DERP Forum

Strengthening Relationships with our Regulatory Partners

St. Louis, Missouri

May 8-9, 2019

NJDEP Maximum Contaminant Levels (MCLs) for PFOA, PFOS & PFNA: Regulatory and Scientific Basis

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Current Status of NJDEP PFAS Standards & Regulations

Perfluorononanoic Acid (PFNA):

- **MCL – 13 ng/L** (adopted September 2018).
  - **First MCL in the nation for any PFAS.**
  - Public water system monitoring is being phased in:
    - 2019: Small groundwater systems and nontransient noncommunity water systems.
    - 2020: Large groundwater systems and all surface water systems.
- **Ground Water Quality Standard – updated to 13 ng/L** by reference to MCL (September 2018).
- **Added to NJ Hazardous Substances List** (January 2018).

Perfluorooctanoic Acid (PFOA) & Perfluorooctane Sulfonate (PFOS):

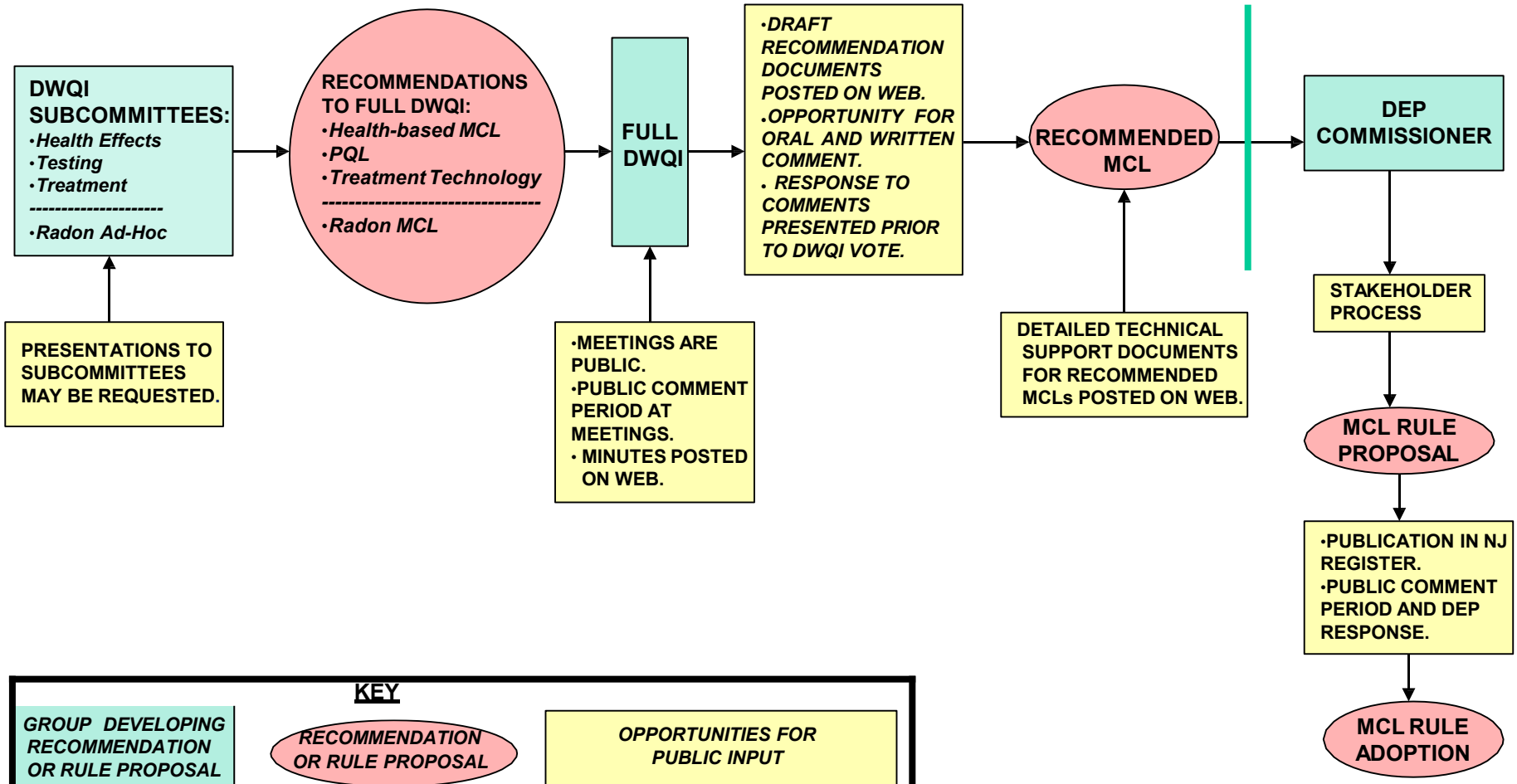
- **NJ Drinking Water Quality Institute (DWQI) MCL recommendations: PFOA - 14 ng/L (March 2017); PFOS - 13 ng/L** (June 2018).
- **Interim Ground Water Quality Standards: PFOA – 10 ng/L; PFOS – 10 ng/L.**
  - Established March 2019.
- **Rule proposal (April 1, 2019) –** public comment period until **May 31, 2019:**
  - **MCLs** and **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**.

