Occurrence and Human Health Risk Assessment of Per- and Polyfluoroalkyl Substances (PFAS) in New Jersey's Environment

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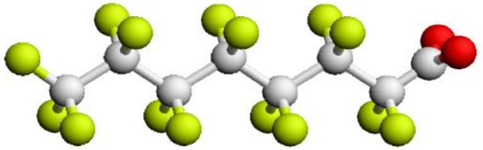
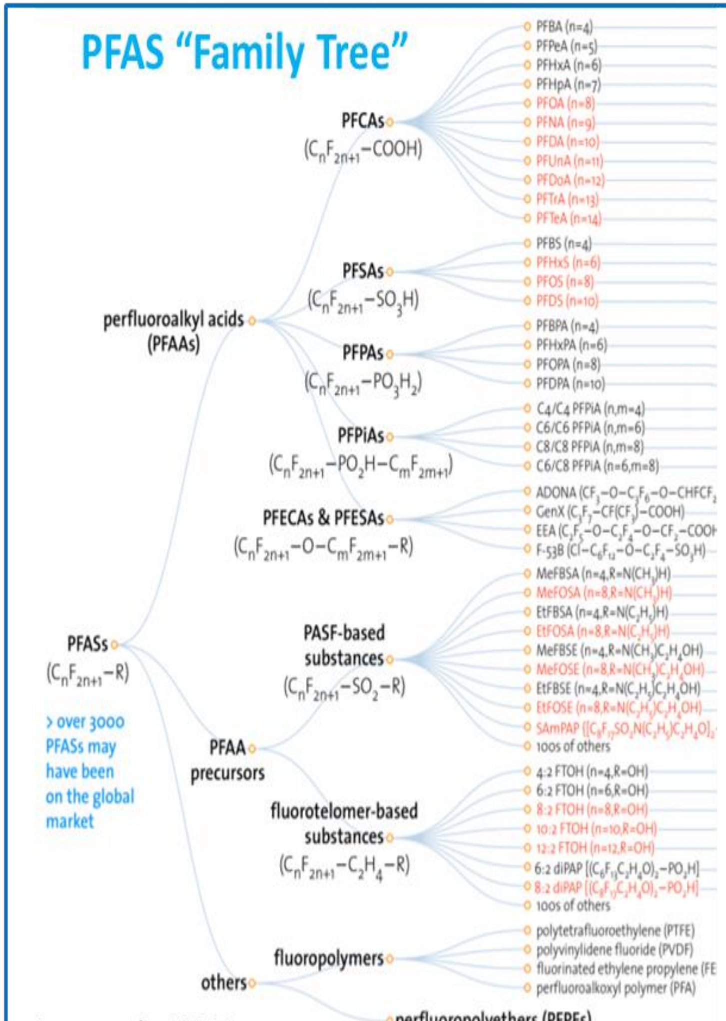
ATSDR Topics in Environmental Exposure Investigation Series Webinar
December 19, 2019

What are Per- and Polyfluoroalkyl Substances (PFAS)?



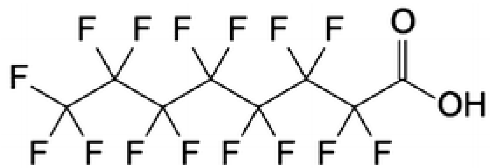
- 1000s of manufactured compounds.
  - *Aliphatic compounds with **at least one totally fluorinated carbon atom**.*
  - *Produced for over 70 years.*
- Due to structure of molecule:
  - *Repel oil & water.*
  - *Highly water soluble.*
- C-F bond is one of strongest known.
  - *Chemically & thermally non-reactive.*
- Unique properties are the basis for:
  - *Commercial & industrial uses.*
  - *Extreme environmental persistence.*
- Most have little or no health effects data.
- Most not detected by routine lab methods.



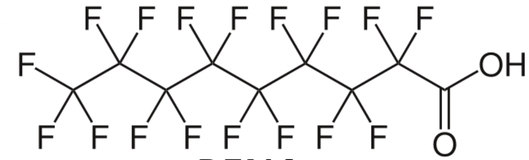
Wang et al., 2017

NJ Focus (so far…) Primarily on Long-Chain Perfluoroalkyl Acids (PFAAs)

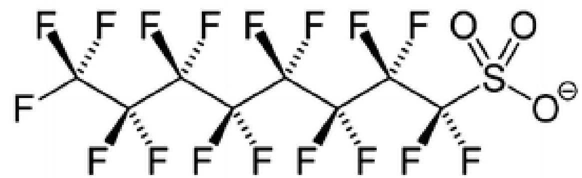
- Most well-known PFAS subgroup.
- **Charged functional group:**
  - *Carboxylates (COO^-)*
  - *Sulfonates (Carboxylates)*
- **Totally fluorinated carbon chain** - length varies.
  - *Long chain:*
    - *$\geq$ 8 carbons - carboxylates*
    - *$\geq$ 6 carbons - sulfonates.*
  - *Generally more bioaccumulative & toxic than short-chain.*
- Considerable health effects data.
- Detected by commercial lab methods.
- Although use in U.S. by major manufacturers has ended…..
  - ***Do not break down.***
  - ***Environmental contamination persists indefinitely.***
  - ***Some replacements are of concern.***



PFOA



PFNA



PFOS

Long-chain PFAAs found in blood serum of almost all U.S. residents:

- ***PFOA:*** *Perfluorooctanoic acid, C8*
- ***PFNA:*** *Perfluorononanoic acid; C9*
- ***PFOS:*** *Perfluorooctane sulfonate, C8-S*
- ***PFHxS:*** *Perfluorohexane sulfonate, C6-S*

Commercial & Industrial Uses of PFAS

- Processing aid in production of fluoropolymer plastics used in non-stick cookware & other products.
  - *Very low levels in final products.*
  - *Examples:*
    - *PFOA; GenX (PFOA replacement)*
    - *PFNA; PFNA replacements.*

- Water/stain resistant coatings for carpets & upholstery.

- Waterproof/breathable clothing

- Grease-proof food packaging.
- Waxes (including ski waxes), polishes, paints, adhesives

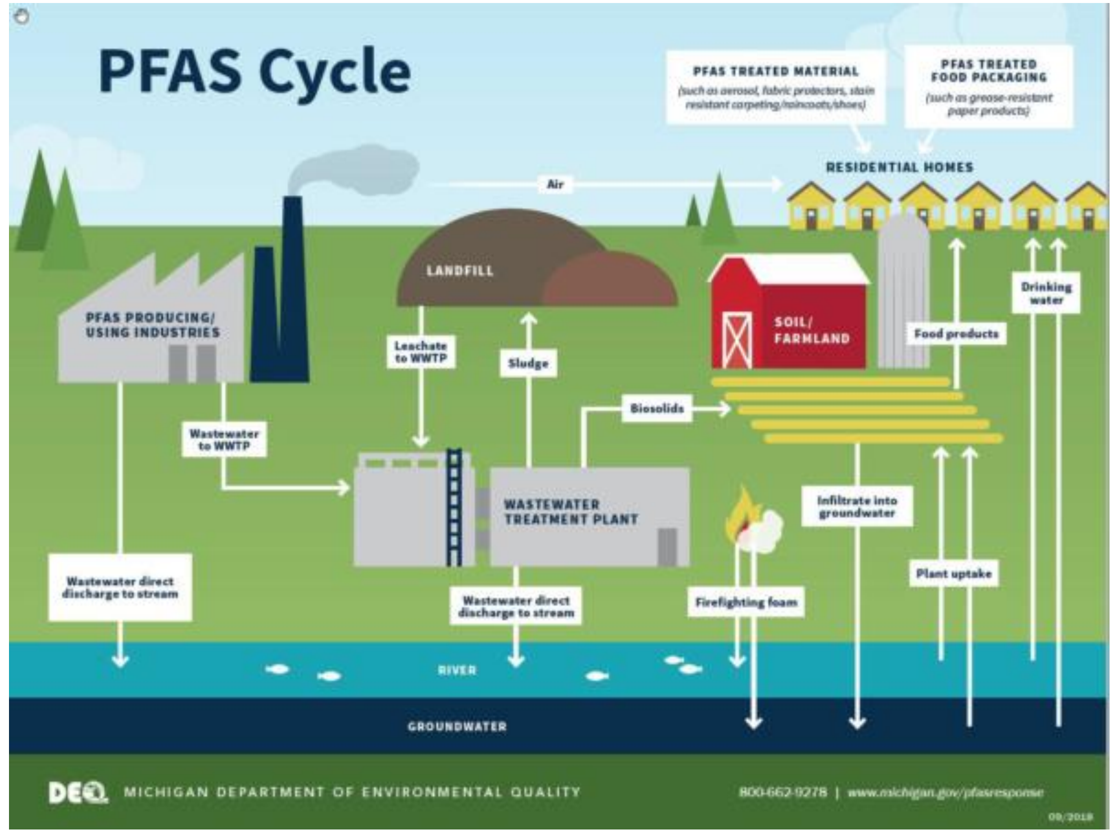
- Cosmetics and personal care products
- Aqueous film forming foams (AFFF) for firefighting

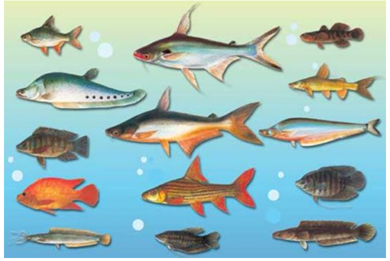
....and many other uses not listed here

PFAS are Found in Environmental Media Worldwide

Including…

- Ground water & surface water
- Drinking water
- Air (indoor & outdoor)
- Biosolids from sewage treatment plants
- Soil
- Sediments
- Dust (outdoor & indoor)
- Plants, including food crops
- Wildlife, including in remote regions (Arctic)
- Polar ice caps





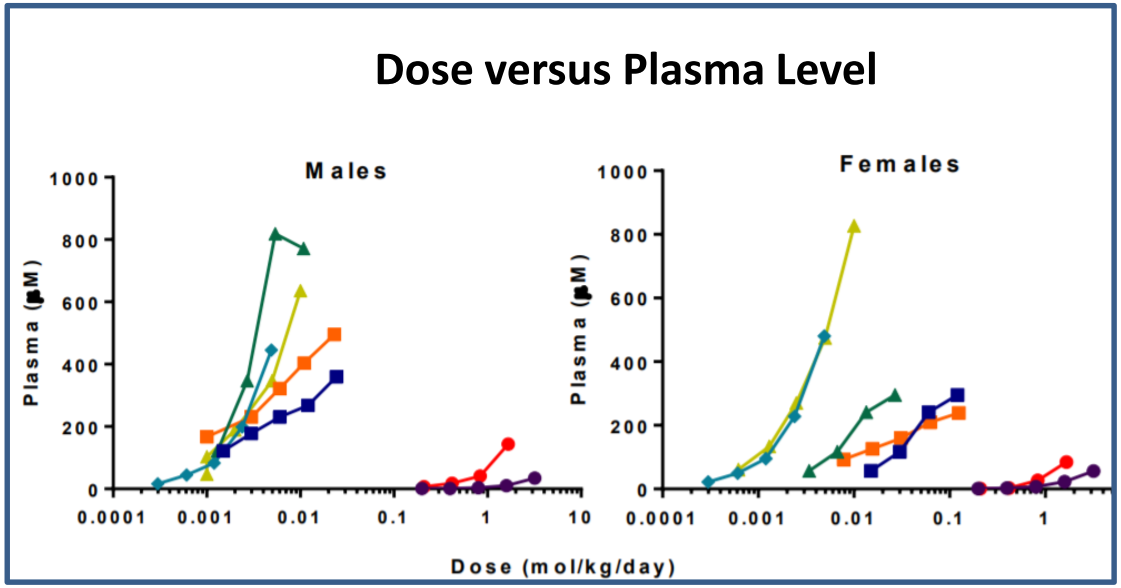
Similarities in Toxicity Among PFAS in Mammalian Studies

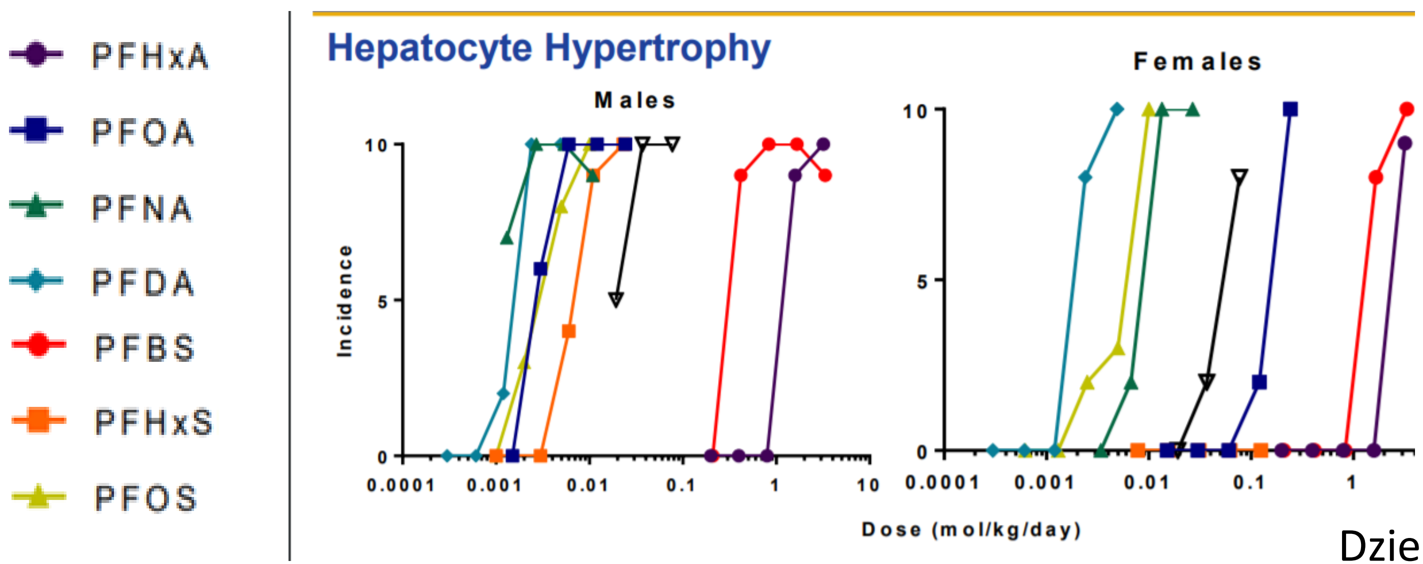
	# of Carbons	*Liver*	*Develop-mental*	*Repro-ductive*	*Immune*	*Hema-tologic*	*Thyroid*	*Neuro-behavioral*	*Tumors*
Perfluoroalkyl Carboxylates									
PFBA	*4*	■	■	■	□	■	■	□	□
PFPeA	*5*	□	□	□	□	□	□	□	□
PFHxA	*6*	■	■	■	□	■	■	□	□ **(Negative)**
PFHpA	*7*	■	□	□	□	□	□	□	□
PFOA	*8*	■	■	■	■	■	■	■	■
PFNA	*9*	■	■	■	■	■	■	□	□
PFDA	*10*	■	■	■	■	■	■	■	□
PFUnA	*11*	■	■	□	■	□	□	□	□
PFDoA	*12*	■	■	■	■	■	□	■	□
Perfluoroalkyl Sulfonates									
PFBS	*4*	■	■	■	■	■	■	□	□
PFHxS	*6*	■	■	□	□	■	■	■	□
PFOS	*8*	■	■	■	■	■	■	■	■
Per- & Polyfluoroalkyl Ether Replacements									
ADONA	*6*	■	■	□	□	■	□	□	□
GenX	*6*	■	■	■	■	■	■	□	■

