NJDEP Drinking Water Standards (MCLs) for PFOA, PFOS & PFNA: Regulatory and Scientific Basis

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Division of Science & Research

Second National PFAS Conference
Northeastern University
June 11, 2019

Federal & State Standards & Guidance for Drinking Water Contaminants

- ***Standards (regulatory)*** – Federal and state *Maximum Contaminant Levels (MCLs)*.
  - **Enforceable**
  - Required **monitoring** of all public water systems
  - **New Jersey** and some other states develop their own drinking water standards
    - Can be more stringent than federal standards, or for contaminants with no federal standards.
- ***Guidance (non-regulatory)*** - USEPA *Drinking Water Health Advisories*; state guidance values.
  - **Not enforceable** – voluntary action often taken.
  - Monitoring of all public water systems **not required.**

NJ PFAS MCLs Continue NJ Work on Emerging Drinking Water Contaminants since 1980s

- ***1980s*** - Volatile organic chemicals found in NJ waters.
  - "Emerging contaminants" of the time - No federal standards.
- ***1984 - New Jersey Safe Drinking Water Act Amendments***
  - Require development of MCLs:
    - 22 listed contaminants.
    - Additional contaminants based on occurrence & health effects.
  - Established ***Drinking Water Quality Institute*** *(DWQI)* to recommend MCLs to NJDEP.
  - NJDEP Commissioner decides whether to propose MCLs as regulatory standards.
- NJ scientists have developed MCLs for many types of drinking water contaminants since 1984***.***

DWQI MCL Recommendations (1984 – Present)

Earlier MCL Recommendations
(1984-2009)

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

…and many others

Recent MCL Recommendations
(2009-present)

- 1,2,3-Trichloropropane*
- **PFNA***
- **PFOA & PFOS****
- 1,4-Dioxane - current evaluation