NJ Drinking Water Quality Institute MCL Recommendation Process

- **NJ DWQI - Advisory body established by NJ SDWA to recommend MCLs to NJDEP Commissioner.**
  - Members: Majority external to state government. NJDEP and NJ DOH Health also represented.
  - NJDEP Commissioner decides whether to propose recommended MCLs as regulatory standards.
- **DWQI Subcommittees conduct detailed reviews of health effects, analytical limitations, and treatment removal technologies.**
- **Health-based MCL is the goal:**
  - Non-carcinogens – no health effects expected from lifetime exposure.
  - Carcinogens – 1 in 1 million lifetime cancer risk.
  - *For PFAS, primary basis is animal toxicology studies:*
    - *Consider sensitive effects not considered in USEPA Health Advisories.*
    - *Supported by epidemiological studies associating low exposures with human health effects.*
- **Practical Quantitation Level (PQL) - Level that can be reliably measured by drinking water labs.**
- **Availability of treatment removal technology.**
- **PFAS MCLs were not limited by analytical or treatment factors.**
  - **Therefore, recommended PFAS MCLs were 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



All DWQI reports are posted at
https://www.state.nj.us/dep/watersupply/g_boards_dwqi.html

NJDEP, USEPA & ATDSR Toxicity Factors & Drinking Water Values for PFOA & PFOS

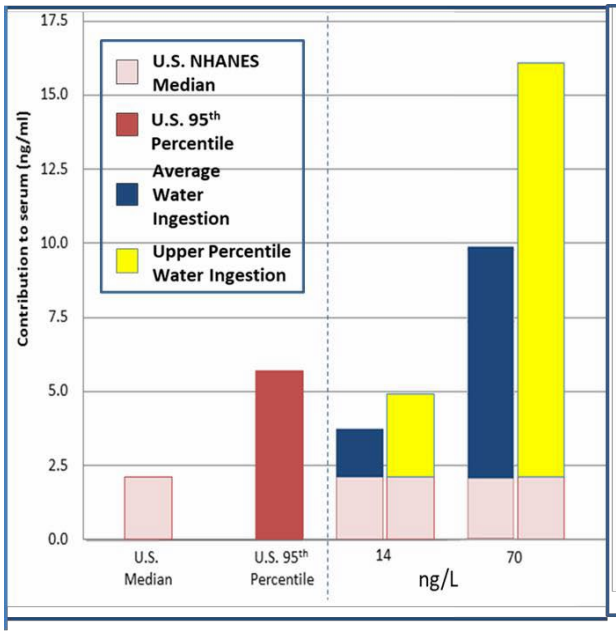
RfD – NJ or USEPA Chronic Reference Dose; MRL – ATSDR Intermediate Minimal Risk Level; HBMCL – NJ Health-based Maximum Contaminant Level; LHA – USEPA Lifetime Health Advisory