■	Effect reported in one or more laboratory animal study
□	Effect was evaluated but not found, or effect has not been evaluated

National Toxicology Program 28-Day Rat Studies of 7 PFAAs

ESTIMATED HALF-LIFE			
	# of Carbons	M	F
PFHxA	6	2 hours	
PFOA	8	5 days	3 hours
PFNA	9	30 days	1-2 days
PFDA	10	27-50 days	
PFBS	4	3 hours	
PFHxS	6	29 days	2 days
PFOS	8	50 days	





Dzierlenga et al. 2019

NJ PFAS Evaluation & Regulation Continues NJ Work on Emerging Drinking Water Contaminants since 1980s

- ***1980s*** - Volatile organic chemicals found in NJ waters in NJDEP study.
  - *"Emerging contaminants" of the time - No federal standards.*
- ***1984 -*** New Jersey Safe Drinking Water Act Amendments
  - Requires NJ Maximum Contaminant Levels (standards; MCLs) for:
    - *23 listed contaminants.*
    - *Additional contaminants based on occurrence & health effects.*
  - Establishes Drinking Water Quality Institute (DWQI) to recommend MCLs to NJDEP.
    - *Appointed members from environmental health community, academia, and water purveyors.*
    - *Also – members from NJDEP and NJ Dept. of Health.*
- NJDEP Commissioner decides whether to propose MCLs as regulatory standards.
  - *Enforceable (in contrast to guidance).*
  - *Require testing of all New Jersey public water systems.*
- NJ scientists have evaluated many types of drinking water contaminants since 1984**.**

DWQI & NJDEP Evaluations (1984 – Present)

Earlier Evaluations
(1984 - 2009)

- Volatile Organic Contaminants
- Methyl tertiary butyl ether (MTBE)
- Radium
- Arsenic
- Perchlorate
- Radon

…and many others

Recent Evaluations
(2014 - present)

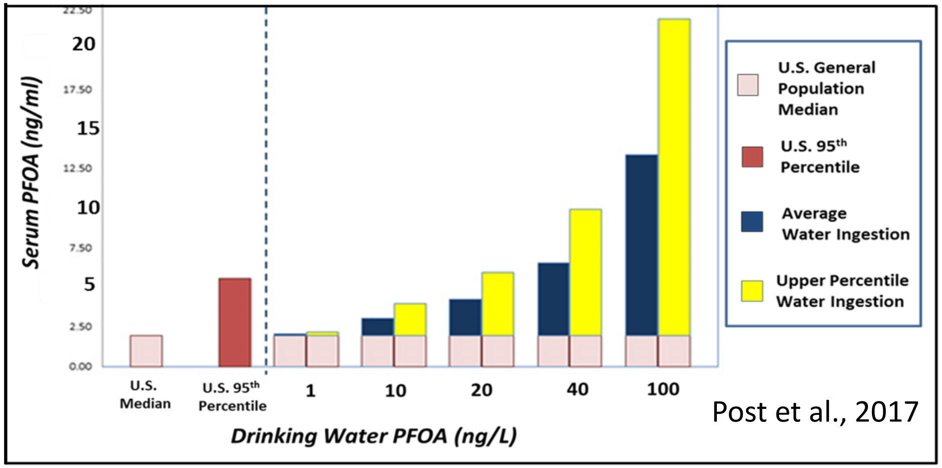
- 1,2,3-Trichloropropane*
- **PFNA***
- **PFOA & PFOS****
- 1,4-Dioxane – currently underway

** MCLs adopted by NJDEP in September 2018.* ***FIRST MCL IN THE U.S. FOR ANY PFAS***

*** MCLs proposed by NJDEP on April 1, 2019.*

Why Are Long-Chain Perfluoroalkyl Acids (PFAAs) of Particular Concern as Drinking Water Contaminants?

- Widespread drinking water occurrence.
- Do not break down in the environment – “Forever Chemicals”.
- Ubiquitous in human blood serum.
- Long human half-lives (~2-8 years).
  - *Bioaccumulate.*
  - *Remain in the body for many years after exposure ends.*
- Multiple types of animal toxicity, some at low doses.
- Evidence for multiple human health effects from low exposures.



Post et al., 2017

- **Low drinking water levels can dominate other exposures (e.g. food/food packaging, consumer products).**
  - *Unlike other persistent, bioaccumulative, and toxic (PBT) chemicals (PCBs & dioxins) – Drinking water is not an important exposure route.*
- Higher drinking water exposures to infants, a sensitive subgroup.
- **Overall - suggests need for caution about exposure from drinking water.**

NJDEP & DWQI Focus on PFAS in Drinking Water Since 2006

Environ. Sci. Technol. **2009,** *43,* 4547–4554

Occurrence and Potential Significance of Perfluorooctanoic Acid (PFOA) Detected in New Jersey Public Drinking Water Systems

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the U.S. populatio
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Review

Perfluorooctanoic acid (PFOA), an emerging drinking water contaminant: A critical review of recent literature☆,☆☆

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Environmental Science & Technology

Article

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Occurrence of Perfluorinated Compounds in Raw Water from New Jersey Public Drinking Water Systems

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ELSEVIER

Associations of perfluorinated chemical serum concentrations and biomarkers of liver function and uric acid in the US population (NHANES), 2007–2010

CrossMark

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Environ Sci Pollut Res
DOI 10.1007/s11356-017-0309-3

RESEARCH ARTICLE

Occurrence and source identification of perfluoroalkyl acids (PFAAs) in the Metedeconk River Watershed, New Jersey

Nicholas A. Procopio[1] · Robert Karl[2] · Sandra M. Goodrow[1] · Joseph Maggio[2] · Judith B. Louis[1] · Thomas B. Atherholt[1]

PLOS | BIOLOGY

PERSPECTIVE

Key scientific issues in developing drinking water guidelines for perfluoroalkyl acids: Contaminants of emerging concern

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Review article

The derivation of a Reference Dose (RfD) for perfluorooctane sulfonate (PFOS) based on immune suppression

Check for updates

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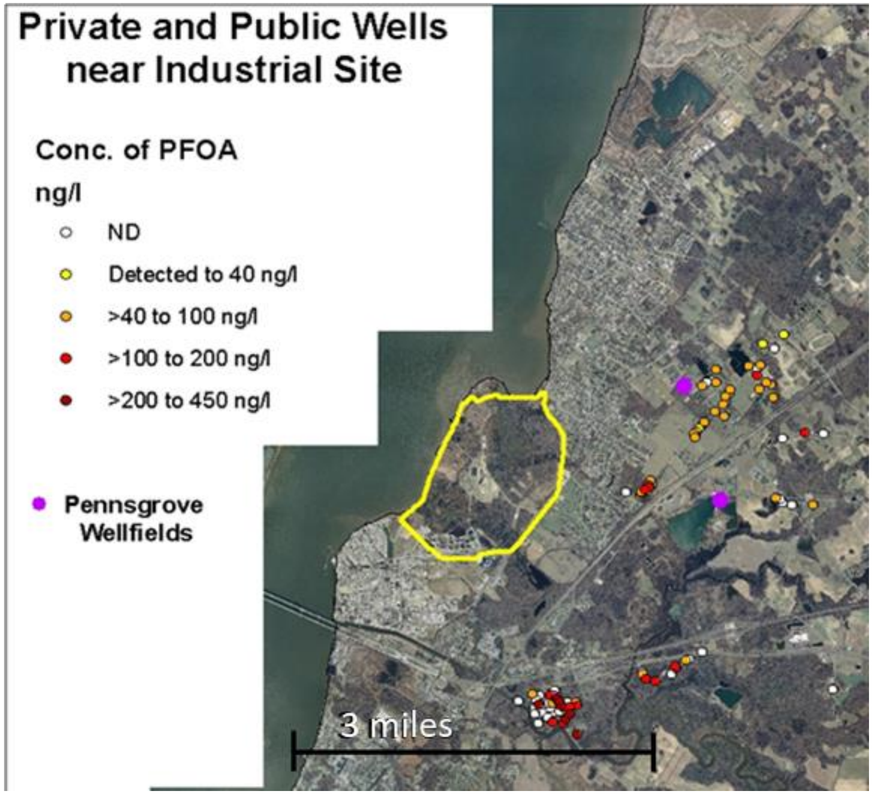
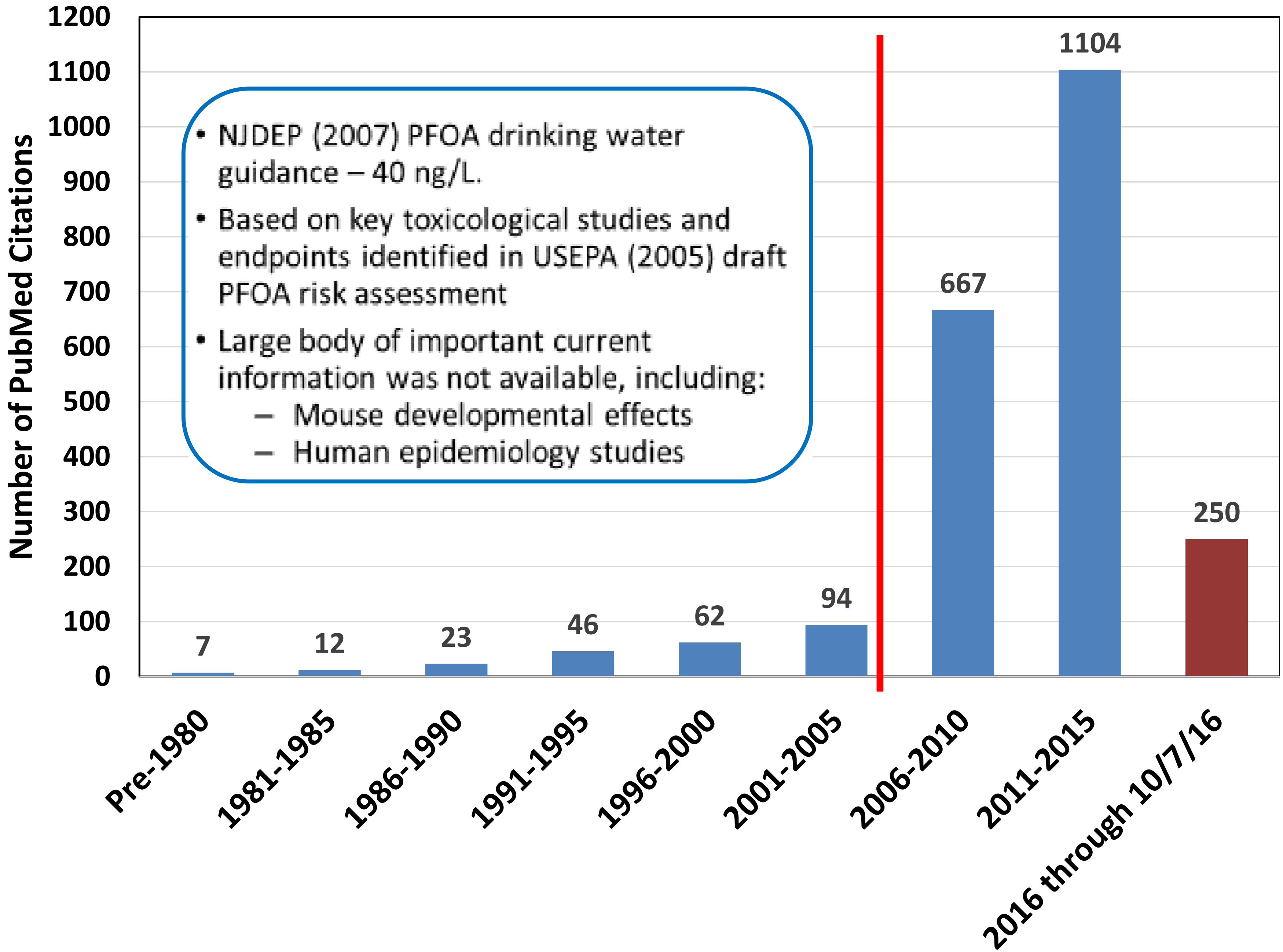
Bureau for Risk Analysis, Division of Science, Research and Environmental Health, New Jersey Department of Environmental Protection, Trenton, NJ, USA

Initial NJDEP Awareness & Actions on PFOA in NJ Waters in 2004-07

- ***2004:*** Reported in **groundwater** at large industrial site in Southwest NJ.
- ***2006:*** Nearby **public water system.**
    - Found in **tap water** by Delaware Riverkeeper Network.
    - Found in **supply wells** by potential industrial source.
    - Found later in nearby **private wells.**
- ***2006-2007:*** **NJDEP Actions**:
    - Statewide drinking water **occurrence study** of PFOA and PFOS (2006).
    - **Drinking water guidance** (NJDEP, 2007; Post et al., 2009) **– 40 ng/L (ppt)**
      - *Requested by affected water system.*

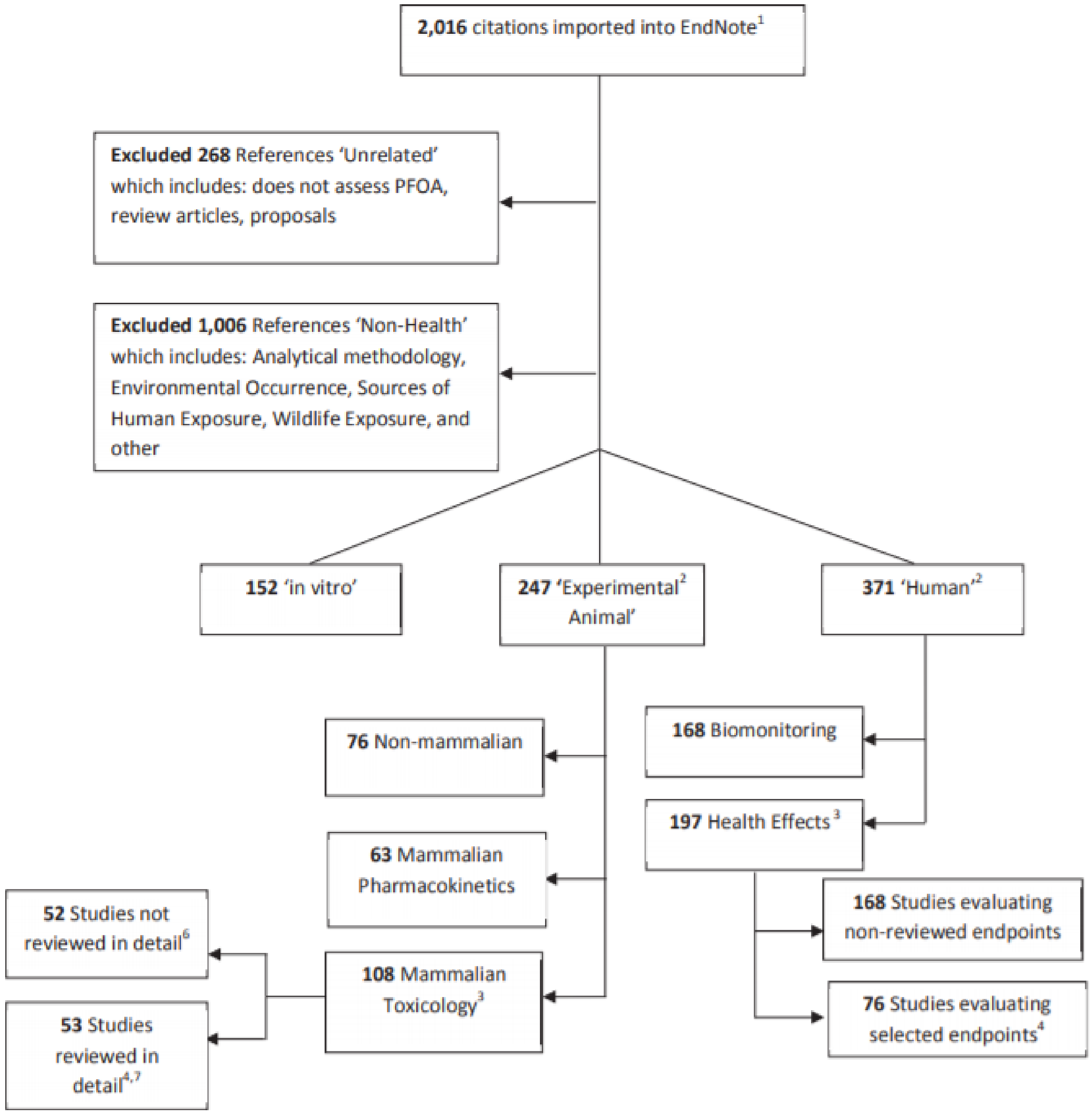


Great Increase in PFAS Research in Recent Years: Example-PFOA



DWQI PFOA Literature Review Strategy

More than 2000 citations identified and screened in 2016.

