinoma.	4.5E-07	143
Massachusetts (MA)	Based on USEPA RfD, with application of additional UF.	6.3E-06	*NA*
Michigan	Developmental delays (skeletal alteration). The same as ATSDR (2018) critical studies (Onishchenko, et al,	3.9E-06	*NA*
Minnesota	Developmental (reduced ossification, accelerated puberty), increased marenal liver weight	1.8E-05	NA
New Hampshire	Increased liver weight (Lovelss et al., 2006; NJ DWQI 2017)	6.1E-06	NA
New Jersey	Increased liver weight (Lovelss et al., 2006)	2.0E-06	NA
Texas	Mammary gland developmental effects (Macon et al. 2011)	1.2E-05	NA
Washington	Developmental effects in mice.	3.0E-06	NA

Breaking news… EPA draft toxicity values for PFAS
In support of updated health advisories

- Based on epidemiology studies: decreased antibody response to DPT vaccine with increasing PFAS serum level in children
  - Lines of evidence support immune impairment as a target effect of PFAS exposure
  - Decreased antibody response is a biomarker, *not an adverse health effect*
  - National Toxicology Program concluded that PFAS may lower antibody response, but low chance for increased infectious response
- RfD based on intake required to produce a 0.2 ng/mL increase in serum PFAS
  - 5% increased risk for lower antibody levels; lower 95% confidence interval
  - Serum level in study population: 4.06 ng/mL (consistent with general population)
- Toxicity values that are ~2E-09 (orders of magnitude lower than current RfDs)

Risk assessment for PFAS differs from other chemicals: *Toxicity Values*

- Based on effects in laboratory animals that may not be observed in humans
- Protective for low risk of biomarkers, not necessarily adverse health effects
- Based on modelled exposures with many assumptions; highly influenced by differences in half-life of PFAS in laboratory animals vs. humans
- Do the toxicity values correlate to PFAS levels in which epidemiology studies identified an adverse effect?

Why do drinking water values/standards differ?

Regulatory Entity	PFAS Compound	Toxicity value (RfD)	Drinking Water Intake (DWI) Critical receptor	Relative Source Contribution (RSC)	Regulatory value (ug/L)
EPA - office of water	PFOA/PFOS	2.0E-05	lactating woman	0.2	0.07*
Michigan	PFOA	3.9E-06	mother, infant, adult	0.5	0.008
	PFOS	2.9E-06	mother, infant, adult	0.5	0.016
Minnesota	PFOA	1.8E-05	infant and mother	0.5	0.035
	PFOS	3.1E-06	infant and mother	0.5	0.015
New Hampshire	PFOA	6.1E-06	infant and mother	0.5	0.012
	PFOS	3.1E-06	infant and mother	0.5	0.015
New Jersey	PFOA	2.0E-06	adult	0.2	0.014
	PFOS	1.8E-06	adult	0.2	0.013
Massachusetts	PFOA/PFOS	6.3E-06	nursing mother	0.2	0.02**
Vermont	PFOA/PFOS	2.0E-05	infant	0.2	0.02***

(shaded) Different values/assumptions than used by USEPA

* Applies to sum of PFOA and PFOS

** Applies to sum of 6 PFAS compounds

*** Applies to sum of 5 PFAS compounds

$$\text{DW Advisory} = \frac{\text{RfD} \times \text{BW}}{\text{DWI}} \times \text{RSC}$$

States are:

- Deriving their own toxicity values (different interpretations of the same studies)
- Using different receptors
- Using different RSC values
- Using models that account for multiple life stage exposures

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Breaking news… EPA draft Health Advisories for PFAS

- June 15, 2022: EPA released draft health advisories for four PFAS:
  - PFOA – 0.004 ng/L
  - PFOS – 0.02 ng/L
  - GenX – 10 ng/L
  - PFBS – 2,000 ng/L
- Values are 2 to 3 orders of magnitude lower than current lowest values (among states)
- Values for PFOA and PFOS are much lower than laboratory reporting limits
- EPA is setting the reporting limit for PFOA at 4 ng/L (1000X the HA) for the next unregulated contaminant monitoring rule (UCMR 5) event

Drinking water standards vs. risk-based values

- Drinking water standards for PFAS are *lower* than risk-based values

Regulatory Entity	PFAS Compound	Toxicity value (RfD)	Drinking Water Intake (DWI) Critical receptor	Relative Source Contribution (RSC)	Regulatory value (ug/L)
EPA - office of water	PFOA/PFOS	2.0E-05	lactating woman	0.2	0.07*
Michigan	PFOA	3.9E-06	mother, infant, adult	0.5	0.008
	PFOS	2.9E-06	mother, infant, adult	0.5	0.016
Risk-based values		2E-05	'Standard child'	NA	0.400
		3E-06	'Standard child'	NA	0.060
		2E-09	'Standard child'	NA	0.00004 (10X HA)

- Of the chemicals with drinking water standards, only about 33% have MCLs set at values *lower* than risk-based values (i.e., usually, MCLs are higher than risk-based values)

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Health Advisories vs. MCLs for PFAS

- EPA's proposed Health Advisories may be adopted as MCL Goals (MCLGs)
- Safe Drinking Water Act (SDWA) gives EPA authority to set MCLs at levels above the MCLG
  - EPA must determine if the benefits of the MCL justify the costs based on health risk reduction cost analysis
  - EPA may set MCL less stringent than the feasible level if the benefits of the feasible level do not justify the costs

- UCMR 5 monitoring data to be used to help set MCL (?)

Risk assessment for PFAS differs from other chemicals: *Drinking water standards*

- Use exposure scenarios inconsistent with other chemicals (e.g., lactating mother)
- Based on toxicity values and RSCs that are inconsistent across regulatory frameworks
- EPA's proposed health advisories may result in standardization, but are clearly not achievable
- MCLs will need to consider what is feasible, based on cost-benefit analysis
  - How widespread are PFAS at very low concentrations?

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Conclusions – is it March or July?

- The significance of exposures, exposure pathways, and media concentrations is highly influenced by the toxicity values
- Approach for evaluating risks (exposures) is understood
- Until toxicity mechanisms in humans are well understood, correlating PFAS exposure to biomarkers that are indicative of adverse health effects will be challenging
  - One of the reasons for current disparity among state and federal drinking water values
  - Toxicity values reflect this: ‘go low in the face of uncertainty’

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