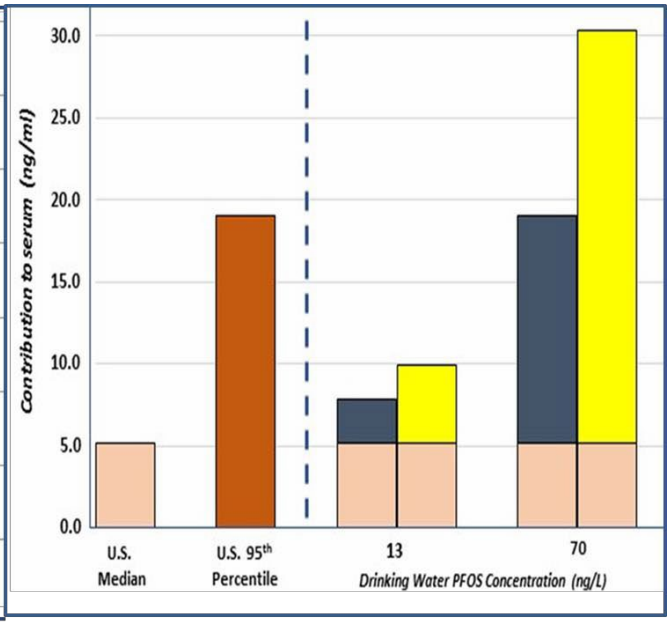
		Toxicological Basis	RfD/MRL (ng/kg/day)	HBMCL or LHA (ng/L)*
PFOA	NJ	Delayed mammary gland development	0.11	*(0.77**)*
		Not recommended due to lack of precedent as basis for risk assessment.		
		Increased liver weight • Includes **database uncertainty factor of 10** for more sensitive developmental effects (e.g. mammary gland development)	2	14
	USEPA	Delayed ossification & accelerated puberty in offspring	20	70**
	ATSDR	**Behavioral & skeletal effects in offspring**	3	--
PFOS	NJ	Immunotoxicity – Decreased plaque forming cell response (Pachkowski et al., 2017)	1.8	13
	USEPA	Decreased offspring body weight.	20	70**
	ATSDR	**Decreased offspring body wt.; immunotoxicity**	2	--

***Exposure Assumptions:** *Water consumption*: NJ: 0.029 L/kg/day, default adult upper percentile. USEPA: 0.054 L/kg/day, 90th % percentile lactating woman. *Relative Source Contribution*: NJ & USEPA: 20%,default.

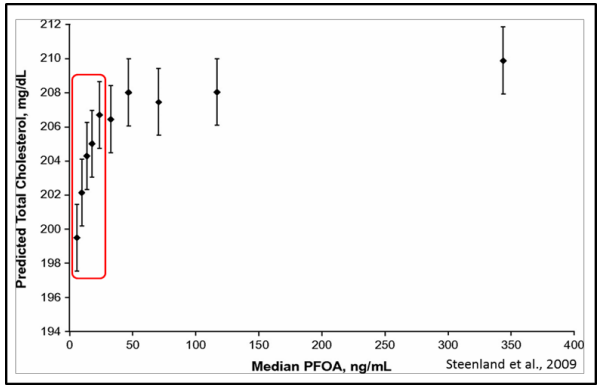
**Applies to total of PFOA and PFOS.

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





Steep Dose-Response at Low Serum Levels – ↑ Cholesterol and PFOA from Drinking Water Exposure