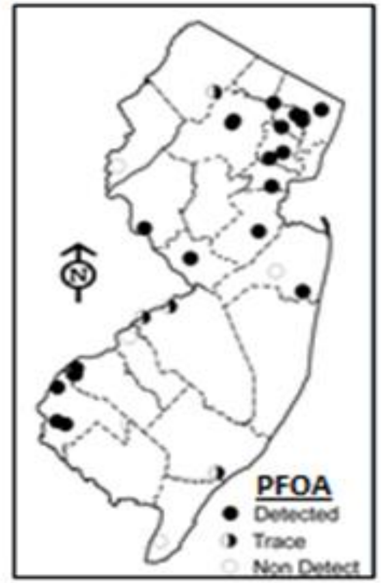


NJ DWQI, 2016

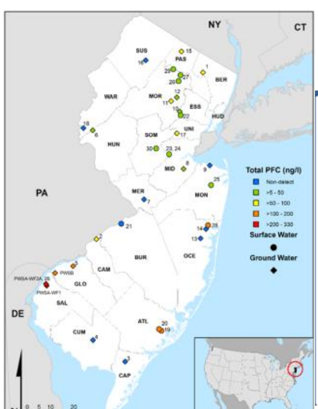
NJDEP Studies of PFAS Occurrence in NJ Public Water Systems

- **First state to conduct statewide PFAS occurrence studies.**
  - ***2006 study:*** 23 water systems - PFOA and PFOS.
  - ***2009-10 study:*** 31 water systems – 10 PFAAs.
  - Reporting Levels 4-5 ng/L (ppt)
- **Multiple PFAS** (up to 8) found in many water systems.
  - **PFOA** – most frequent, ~60% of systems.
  - **PFOS** – 30% of systems.
  - **PFNA** – Paulsboro, Gloucester County
    - *Highest level reported in drinking water worldwide.*
- **Current (2019) Data:** PFOA, PFOS and/or PFNA detected above NJ MCL (13-14 ng/L) in ~11% of ~1100 water systems tested.
- Many NJ water systems have taken voluntary action.

2006 Study
(PFOA & PFOS – 23 PWS)

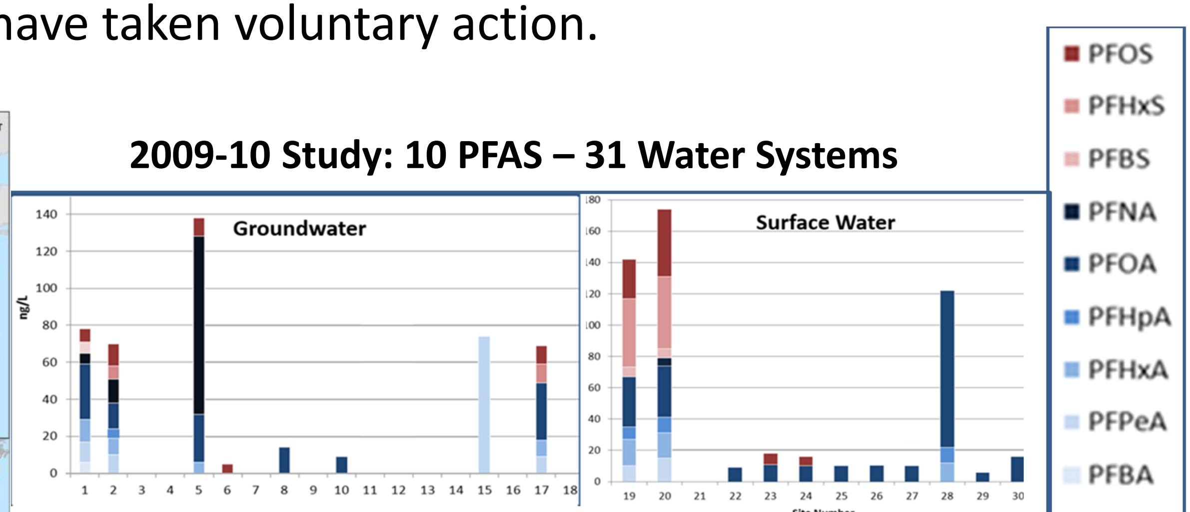


Post et al., 2009



Post et al., 2013

2009-10 Study: 10 PFAS – 31 Water Systems



New Jersey vs. National PFAS Drinking Water Occurrence: 2013-15 USEPA Unregulated Contaminated Monitoring Rule 3 (UCMR3) Study

Compound	***Reporting Level (ng/L)***	***New Jersey Public Water Systems***		***U.S. Public Water Systems Other than NJ***	
		# Detects*	***% Detects***	***# Detects***	***% Detects***
PFOA (C8)	20	**19/175**	**10.9%**	**98/4745**	**2.1%**
PFNA (C9)	20	**4/175**	**2.3%**	**10/4745**	**0.2%**
PFOS (C8-S)	40	6/175	3.4%	89/4745	1.9%
PFHxS (C6-S)	30	2/175	1.1%	53/4745	1.1%
PFBS (C4-S)	90	0/175	0%	8/4745	0.2%
PFHpA (C7)	10	6/175	3.4%	80/4745	1.7%

- All large (>10,000 users) and a few small public water systems in U.S.
- **PFOA and PFNA - much more frequent in NJ than nationally.**
  - *PFNA – Southwestern NJ (Gloucester and Camden Counties).*
  - *PFOA – Various locations statewide.*

Sources of PFAS in Drinking Water & Other Environmental Media

- Industrial facilities where PFAS are made or used.

- Wastewater treatment plants.

  - *Discharge of treated wastewater.*
  - *Application of sludge/biosolids on agricultural land.*

- Release of fire fighting foams.

  - *Military bases.*
  - *Airports.*
  - *Firefighter training sites.*

- Leaching from landfills where PFAS-containing products are disposed.

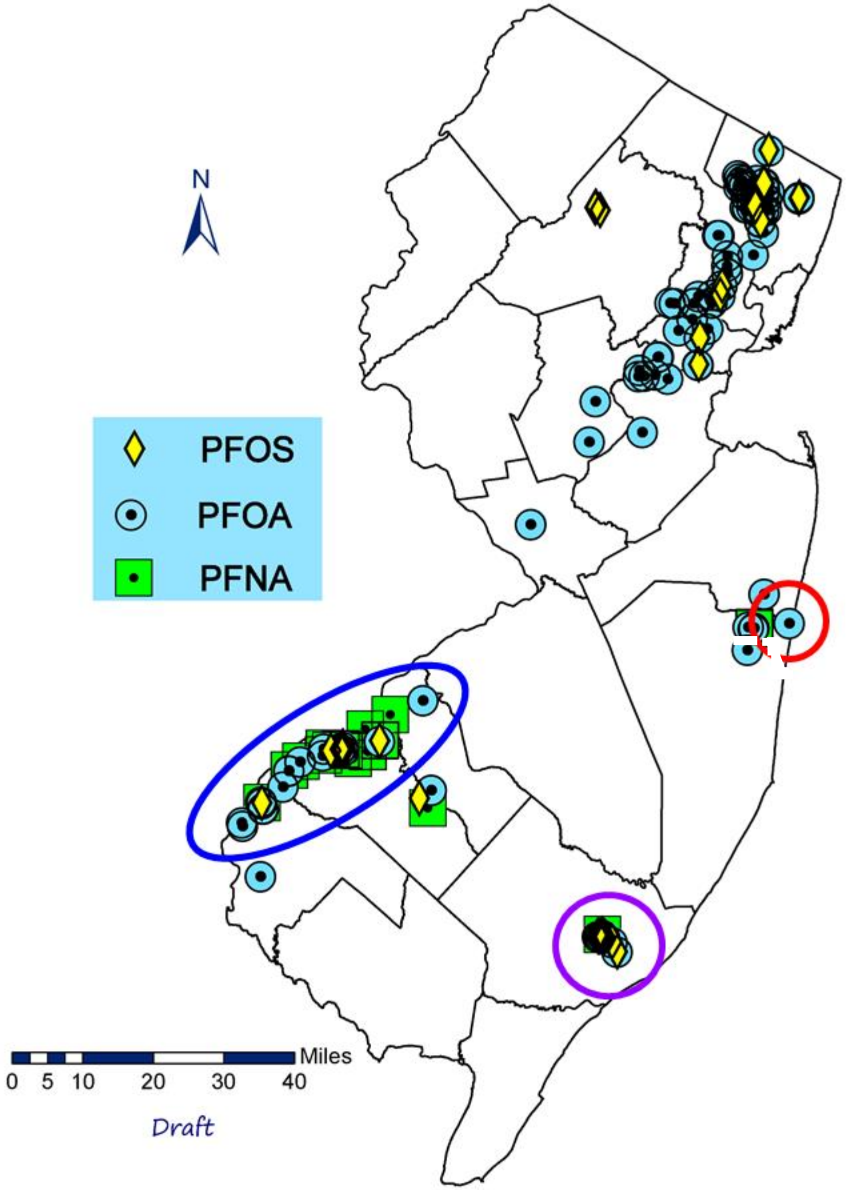
Some Likely Sources of PFAS in NJ Public Water Systems

- **PFOA and PFOS in Northeast NJ**
  - *Sources unknown for most sites.*
  - *Efforts to identify sources are ongoing.*

- **PFOA & PFNA in Southwest NJ.**
  - *Two large industrial sites.*
  - *Current NJDEP multi-media study with USEPA ORD using research analytical methods.*

- **PFOA in surface water source**
  - *Small industrial facility upstream of river intake (Procopio et al., 2017).*

- **Multiple PFAAs (carboxylates & sulfonates)**
  - *Military use of aqueous film forming foam.*



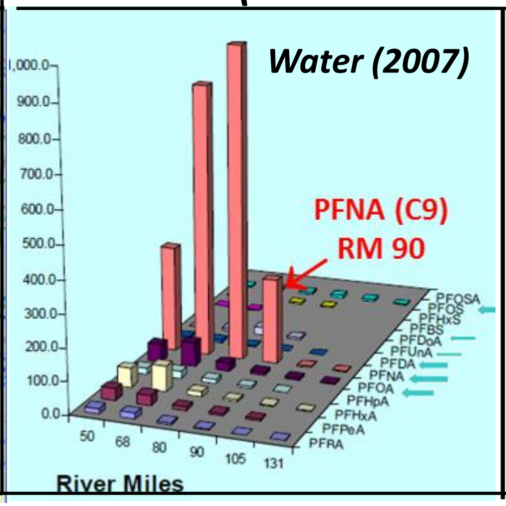
(Raw and finished water sampling locations shown; multiple data points shown for some pubic water systems.)

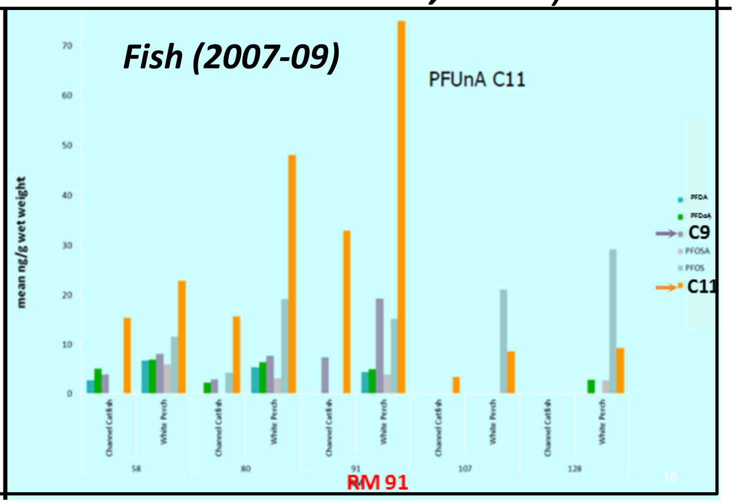
PFNA (C9) in Drinking Water, Surface Water, & Fish in Gloucester County, NJ

- PFNA rarely detected nationally or elsewhere in NJ.
- **Wells of 2 Gloucester County public water systems -** highest drinking water levels reported worldwide.
    - *Later found in **10 additional nearby PWS** and in nearby **private wells.***
- **Delaware River** in this vicinity - Highest surface water levels reported worldwide (~ 1 ppb).
- Also, elevated PFNA and PFUnA (C11) in **fish** at same river locations.

PFNA in Public Water Wells

PFAS in Tidal Delaware River
(Delaware River Basin Commission, 2012)





Identification of Industrial Source of PFNA
(from information in Prevedouros et al., 2006)

- PFNA was primary component of "Surflon® S-111" PFAS mixture used in production of fluoropolymer (polyvinylidene fluoride; PVDF) at Thorofare, NJ facility.
- Large amounts (tons/year) released to air & water for > 20 years.
- Use ceased in 2010.
- PFNA in drinking water from industrial source has not been investigated elsewhere.

TABLE S2. Commercial PFCA Products Characterization

Product Identification	Figure S1 Process	% Branched Isomers	8 PFO	9 PFN	10 PFD	11 PFU	12 PFDD	13 PFTD
Fluorad® FC-143	1	15	99	0.22	≤LOQ	nm	<LOQ	nm
Surflon® S-111*	3	0	0.78	74	0.37	20	0.1	5
APFO - DuPont	2	0	99	nd	≤LOQ	<LOQ	<LOQ	nm

Global production of PVDF by the emulsion process (2002)

Producer	Location	Process	Capacity, ktonne/year
	Calvert City, KY, USA	Emulsion	8.4
	Thorofare, NJ, USA	Emulsion	7.7
	Decatur, AL, USA	Suspension	2.3
	Pierre Bénite, France	Emulsion	2.2
	Tavaux, France	Suspension	5.0
	Ube, Japan	Emulsion?	0.3
	Settsu, Japan	Suspension?	0.1
	Iwaki, Japan	Suspension	1.2
TOTAL			**27.2**

Source: Prevedouros et al. 2006. Environ. Sci. Technol. 40: 32-44. Supporting Information.

Journal of Exposure Science & Environmental Epidemiology
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ARTICLE

Per and polyfluoroalkyl substances (PFAS) blood levels after contamination of a community water supply and comparison with 2013–2014 NHANES

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Abstract

Introduction Per and polyfluoroalkyl substances (PFAS), including perfluorononanoic acid (PFNA) and perfluorooctanoic acid (PFOA), were detected in the community water supply of Paulsboro New Jersey in 2009.

Methods A cross-sectional study enrolled 192 claimants from a class-action lawsuit, not affiliated with this study, who had been awarded a blood test for 13 PFAS. Study participants provided their blood test results and completed a survey about demographics; 105 participants also completed a health survey. Geometric means, 25th, 50th, 75th, and 95th percentiles of exposure of PFNA blood serum concentrations were compared to that of the 2013–2014 NHANES, adjusted for reporting level. Associations between PFNA, PFOA, PFOS, and PFHxS and self-reported health outcomes were assessed using logistic regression.

Results PFNA serum levels were 285% higher in Paulsboro compared with U.S. residents. PFNA serum levels were higher among older compared with younger, and male compared to female, Paulsboro residents. After adjustment for potential confounding, there was a significant association between increased serum PFNA levels and self-reported high cholesterol (OR: 1.15, 95% CI: 1.02, 1.29).

Discussion/Conclusion Further investigation into possible health effects of PFAS exposure in Paulsboro and other community settings is warranted. Since exposure has ceased, toxicokinetics of PFAS elimination should be explored.

Table 3 Geometric mean and selected percentiles of selected per- and polyfluoroalkyl substances (PFAS) concentrations in serum (μg/L) for the population 12 years of age and older in Paulsboro New Jersey compared with U.S. NHANES 2013–2014 ($n = 165$)

PFAS		*n*	Geometric Mean (95% CI)	25th (95% CI)	50th (95% CI)	75th (95% CI)	95th (95% CI)
PFHxS	Paulsboro	124	2.03 (1.84, 2.25)	1.33 (1.20, 1.45)	2.02 (1.67, 2.38)	2.77 (2.49, 3.05)	4.70 (3.63, 5.76)
	NHANES	1432	2.18 (2.02, 2.36)	1.31 (1.24, 1.38)	1.93 (1.76, 2.10)	3.10 (2.74, 3.45)	6.46 (4.48, 8.44)
PFOA	Paulsboro	165	3.03 (2.70, 3.40)	1.94 (1.67, 2.22)	2.98 (2.43, 3.53)	4.69 (3.87, 5.51)	8.80 (6.91, 10.70)
	NHANES	2080	2.08 (1.91, 2.26)	1.35 (1.28, 1.43)	2.05 (1.89, 2.21)	3.06 (2.74, 3.37)	5.57 (4.63, 6.51)
PFOS	Paulsboro	164	5.37 (4.75, 6.06)	3.09 (2.57, 3.60)	5.66 (4.73, 6.59)	9.28 (7.93, 10.62)	14.76(11.62, 17.90)
	NHANES	2098	5.39 (4.98, 5.84)	3.20 (2.88, 3.51)	5.34 (4.95, 5.72)	8.76 (8.08, 9.43)	18.48 (15.26, 21.70)
PFNA	Paulsboro	165	3.50 (3.04, 4.04)	2.01 (1.60, 2.42)	3.89 (3.18, 4.60)	5.99 (4.47, 7.51)	12.41 (9.68, 15.13)
	NHANES	1599	0.91 (0.87, 0.96)	0.58 (0.57, 0.59)	0.78 (0.75, 0.81)	1.18 (1.09, 1.28)	2.22 (1.90, 2.54)

CDC and ATSDR Award $7 Million to Begin Multi-Site PFAS Study

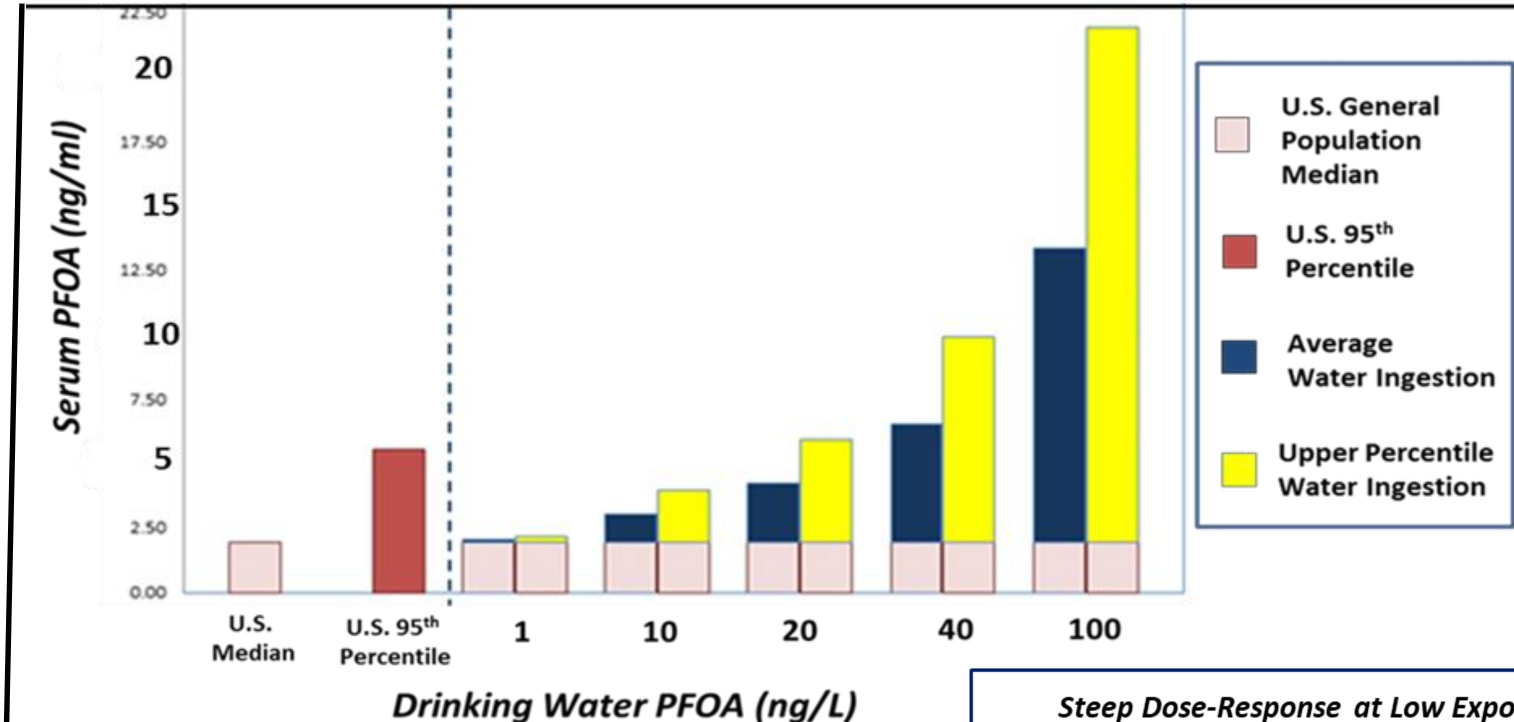
Press Release
For Immediate Release: September 23, 2019
Contact: Media Relations
(404) 639-3286

The Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registry (ATSDR) are announcing the start of a multi-site health study to investigate the relationship between drinking water contaminated with per- and polyfluoroalkyl substances (PFAS) and health outcomes. CDC and ATSDR are making awards, in the amount of $1 million each, to the following institutions to look at exposures in communities listed:

- Colorado School of Public Health, University of Colorado Anschutz Medical Campus, to look at exposures in El Paso County, CO
- Michigan State Department of Health and Human Services to look at exposures in Parchment/Cooper Township, MI, and North Kent County, MI
- RTI International and the Pennsylvania Department of Health to look at exposures in Montgomery County, PA
- Rutgers Biomedical and Health Sciences – School of Public Health to look at exposures in Gloucester County, NJ
- Silent Spring Institute to look at exposures in Hyannis, MA, and Ayer, MA
- University at Albany, SUNY and New York State Department of Health to look at exposures in Hoosick Falls, NY, and Newburgh, NY
- University of California – Irvine to look at exposures in communities near the UC Irvine Medical Center

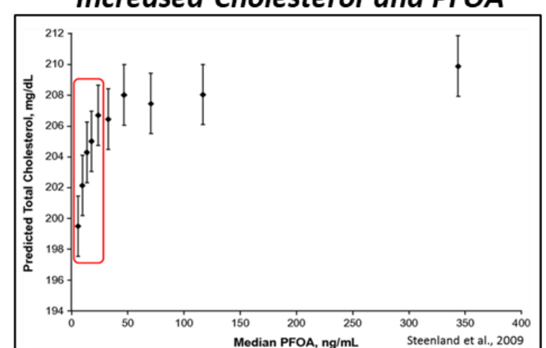
DWQI & NJDEP Health Effects Evaluation & Risk Assessment of PFOA, PFOS, & PFNA

DWQI Conclusion: Low Drinking Water Concentrations of Long-Chain PFAAs Can Dominate Other Exposure Sources



- Clearance factor (based on $t_{1/2}$ & V_D) predicts PFOA serum:drinking water ratio:
  - *114:1 - average water consumption*
  - *200:1 - upper % water consumption.*
- Supported by empirical data from several locations.
- Higher ratios predicted for other long-chain PFAAs (PFOS, PFNA) with longer half-lives.

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.

Relationship Between Drinking Water and Serum Concentrations for Long-Chain PFAAs

- Clearance factor (CL) - relates dose to blood serum level.
  - *CL (L/kg/day) = Volume of Distribution (L) x (ln 2 ÷ Half-life [days])*
- Combine with water ingestion rate (L/kg/day) to relate water & serum levels.

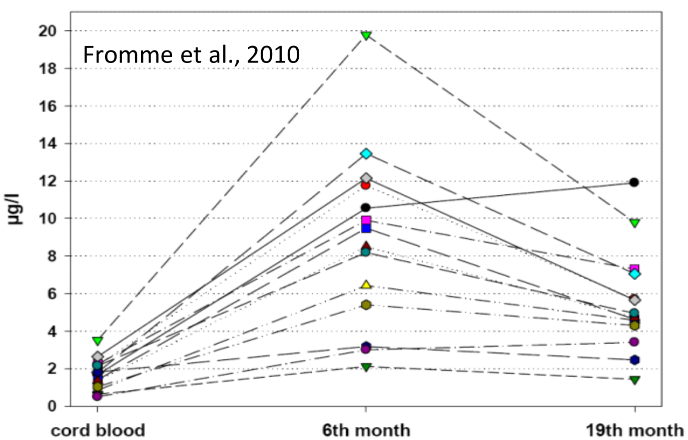
Dose (µg/kg/day) = Serum Conc. (µg/L) x CL (L/kg/day)

Dose (µg/kg/day) = Drinking Water Conc. (µg/L) x Ingestion Rate (L/kg/day)

$$\textbf{Serum:Water Ratio} = \frac{\text{Serum Conc. (µg/L)}}{\text{Drinking Water Conc. (µg/L)}} = \frac{\text{Ingestion Rate (L/kg/day)}}{\text{CL (L/kg/day)}}$$

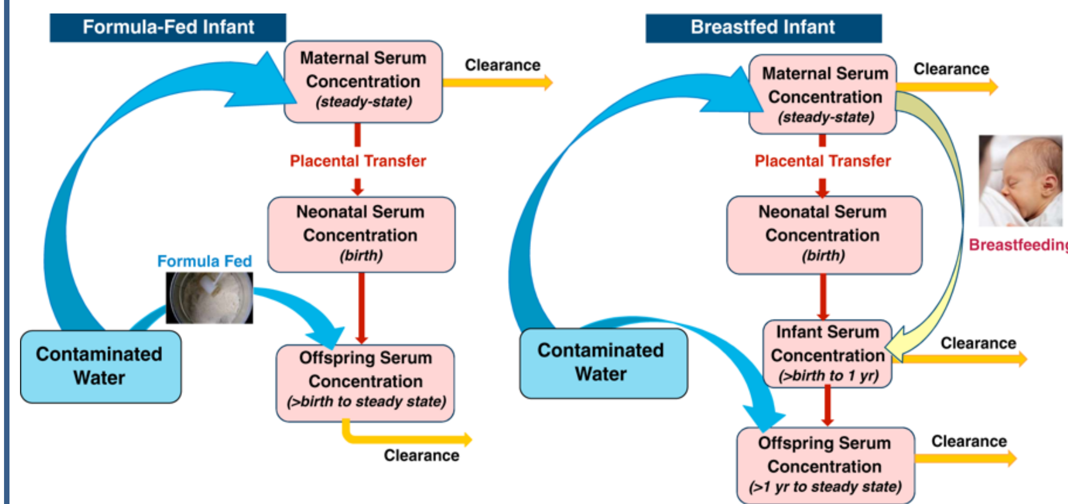
Greater Increases in Blood Serum PFAA Levels in Infants

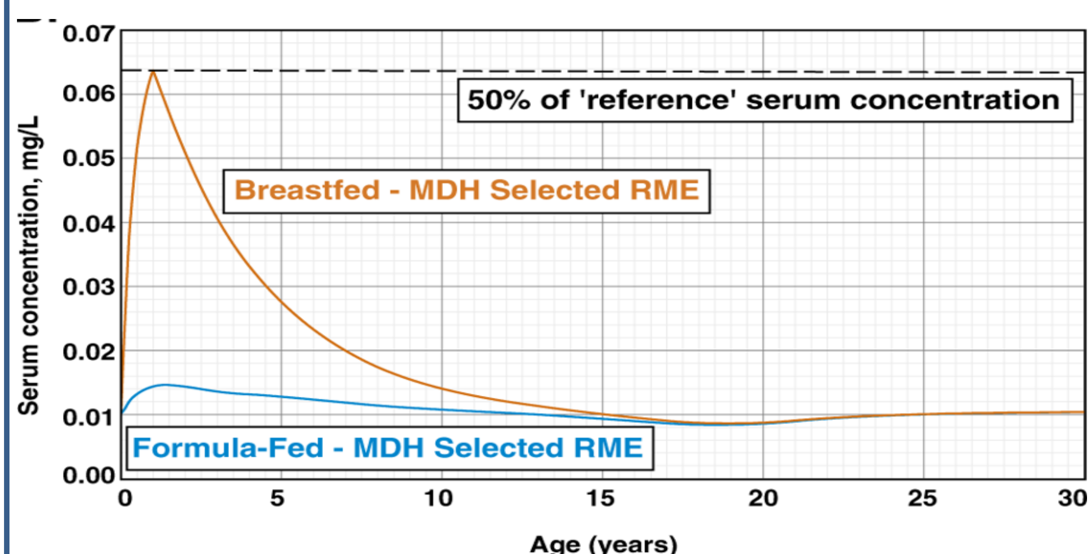
- Higher exposures from breast milk or formula:
  - *PFAAs level in breast milk $\geq$ in maternal drinking water.*
  - *Infants ingest much more fluid per body wt.*
- Sensitive subpopulation for developmental & other short-term effects.



MN Dept. of Health Model for Early Life PFAA Exposure

(Goeden et al., 2019)





New Jersey Conclusions: Human Epidemiology Data in Risk Assessment of Long-Chain PFAAs

- Human data are preferred as basis for risk assessment if suitable.
  - But some other regulated contaminants have little or no human data.
- Evidence for multiple human health effects at low exposures to long-chain PFAAs:

↑ *cholesterol (PFOA, PFOS, PFNA)*
↑ *uric acid (PFOA)*

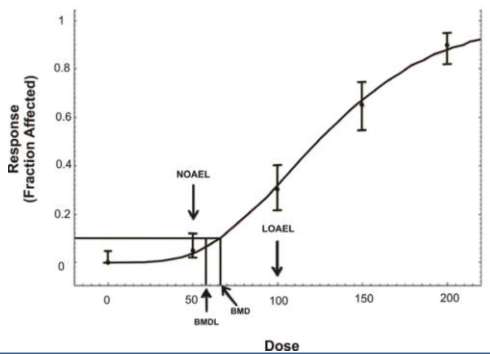
↑ *liver enzymes (PFOA, PFNA)*
↓ *birth weight (PFOA)*

↓ *vaccine response (PFOA, PFOS)*
↑ *infectious disease (PFOS)*
↑ *testicular & kidney cancer (PFOA)*

- *Some effects are generally consistent & data support criteria for causality.*
- *Generally concordant with toxicity in animal studies.*
- However, limitations preclude human data as primary basis for risk assessment.
  - *Exposures to multiple PFAS are correlated, so dose-response for each PFAS cannot be determined.*
- **Conclusion: Human data provide support for public health protective approach based on animal toxicology data.**
  - *More human data than for many other drinking water contaminants.*
  - *Justify concern about additional exposure from drinking water.*

DWQI Risk Assessment Approach for PFAS

Based on **Reference Dose** for most sensitive non-cancer endpoint that are well-established, adverse, and relevant to humans.