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

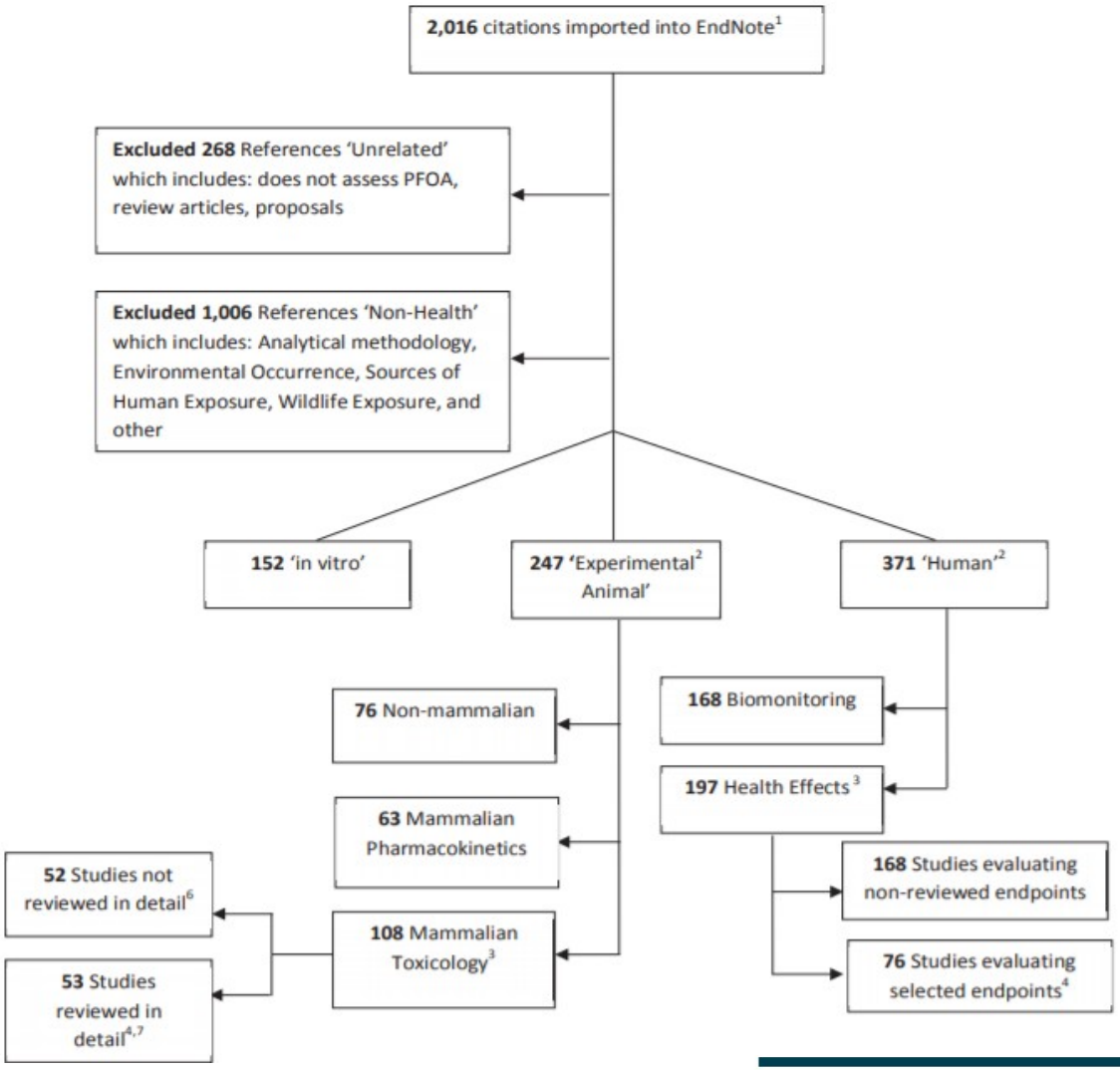
Basis for NJDEP MCL for PFNA

- **PFNA is similar to PFOA, but with 9 carbons instead of 8 carbons.**
- **"New Jersey-specific contaminant" – not evaluated by USEPA.**
  - *Infrequently found nationally in USEPA Unregulated Contaminated Monitoring Rule 3.*
  - *Found in NJ public water systems and private wells near likely industrial source.*
  - *Levels in two NJ public water systems, and in Delaware River nearby, highest reported in drinking water/surface water worldwide.*
- **Toxicity in animal studies (hepatic, developmental, immune, male reproductive) generally similar to PFOA but:**
  - *More **persistent** in the body.*
  - *Effects occur at **lower doses.***
  - *More **severe** effects (e.g. delayed offspring growth persists to adulthood).*
- **Human half-life of PFNA is estimated to be twice that of PFOA.**
- **Reference dose (RfD) is based on ↑ liver weight in pregnant mice (Das et al., 2015).**
- **Uncertainty factor of 3 for more sensitive effects at lower doses:**
  - ***Hepatic necrosis** at much lower doses and serum levels (shown graphically) in other studies. However, numerical serum data needed for RfD were not provided.*
  - *Mammary gland development delay – low-dose effect of PFOA; not studied for PFNA.*
- **Health-based MCL and MCL are 13 ng/L.**

Extra Slides

Literature Review Strategy: Example - PFOA

More than 2000 citations identified and screened.



NJ DWQI, 2016

Relationship Between Drinking Water Concentration and Increased Serum Level for PFOA

- **Clearance factor** (CL) - relates external dose to blood serum level.
  - PFOA (Lorber & Egeghy, 2011): PFOS (USEPA, 2016).
  - CL (L/kg/day) = Volume of Distribution (L) x (ln 2 ÷ Half-life [days])
- Combine clearance factor with **average water ingestion rate** (USEPA Exposure Factors Handbook) to relate drinking water concentration to increase in serum level.

$$\text{Dose } (\mu g/kg/day) = \text{Serum Conc. } (\mu g/L) \times \text{CL } (L/kg/day)$$

$$\text{Dose } (\mu g/kg/day) = \text{Drinking Water Conc. } (\mu g/L) \times \text{Ingestion Rate } (L/kg/day)$$

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

- **PFOA** - Predicted serum:drinking water ratios for increase in serum levels:
  - ***114:1*** - *average water consumption.*
  - ***200:1*** - *upper percentile water consumption.*
- Ratio of **>100:1 supported by empirical data** from several studies over a wide range of drinking water levels (<10 ng/L to >10,000 ng/L).
  - *Several locations – Little Hocking, Ohio; other Ohio & West Virginia C8 Study sites; Minnesota; Hoosick Falls, NY.*