Reference Dose (ng/kg/day) = Point of Departure / Uncertainty Factors

Definition: "Daily oral dose to humans (including sensitive subgroups) likely to be **without appreciable risk** of deleterious effects during a lifetime."

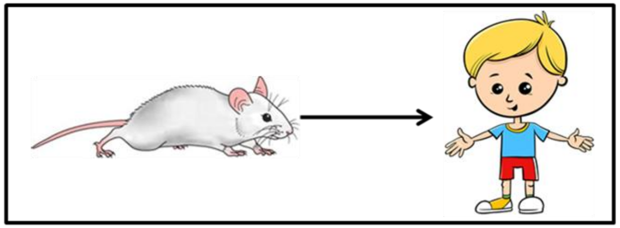
Carcinogenicity evaluation:

- **PFOA** & **PFOS:** *"Suggestive evidence for carcinogenicity in humans"*
  - Cancer risk (at 1-in-1 million risk level) was not driving factor.
- **PFNA:** No chronic studies.

***NOTE*: New NTP chronic rat PFOA study** (draft - 10/15/19; peer review – 12/12/19) was not considered.

- *"Clear evidence"* in males; *"Some evidence"* in females.
- Benign & malignant tumors of pancreas, liver, possibly uterus.
- Much higher tumor incidence than in earlier chronic studies.

Animal-to-Human Comparison in DWQI PFAS Risk Assessment



- Based on **internal dose (serum level),** not administered dose.
- Because half-life much longer in humans than animals → **Same dose results in much higher internal dose (serum level) in humans than animals.**
- Reference Doses are based on studies that provide **blood serum PFAS data.**

	# of Carbons	Mouse	Rat		Human
			M	F	
PFOA	8	18 days	5 days	3 hours	~2-3 years
PFNA	9	50 days	30 days	1-2 days	Estimated as twice PFOA
PFOS	8	37 days	50 days		~3-5 years

Development of NJ PFAA Reference Doses

<u>Serum Level</u> Point of Departure (POD) for animal endpoint

(ng/ml; BMDL, NOAEL, or LOAEL)

↓

Apply Uncertainty Factors

(Note: Animal-to-Human – 3; Toxicokinetic differences accounted for by use of serum level as dose metric)

Target Human Serum Level (ng/ml; µg/L)

↓

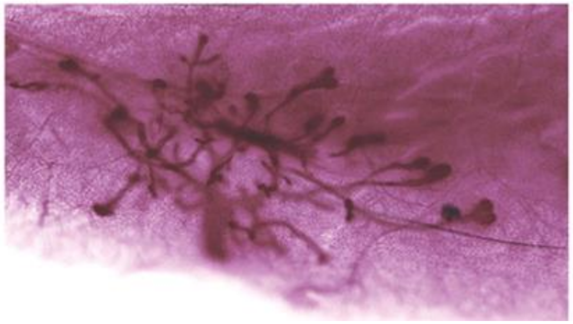
Apply Clearance Factor:

Target Human Serum Level (µg/L) x ***Clearance (L/kg/day)***

= RfD (µg/kg/day)

Reference Dose (µg/kg/day)

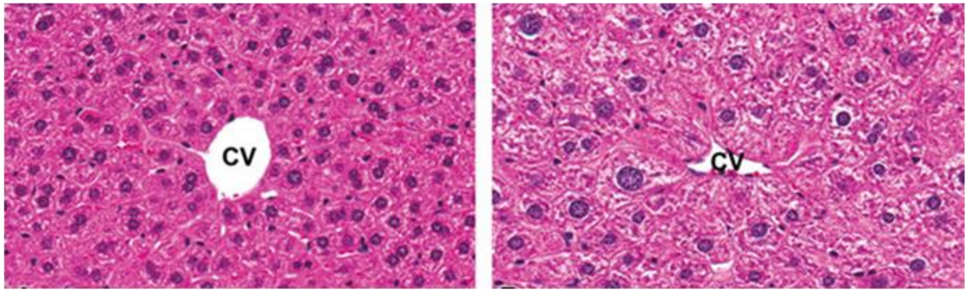
DWQI PFOA Reference Dose: Delayed Mammary Gland Development



- **Most sensitive effect with serum PFOA data.**
- **Well established** - 9 mouse studies; from gestational and/or lactational exposure.
  - *Only 1 negative study with problematic issues.*
- **Adverse** - Structural changes persist until adulthood.
- **Human relevance:**
  - *Considered relevant to humans.*
  - *PFOA associated with ↓ duration of breastfeeding in several human studies.*
- **Reference Dose: 0.11 ng/kg/day; *below general population exposure*.**
  - Benchmark Dose modeling (data from Macon et al., 2011).
    - ↓ *mammary gland developmental score*
    - ↓ *number of terminal end buds.*
  - **Health-based MCL would be 0.77 ng/L - Not recommended:**
    - ***No precedent** for this effect as primary basis for risk assessment.*
- **Uncertainty Factor** for more sensitive mammary gland effects.

DWQI PFOA Reference Dose: Increased Liver Weight

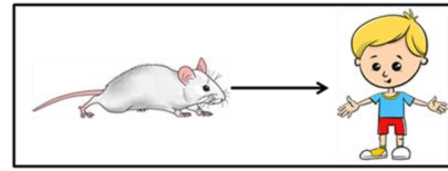
- **Increased liver weight and hepatocellular hypertrophy -** well-established effects in monkeys and rodents.



Pregnant mice dosed on GD 1-17. Quist et al., 2014

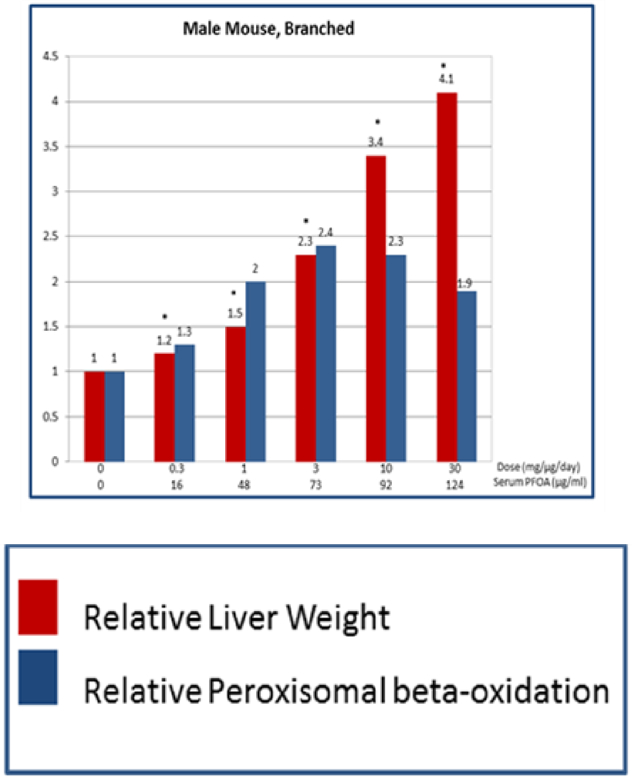
- **Most sensitive effect** with serum PFOA data, except mammary gland.
- **Co-occur with and/or progress** to more severe hepatic effects (*e.g. necrosis).*
- Reference Dose (2 mg/kg/day)
  - *Based on increased liver weight in mice (Loveless et al., 2007).*
  - *Includes **additional uncertainty factor** for delayed mammary gland development and other low-dose developmental effects.*

DWQI Mode of Action Analysis for PFOA: Human Relevance of Rodent Hepatic Toxicity



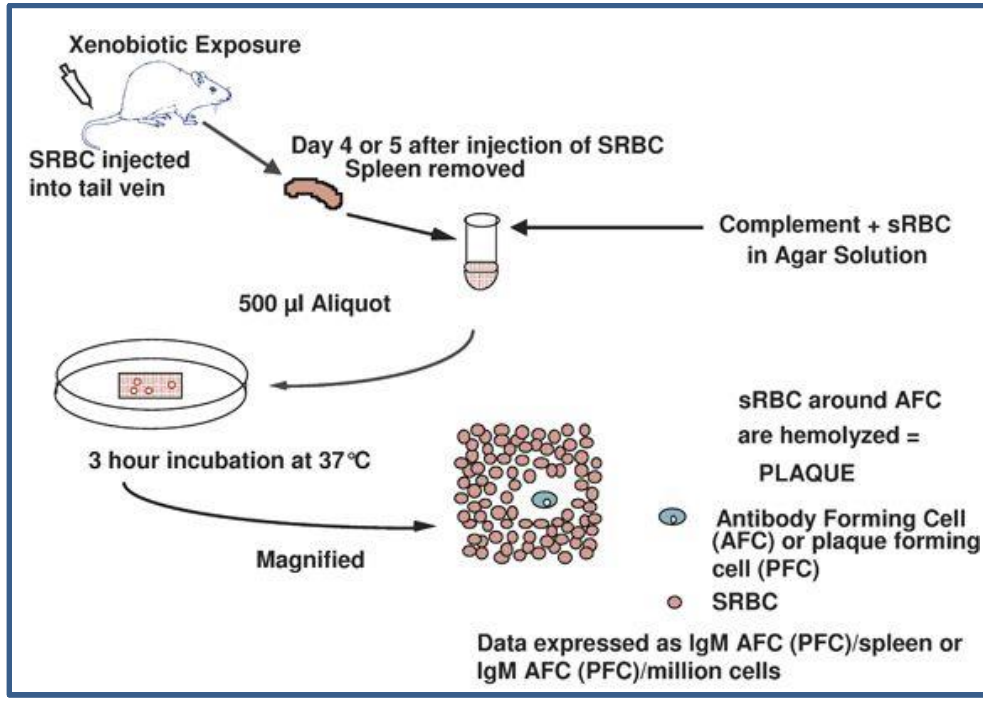
- PFOA activates peroxisome proliferator activated receptor (PPAR-α) and other nuclear receptors.
  - *Involved with hepatic, developmental, and other effects.*
  - *PPAR-α is functional in human liver.*
  - *Rodent liver tumors due to PPAR-α activation may not be relevant to humans.*
- **Are non-cancer hepatic effects of PFOA relevant to humans?**
- Extensive review of data from:
  - *Non-human primates*
  - *Standard rodent strains*
  - *Humanized PPAR-α mice.*
  - *PPAR-α null mice*
  - *Human tissues.*
  - *In vitro studies.*
- ***Overall DWQI conclusion:***
  Non-cancer liver toxicity of PFOA in rodents is relevant to humans for the purposes of risk assessment.

Example of Approach Used



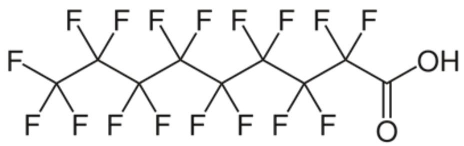
DWQI PFOS Reference Dose: Decreased Immune Response
(Pachkowski et al. 2019. Env. Research)

- Based on **decreased plaque forming cell response** in mice (Dong et al., 2009).
  - *Measures antibody response to foreign antigen.*
- Well established – 4 positive studies; only 1 negative study.
- No reason to discount human relevance.
- Supported by human data:
  - ↓ *antibody response to vaccines.*
  - ↑ *incidence of infectious disease.*
- Reference Dose – 1.8 ng/kg/day



- Other federal and state PFOS evaluations:
  - *NTP (2016) systematic review: Presumed human immune hazard.*
  - *ATSDR (2018 draft) and at least 5 other states (CA, MI, MN, NH, NY) assessments based on decreased immune system response.*

DWQI PFNA Reference Dose: Increased Liver Weight

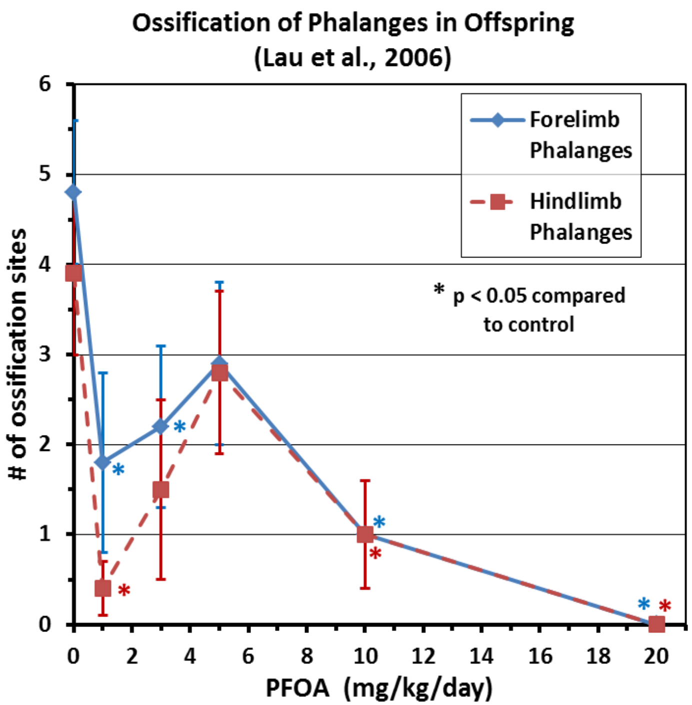


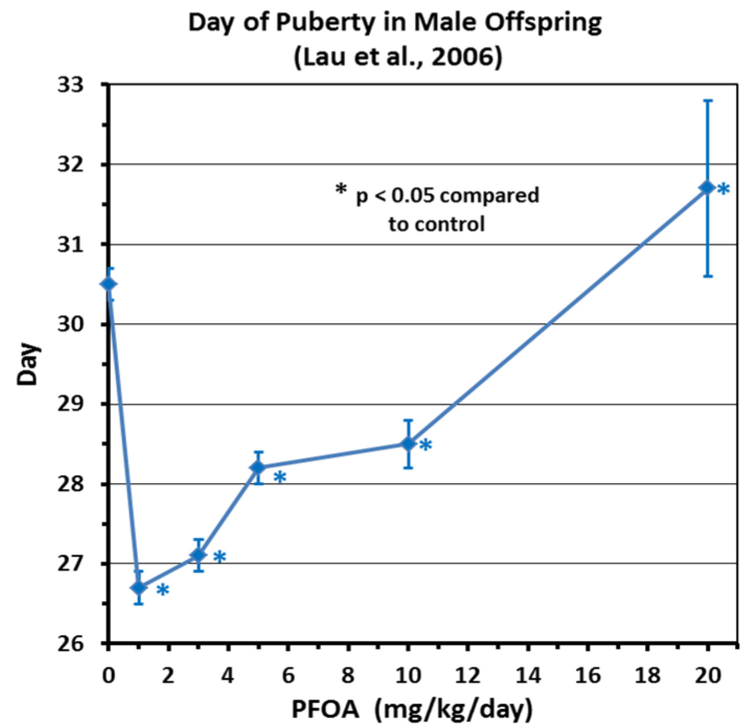
- "NJ-specific contaminant" – not evaluated by USEPA.
- Toxicity (hepatic, developmental, immune, male reproductive) generally **similar to PFOA** but:
  - *Longer half-life.*
  - *Effects at lower doses.*
  - *Some effects are more severe.*
- Human half-life - estimated as twice PFOA:
  - *Comparison of rodent half-lives for PFOA and PFNA.*
  - *Limited human half-life data - urinary excretion.*
- RfD based on **↑ liver weight** in pregnant mice (Das et al., 2015)
  - *Only study at the time with **serum PFNA data.***
- **Liver damage (necrosis) - much more sensitive effect,** but could not be used:
  - *Numerical serum PFNA data not provided by study sponsors.*
  - *Uncertainty factor of 3 for more sensitive effects.*
- Reference Dose - 0.74 ng/kg/day (3-fold lower than PFOA)
- DWQI conclusions supported by recent NTP 28-day rat study..

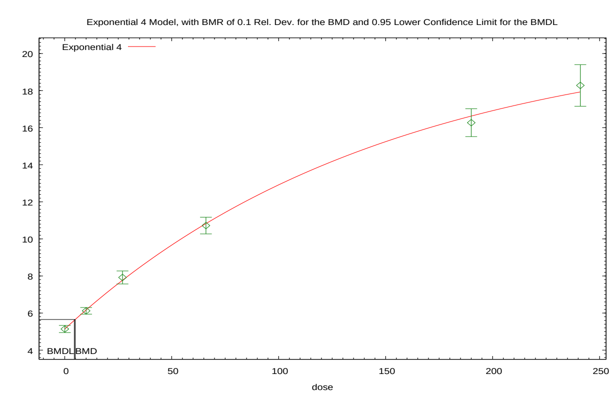
NJ, USEPA, ATSDR & European Food Safety Authority (EFSA) Toxicity Factors (ng/kg/day) for PFOA & PFOS

Agency	*Species*	PFOA *Basis*	PFOA *Tox. Factor*	PFOS *Basis*	PFOS *Tox. Factor*
USEPA	**Animal**	**Development: Delayed bone development & earlier male puberty (mouse)**	**20**	**Developmental: ↓ offspring body weight (rat)**	**20**
New Jersey		**↑ Liver weight (mouse):** • **Uncertainty factor for mammary gland delay.**	**2**	**Immune suppression (mouse)**	**1.8**
ATSDR Draft		**Developmental: Behavioral & skeletal changes (mouse)**	**3**	**↓ Offspring body weight (rat);** • **With uncertainty factor for immune toxicity (mouse)**	**2**
EFSA	**Human**	**↑ cholesterol (also ↑ liver enzyme ALT, ↓ birth weight)**	**0.8**	**↑ cholesterol; ↓ vaccine response; ↓ birth weight**	**1.8**

Dose-Response for Developmental Endpoints Used as Basis for USEPA PFOA Health Advisory







Reference Dose is Combined with Drinking Water Exposure Assumptions to Derive Health-based MCL

Health-based MCL =

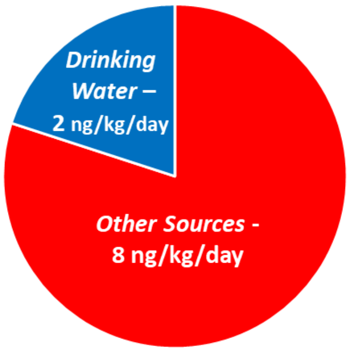
$$\frac{\text{Reference Dose (mg/kg/day)} \times \text{Body Wt. (kg)} \times \text{Relative Source Contribution (\%)}}{\text{Drinking Water Consumption (L/day)}}$$

Drinking Water Ingestion Rate *(L/kg/day)*

- NJ – Default adult ingestion rate.
- Other assessments:
  - *Ingestion rates for sensitive subgroups.*
    - *Lactating women (higher)*
    - *Infants (highest).*
  - *Minnesota Dept. of Health model for prenatal and infant exposure.*

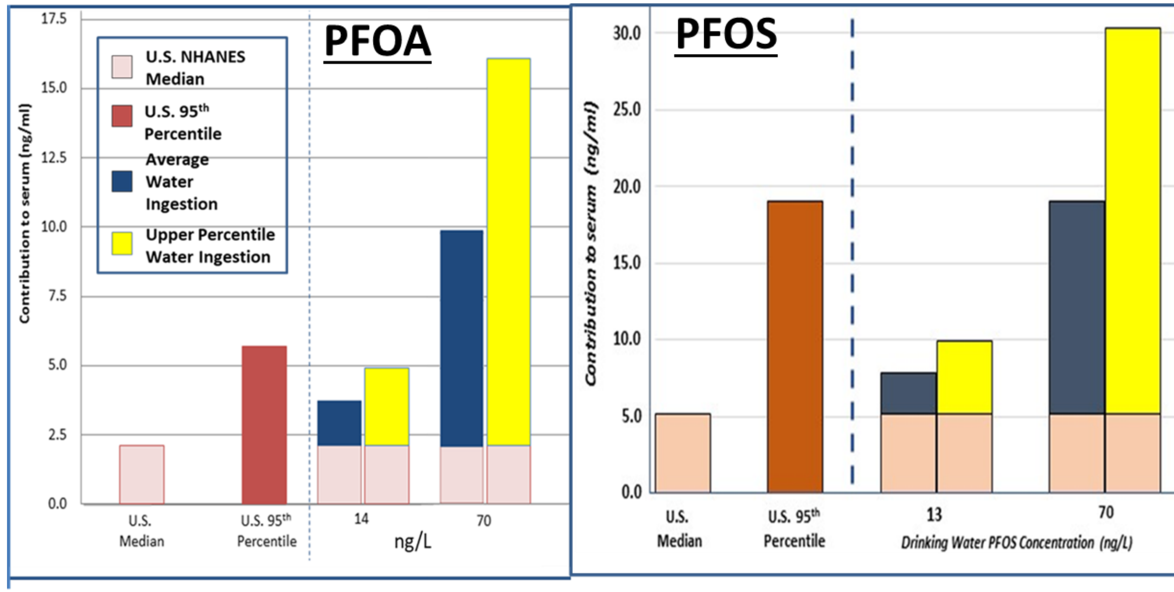
Relative Source Contribution factor:

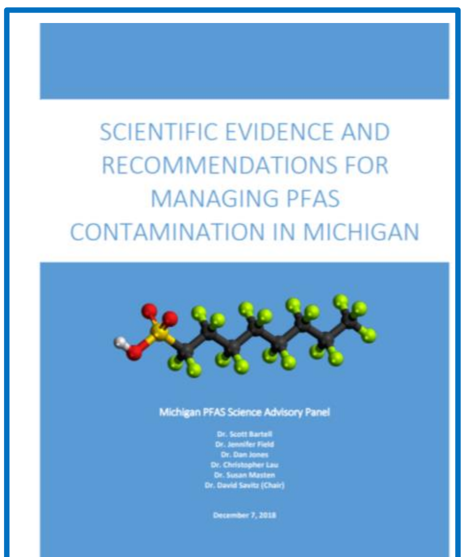
- Accounts for non-drinking water exposure sources (e.g. food, consumer products, air).
  - *NJ used default assumption: 20% of Reference Dose from drinking water; 80% from other sources.*
  - *Higher chemical-specific value can be used if data available.*



Increases in Serum PFOA & PFOS Predicted from NJ Health-based MCLs (13-14 ng/L) & USEPA Health Advisories (70 ng/L)

"NJ Drinking Water Quality Institute Health Effects Subcommittee concludes that these [blood serum PFAS] increases [at 70 ng/L] are **not desirable and may not be protective of public health."**





Michigan PFAS Science Advisory Panel Report (Dec. 2018)

"If one accepts the probable links between PFOA exposure and adverse health effects detected in the epidemiological literature as critical effects for health risk assessment, **then 70 ppt in drinking water might not be sufficiently protective for PFOA."**

Factors Considered in DWQI PFAS MCL Recommendations

- **Health-based MCL**
- **Practical Quantitation Level (PQL)**
  - Level reliably measured by drinking water laboratories.
- Availability of **treatment removal technology.**

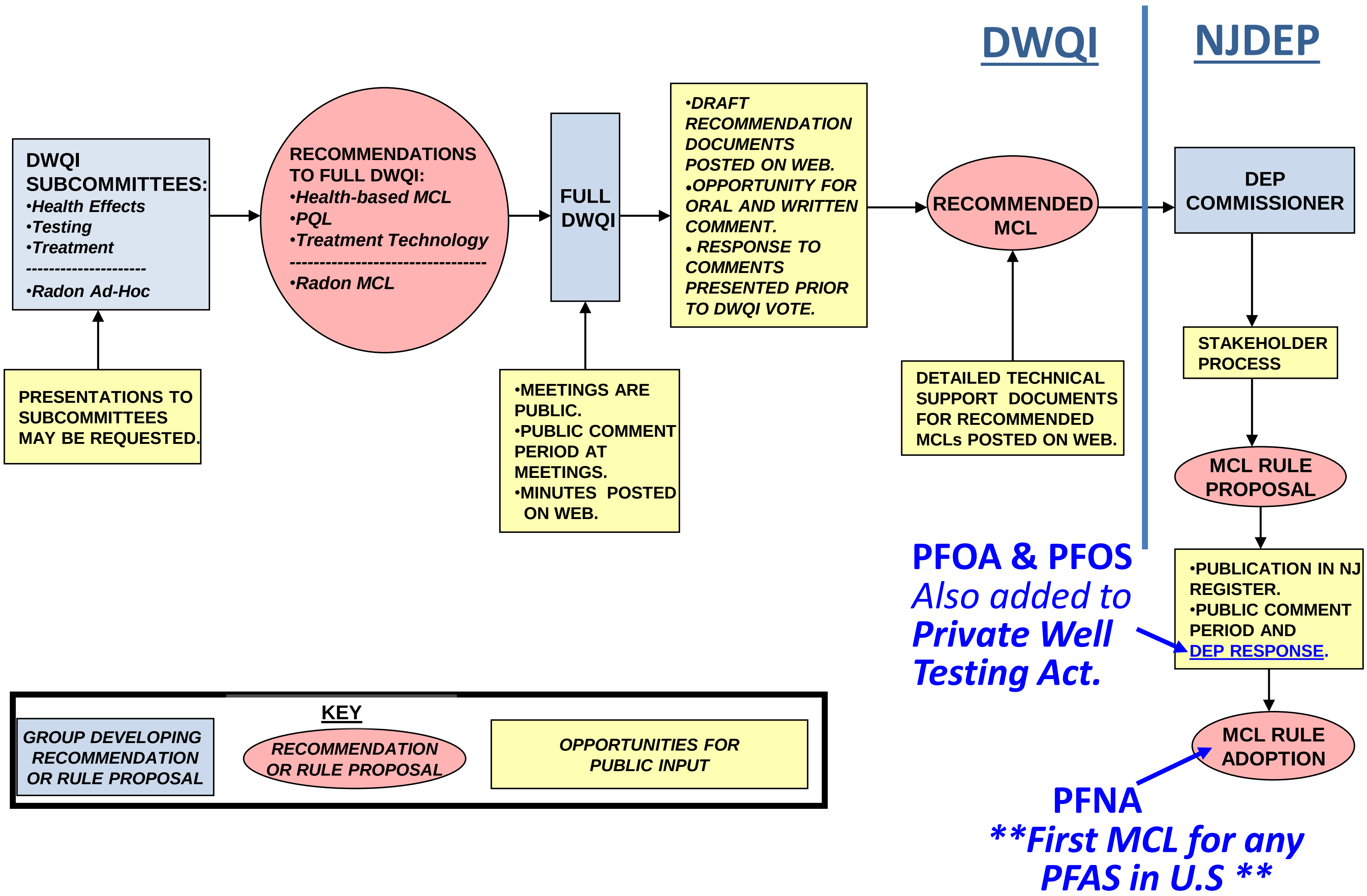
*** Health-based MCL is the goal ***

- PFAS MCLs not limited by analytical or treatment factors.

- **Therefore, PFAS MCLs are set at Health-based MCLs.**

(Units: ng/L)	Health-based MCL	Analytical PQL	Treatment Removal	Recommended MCL
PFOA	**14**	**6**	**Not limiting**	**14**
PFOS	**13**	**4.2**	**Not limiting**	**13**
PFNA	**13**	**5**	**Not limiting**	**13**

Public Participation in NJDEP MCL Development Process



Current Status of NJDEP PFAS Regulations

PFNA:

- **MCL & Ground Water Quality Standard** – 13 ng/L (*2018*).
- **First MCL in the nation for any PFAS.**
- Quarterly monitoring by public water systems has begun:
  - *2019*: ~ 1100 small groundwater systems; nontransient noncommunity systems (e.g. schools, factories).
    - Most are also voluntarily reporting PFOA & PFOS.
    - Through 3rd quarter of 2019: ~11% of systems detected 1 or more PFAS above MCL.
    - MCL violations issued for 6 systems, based on running annual average > PFNA MCL.
  - *2020*: Large groundwater systems; all surface water systems.
- Added to **NJ Hazardous Substances List** (*2018*).

PFOA & PFOS:

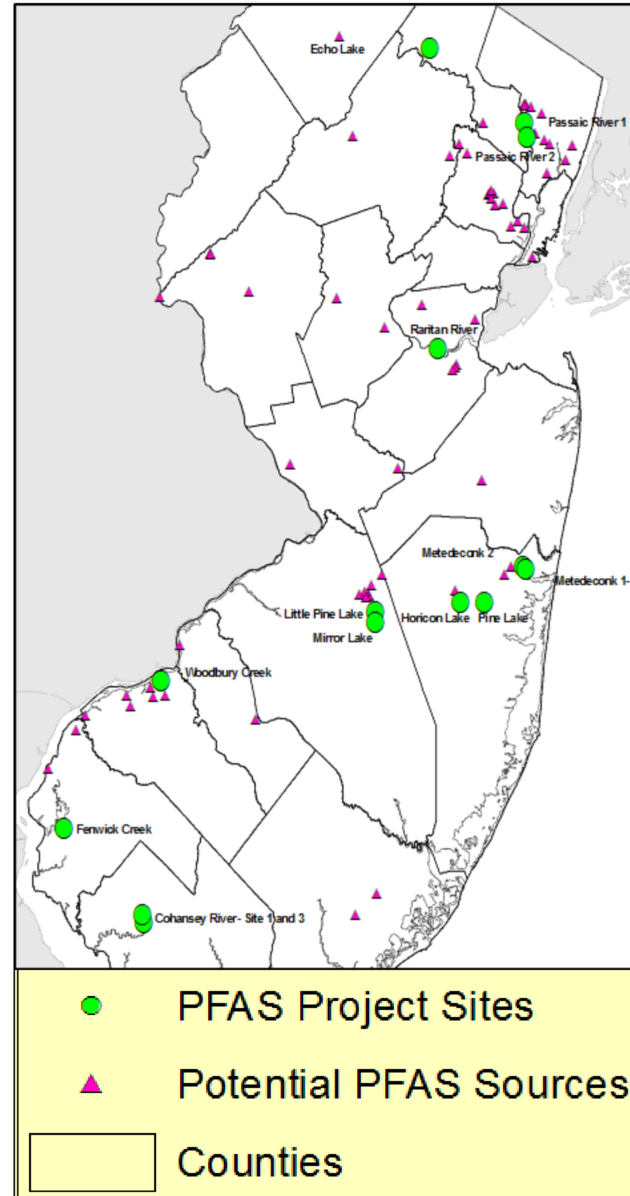
- **Interim Ground Water Quality Standards:** PFOA-10 ng/L; PFOS-10 ng/L (*March 2019*).
- Rule proposal (*April 2019*):
  - **MCLs** & **Ground Water Quality Standards:** PFOA – 14 ng/L; PFOS – 13 ng/L.
  - Add to **NJ Hazardous Substances List.**
  - Add to **NJ Private Well Testing Act**.
- In New Jersey, rule adoptions must occur within one year of rule proposal.

NJDEP Study of PFAS in Fish Tissue, Sediments & Surface Water

- 11 sites statewide selected for:
  - Proximity of potential source.
  - Recreational and/or subsistence fishing.
- ~100 fish collected.
  - 12 species (2-4 species per site)
  - 3 trophic levels
- Shorter-chain PFAAs detected in almost all surface water samples, but not in fish.

Compound	# of Sites (n=11)	# of Species-Sites (n=32)	Maximum conc. (ng/g)
PFOS	**11**	30	**162.5**
PFUnA	**11**	31	**27.2**
PFDoA	**10**	28	5.42
PFDA	**10**	24	3.57
PFOSA	3	5	2.83
PFHxS	3	4	1.66
PFNA	2	4	1.39
PFOA	1	2	0.72

Reporting Levels: 0.5 – 1 ng/g (ppb)



NJ Fish Consumption Advisories for PFAS (2018)

	General Population			High Risk Population*		
	PFOA (ng/g; ppb)	PFNA (ng/g; ppb)	PFOS (ng/g; ppb)	PFOA (ng/g; ppb)	PFNA (ng/g; ppb)	PFOS (ng/g; ppb)
Unlimited	0.62	0.23	0.56	0.62	0.23	0.56
Once/Week	4.3	1.6	3.9	4.3	1.6	3.9
Once/Month	18.6	6.9	17	18.6	6.9	17
Once/3 months	57	21	51	N/A	N/A	N/A
Once/Year	226	84	204	N/A	N/A	N/A
Do Not Eat	**>226**	**>84**	**>204**	**>18.6**	**>6.9**	**>17**

* *High risk – infants, children, pregnant & nursing women, women of childbearing age.*

- **Consumption Advisory Triggers** based on NJ Reference Doses.
  - *Assume 227 g (8 oz.) meal size, 70 kg body weight.*
- **Advisories for <u>PFOS</u> at all study sites.**
  - *Consumption frequency ranges from once per week to once per year.*
  - *For 1 – 3 species at each site.*

Additional Current PFAS Issues

Current Issue:
USEPA & States' PFAS MCLs & Guidance Levels

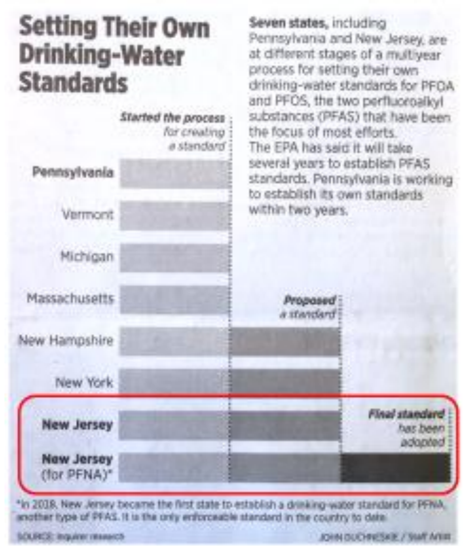
- No federal drinking water standards (MCLs) for PFAS.
- 1996 amendments to Federal Safe Drinking Water Act
  - *Established lengthy & complex process for new MCLs.*
  - *No federal MCLs for new contaminants since 1990s…*

  ...Despite unregulated contaminants of more concern than some regulated ones.
- USEPA intends to make draft decision in 2019 on whether to develop PFOA & PFOS MCLs.
  - *If federal MCLs are developed, process would take many years.*
- USEPA (2016) Drinking Water Health Advisory (guidance) for PFOA & PFOS of 70 ng/L.
  - ***Since 2016, ATSDR and at least 8 states have developed PFOA & PFOS drinking water risk assessments more stringent than USEPA's.***
- NJ and some other states (e.g. CA, MA) have developed their own MCLs for many years.
- Additional states (e.g. MI, NH, PA) have developed PFAS MCLs or plan to do so.
  - *Due to nationwide concerns about PFAS in drinking water.*

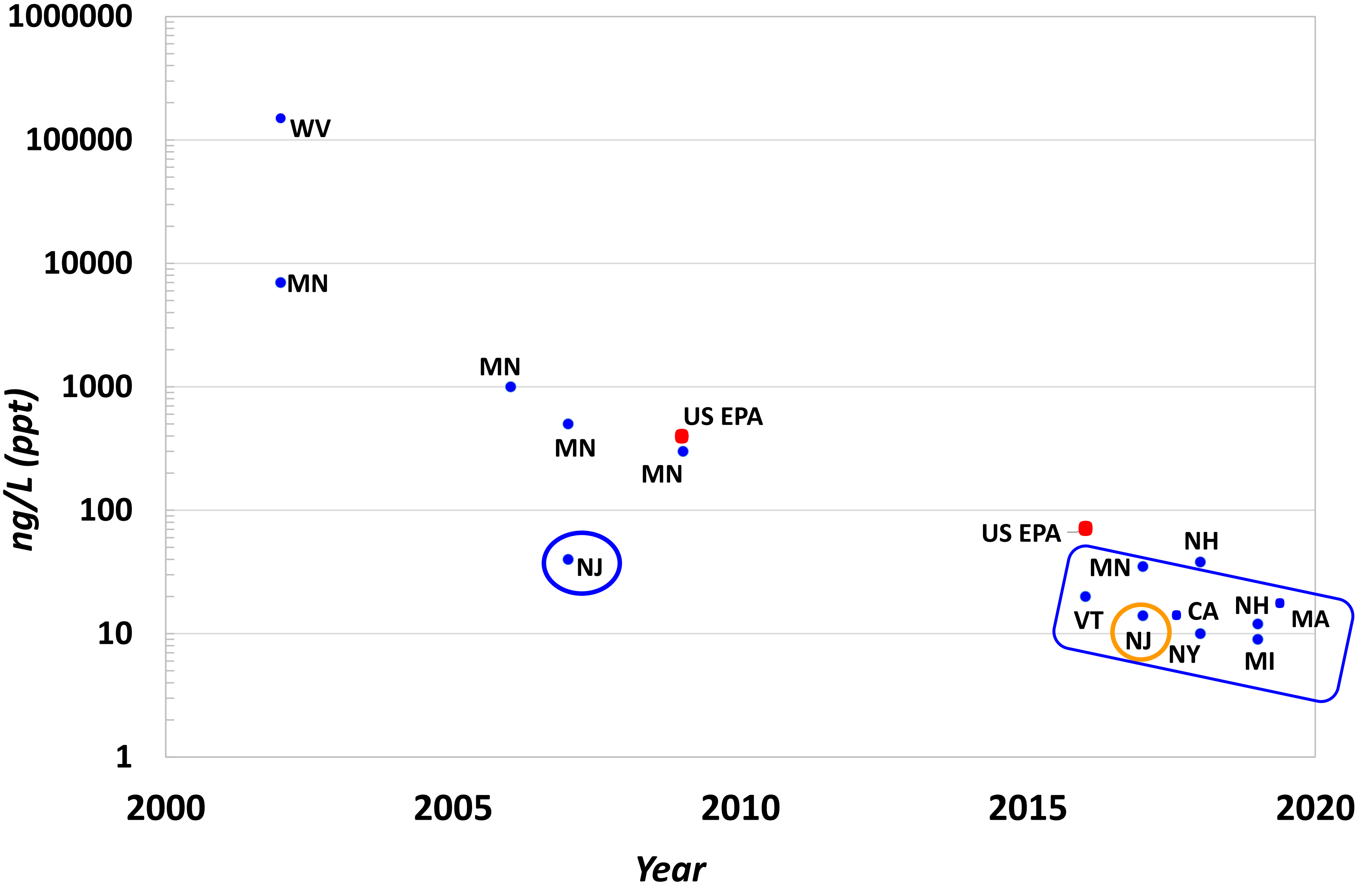
USEPA & State PFAS Drinking Water Guidelines (ng/L; ppt)

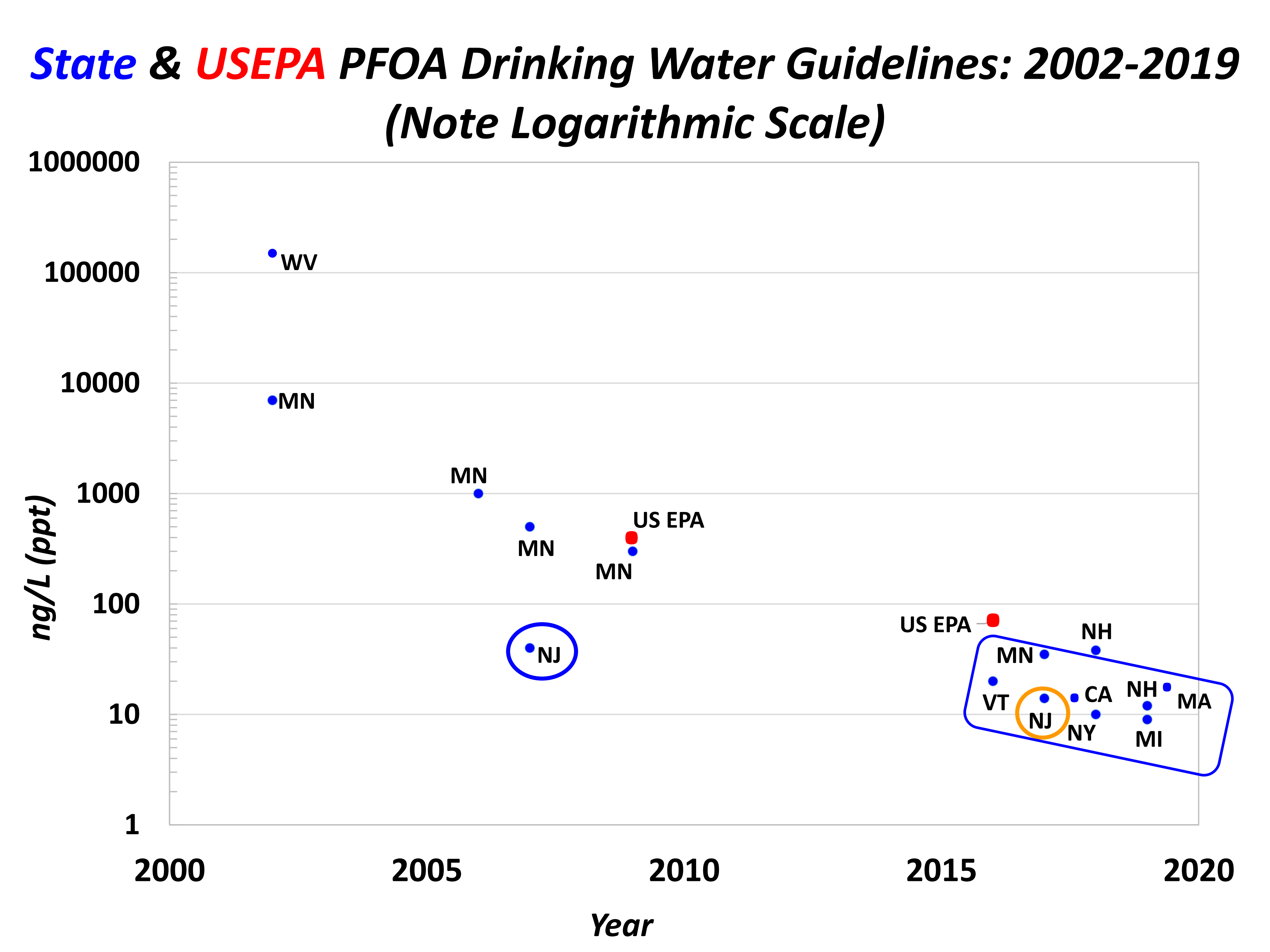
(Includes Standards & Guidance Values – Proposed/Recommended* & Final)

	PFOA	PFOS	PFNA	PFHxS	PFHpA	PFDA	Total?	PFBA	PFHxA	PFBS	GenX
EPA	70	70	---	---	---	---	Yes (2)	---	---	---	---
CA	5.1	6.5	---	---	---	---	No (2)	---	---	---	---
CT	70	70	70	70	70	---	Yes (5)	---	---	---	---
MA*	20	20	20	20	20	20	Yes (6)	---	---	2000	---
MI*	8	16	6	51	---	---	No	---	400,000	420	370
MN	35	15	---	47	---	---	No	7000	---	2000	---
NH	12	15	11	18	---	---	No	---	---	---	---
NJ	14*	13*	13	---	---	---	No	---	---	---	---
NY*	10	10	---	---	---	---	No	---	---	---	---
NC	---	---	---	---	---	---	---	---	---	---	140
VT	20	20	20	20	20	---	Yes (5)	---	---	---	---



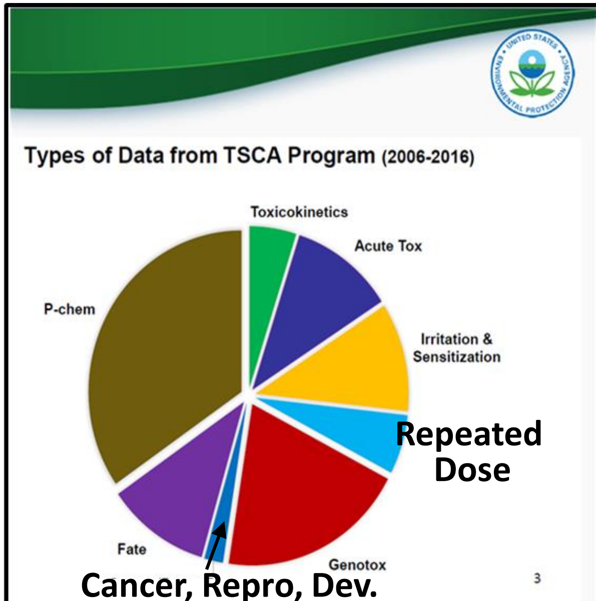
State & USEPA PFOA Drinking Water Guidelines: 2002-2019
(Note Logarithmic Scale)




State & USEPA PFOA Drinking Water Guidelines: 2002-2019
(Note Logarithmic Scale)
1000000
100000
10000
1000
100
10
1
ng/L (ppt)
2000
2005
2010
2015
2020
Year
WV
MN
MN
MN
NJ
US EPA
MN
US EPA
NH
MN
VT
NJ
CA
NY
NH
MA
MI

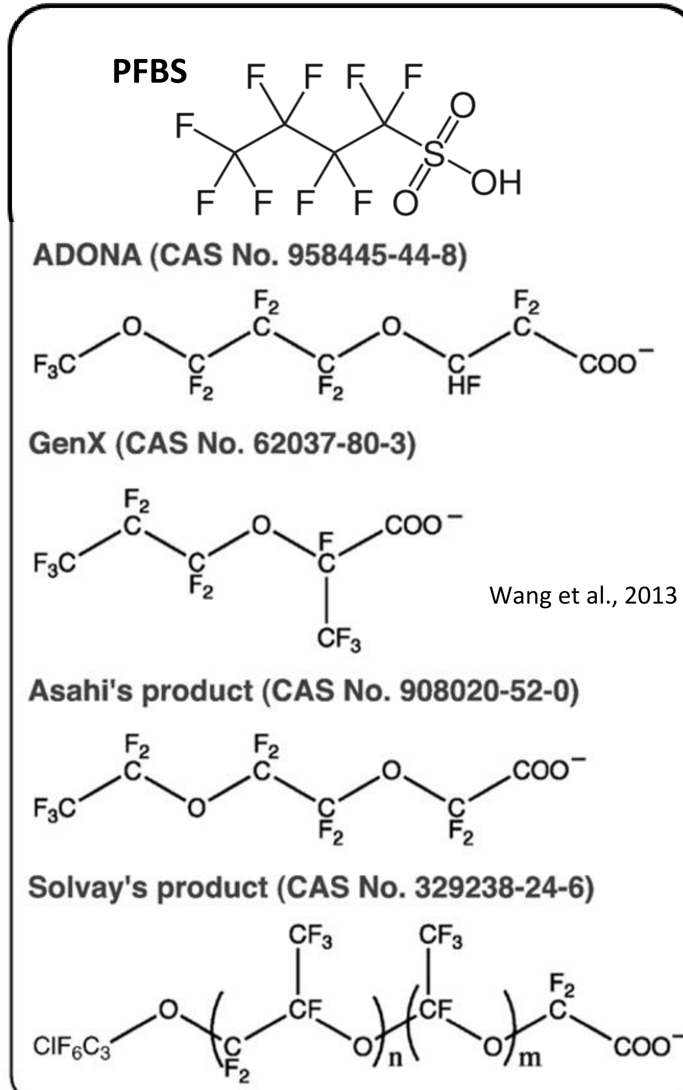
Current Issue: Replacements for Phased Out Long-Chain PFAAs

- 100s of new PFAS/replacements approved by USEPA.
- **Short-chain PFAAs** (e.g. PFBS) or PFAS with **other structures**
- Some have shorter half-lives, but no data for others.
- Most have **no toxicity data and** not detected by commercial labs.



"USEPA had <u>**any**</u> studies for only about 200 of 900 new PFAS reviewed Between 2006 and 2018." USEPA, 2018

- And some have similar toxicity to long-chain PFAS (e.g. **GenX).**
- And, like long-chain PFAS, **do not break down.**
- Recently **detected in environmental media** in NJ and elsewhere.
- Current topic of major scientific, regulatory, and public interest.



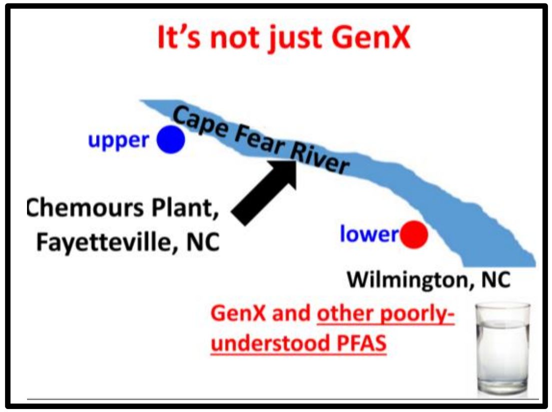
NC STATE UNIVERSITY

Center for Human Health and the Environment

GenX Exposure Study

PFAS blood sample results

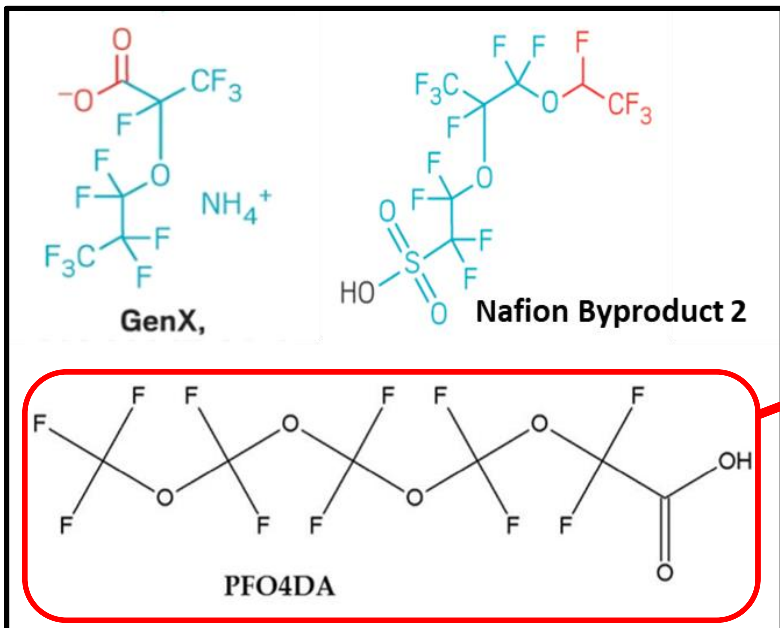
Wilmington, November 13, 2018



Four newly-identified PFAS in blood

1. **Nafion byproduct 2 (99% of samples)** $C_7H_2F_{14}O_5S$
2. **PFO4DA (98%)** $C_6HF_{11}O_6$
3. **PFO5DoDA (87%)** $C_7HF_{13}O_7$
4. **Hydro-EVE (76%)** $C_8H_2F_{14}O_4$

… But not GenX $C_6HF_{11}O_3$



Environmental Science & Technology

Ecotoxicology and Human Environmental Health

Comparative Hepatotoxicity of Novel PFOA Alternatives (Perfluoropolyether Carboxylic Acids) on Male Mice

Hua Guo, Jinghua Wang, Jingzhi Yao, Sujie Sun, Nan Sheng, Xiaowen Zhang, Xuejiang Guo, Yong Guo, Yan Sun, and Jiayin Dai

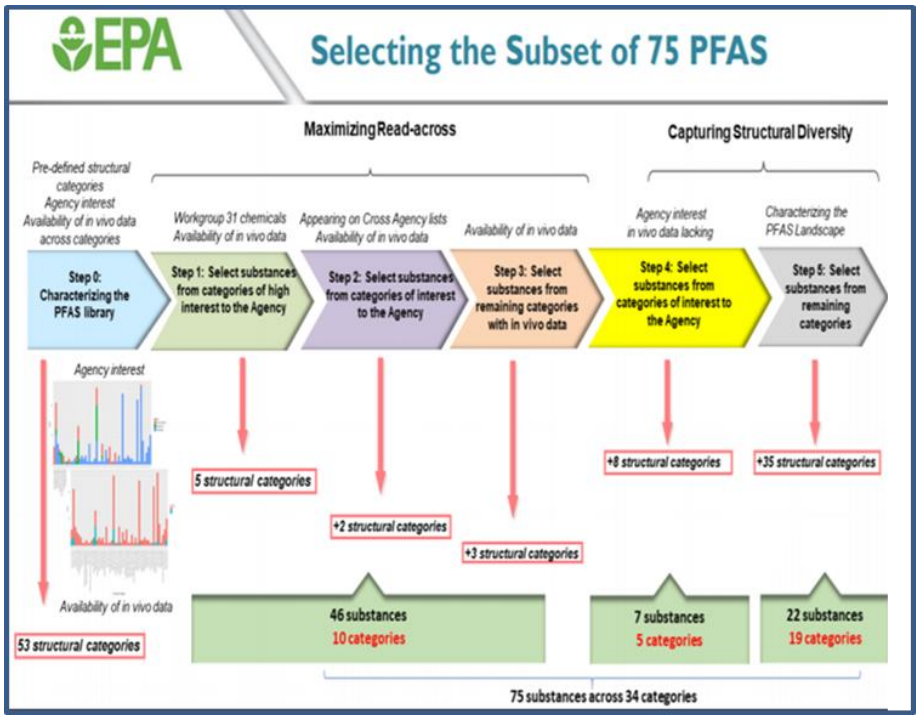
Environ. Sci. Technol., **Just Accepted Manuscript** • DOI: 10.1021/acs.est.9b00148 • Publication Date (Web): 13 Mar 2019

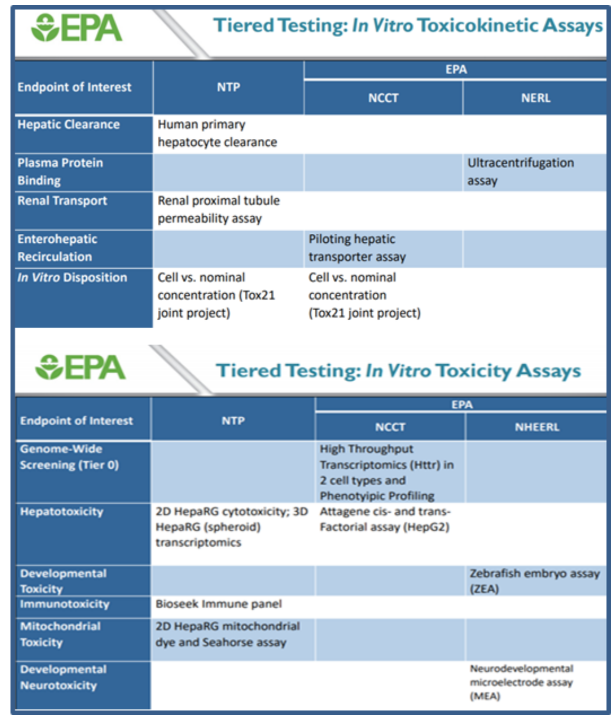
Just Accepted

Current Issue: Toxicity Evaluations for Large Number of PFAS

- Mammalian toxicology testing of large numbers of PFAS is not feasible.
- Current USEPA/NTP effort to develop predictions based on high throughput data.
  - *Read-across for PFAS that have in vivo data.*
  - *Structural diversity to characterize "PFAS landscape."*

BUT…not yet known if predictions will be consistently accurate, and…
High throughput data **cannot be used as primary basis for risk assessment under current risk assessment guidelines**.





EPA

Tiered Testing: *In Vitro* Toxicokinetic Assays

Endpoint of Interest	NTP	EPA	
		NCCT	NERL
Hepatic Clearance	Human primary hepatocyte clearance		
Plasma Protein Binding			Ultracentrifugation assay
Renal Transport	Renal proximal tubule permeability assay		
Enterohepatic Recirculation		Piloting hepatic transporter assay	
In Vitro Disposition	Cell vs. nominal concentration (Tox21 joint project)	Cell vs. nominal concentration (Tox21 joint project)	

EPA

Tiered Testing: *In Vitro* Toxicity Assays

Endpoint of Interest	NTP	EPA	
		NCCT	NHEERL
Genome-Wide Screening (Tier 0)		High Throughput Transcriptomics (Httr) in 2 cell types and Phenotyipic Profiling	
Hepatotoxicity	2D HepaRG cytotoxicity; 3D HepaRG (spheroid) transcriptomics	Attagene cis- and trans-Factorial assay (HepG2)	
Developmental Toxicity			Zebrafish embryo assay (ZEA)
Immunotoxicity	Bioseek Immune panel		
Mitochondrial Toxicity	2D HepaRG mitochondrial dye and Seahorse assay		
Developmental Neurotoxicity			Neurodevelopmental microelectrode assay (MEA)

Finally, other current PFAS issues (<u>not</u> specific to New Jersey) include…

- Risk assessment and/or regulation of PFAS individually or as a group?
- Pollution prevention – source reduction
- Occurrence in multiple environmental media
- Characterization of multiple exposure sources
- Analytical methods for non-target & total PFAS
- Remediation – treatment removal technologies & potential approaches for destruction

…and many other challenging questions.

Many current and former colleagues from:

New Jersey Department of Environmental Protection

New Jersey Department of Health

and the

New Jersey Drinking Water Quality Institute

contributed to the work presented here.

Thank you!

For questions or additional information:

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(609) 292-8497

NJDEP Rules and Regulations Websites

- Adopted rules: https://www.nj.gov/dep/rules/adoptions.html
- Proposed rules: https://www.nj.gov/dep/rules/notices.html

Links to NJDEP & NJ Drinking Water Quality Institute PFAS Reports

NJ Drinking Water Quality Institute Maximum Contaminant Levels Recommendations

- Perfluorooctane Sulfonate (PFOS), June 2018
  - Appendix A – Health-Based Maximum Contaminant Level Support Document for PFOS
  - Appendix B – Report on the Development of a Practical Quantitation Level for PFOS in Drinking Water
  - Appendix C – Second Addendum to Appendix C: Recommendation on Perfluorinated Compound Treatment Options for Drinking Water
  - Appendix D – Responses to Comments on DWQI Health Effects Subcommittee Report: “Public Review Draft - Health-Based Maximum Contaminant Level Support Document: PFOS”
- Perfluorooctanoic Acid (PFOA), March 2017
  - Appendix A – Health-Based Maximum Contaminant Level Support Document” PFOA
  - Appendix B – Report on the Development of a Practical Quantitation Level for PFOA in Drinking Water
  - Appendix C – Addendum to Appendix C: Recommendation on Perfluorinated Compound Treatment Options for Drinking Water
  - Appendix D – Responses to Comments on DWQI Health Effects Subcommittee Report: “Public Review Draft- Health-Based Maximum Contaminant Level Support Document: PFOA”
- Perfluorononanoic Acid (PFNA), July 2015
  - Appendix A – Health-Based Maximum Contaminant Level Support Document: PFNA
  - Appendix B – Report on the development of a Practical Quantitation Level for PFNA
  - Appendix C – Recommendation on Perfluorinated Compound Treatment Options for Drinking Water

NJDEP Studies

- Investigation of Levels of Perfluorinated Compounds in New Jersey Fish, Surface Water, and Sediment (2018)
- Identification of Perfluorinated Carboxylic Acids (PFCAs) in the Metedeconk River Watershed (February 2016)
  Research Project Summary   Full Report
- Occurrence of Perfluorinated Chemicals in Untreated New Jersey Drinking Water Sources (2009-10 Study)
- Determination of Perfluorooctanoic Acid (PFOA) in Aqueous Samples (2006 Study).
  https://www.nj.gov/dep/dsr/dw/final_pfoa_report.pdf

NJDEP PFAS Publications

- Pachkowski, B., Post, G.B., Stern, A.H. (2019). The derivation of a Reference Dose (RfD) for perfluoroctane sulfonate (PFOS) based on immune suppression. Env. Research 171:452-469
- Post, G.B., Gleason, J.A., Cooper, K.R. (2017). Key scientific issues in developing drinking water guidelines for perfluoroalkyl acids: Contaminants of emerging concern. PLoS Biol. 15(12):e2002855. Open access at https://journals.plos.org/plosbiology/article/file?id=10.1371/journal.pbio.2002855&type=printable
- Procopio, N.A., Karl, R., Goodrow, S.M., Maggio, J., Louis, J.B., Atherholt, T.B.. (2017). Occurrence and source identification of perfluoroalkyl acids (PFAAs) in the Metedeconk River Watershed, New Jersey. Environ Sci Pollut Res Int. 24:27125-27135.
- Gleason, J.A., Post, G.B, and Fagliano, J.A. (2015). Associations of perfluorinated chemicals (PFCs) serum concentrations and select biomarkers of health in the US population (NHANES), 2007-2010 Env. Research 136: 8-14.
- Post, G.B., Louis, J.B., Lippincott, R.L., and Procopio, N.A. (2013). Occurrence of perfluorinated chemicals in raw water from New Jersey public drinking water systems. Env. Sci. Technol. 47 (23):13266-75.
- Post, G.B., Cohn, P.D., and Cooper, K.R. (2012). Perfluorooctanoic acid (PFOA), an emerging drinking water contaminant: a critical review of recent literature. Env. Res. 116: 93-117.
- Post, G.B., Louis, J.B., Cooper, K.R., Boros-Russo, B.J., and Lippincott, R.L. (2009). Occurrence and potential significance of perfluorooctanoic acid (PFOA) detected in New Jersey public drinking water systems. Environ. Sci, Technol. 43: 4547–4554.