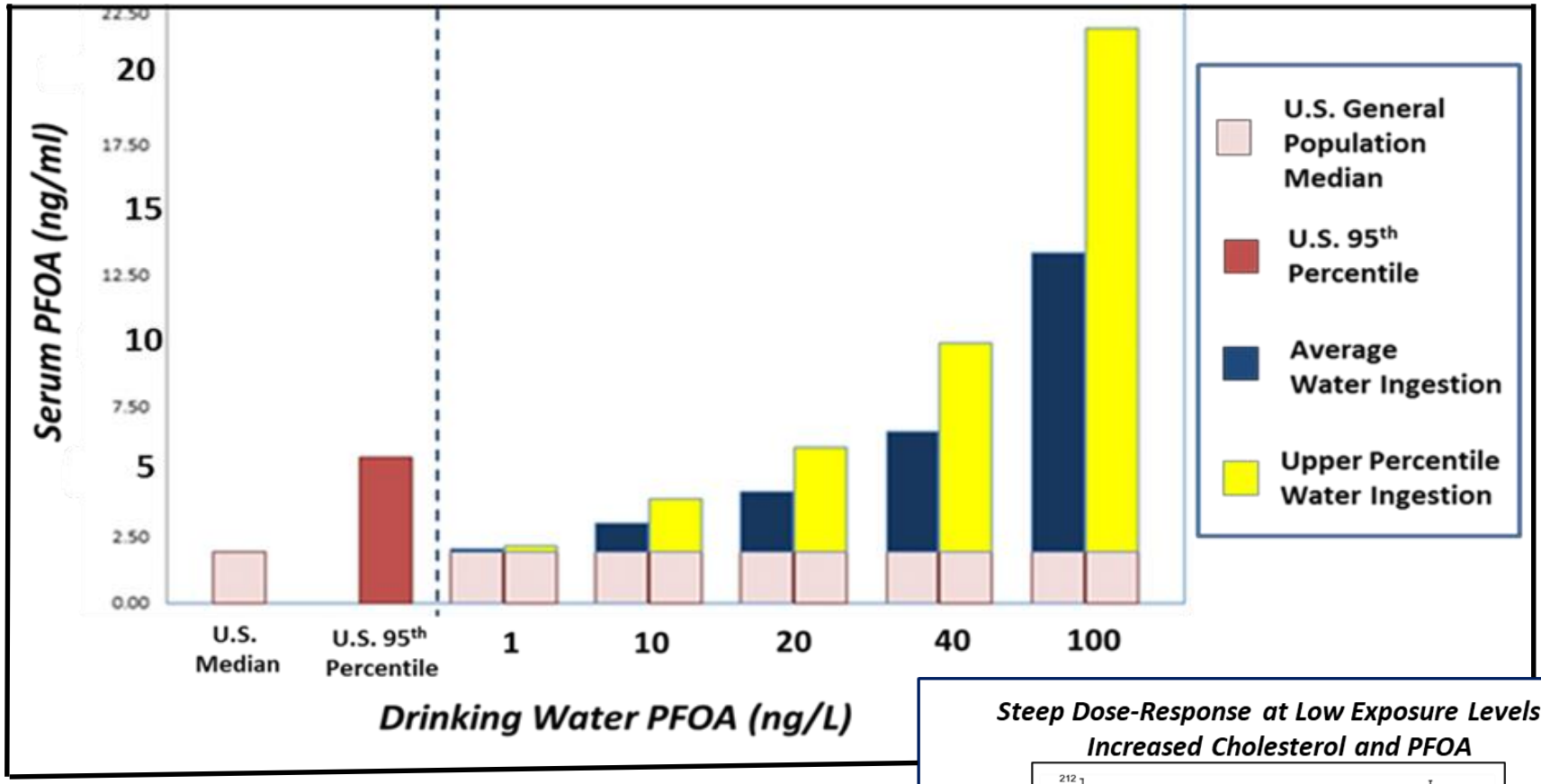
** MCL adopted by NJDEP*

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

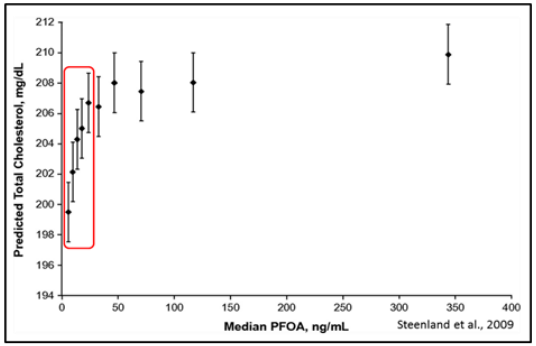
Why Are PFAS such as PFOA, PFOS, & PFNA of Particular Concern as Drinking Water Contaminants?

- Widespread drinking water occurrence.
- Do not break down in environment.
- Found in blood serum of virtually all U.S. residents.
- Bioaccumulate & remain in the body for many years after exposure ends.
- Multiple types of toxicity in animals, including at low doses.
- Low exposure levels associated with human health effects.
- Infant exposures higher than in older individuals.
- **Low drinking water levels can overwhelm other common exposures.**
  - *In contrast, drinking water is not an important exposure route for other persistent, bioaccumulative and toxic (PBT) contaminants (e.g. PCBs, dioxins).*
- **Overall - suggests need for caution about exposure from drinking water.**

"Low Drinking Water Levels Can Overwhelm Other Common Exposures"



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.

Overview: NJDEP Response to PFAS in Drinking Water

- ***2005-2006:*** **PFOA** detected in public water system near industrial source.
- ***2007:*** Drinking water guidance for **PFOA** - 40 ng/L (ppt).
- ***2006; 2009-10****:* First statewide studies of PFAS in public water systems in U.S. (Reporting Levels: 4-5 ng/L; much lower than in UCMR3)
  - **PFOA:** ~60%; **PFOS:** ~30%.
  - **PFNA:** Highest in drinking water reported worldwide in Paulsboro, NJ.
    - Also highest in surface water reported worldwide in nearby Delaware River (~1 ppb).
    - Industrial source later identified.
- ***2013-15:*** UCMR3 study of large U.S. public water systems:
  - PFOA & PFNA ($\geq$ 20 ng/L) in NJ much more often than nationally.

	New Jersey	***U.S. (other than NJ)***
PFOA	**10.9%** (at sites throughout NJ)	**2.1%**
PFNA	**2.3%** (near industrial source)	**0.2%**

- ***2014:*** NJDEP Commissioner asked Drinking Water Quality Institute to recommend MCLs for **PFNA, PFOA, and PFOS**.
  - Completed by June 2018 and accepted by NJDEP.
- Many NJ public water systems have voluntarily acted to reduce exposure.

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

GLORIA B. POST,*,† JUDITH B. LOUIS,† KEITH R. COOPER,‡ BETTY JANE BOROS-RUSSO,§ AND R. LEE LIPPINCOTT†

Division of Science, Research and Technology, New Jersey Department of Environmental Protection, P.O. Box 409, Trenton, New Jersey 08625, Department of Biochemistry and Microbiology, Rutgers University, 76 Lipman Drive, Room 218, New Brunswick, New Jersey 08901, and Bureau of Safe Drinking Water, New Jersey Department of Environmental Protection, P.O. Box 426, Trenton, New Jersey 08625

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Environmental Research

journal homepage: www.elsevier.com/locate/envres

Review

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

Gloria B. Post [a,*], Perry D. Cohn [b], Keith R. Cooper [c]

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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

Gloria B. Post,* Judith B. Louis, R. Lee Lippincott, and Nicholas A. Procopio

Office of Science, New Jersey Department of Environmental Protection, Mail Code 428-01, P.O. Box 420, Trenton, New Jersey 08625, United States

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

Jessie A. Gleason [a,*], Gloria B. Post [b,1], Jerald A. Fagliano [a,2]

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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

Gloria B. Post[1]*, Jessie A. Gleason[2], Keith R. Cooper[3]

1 New Jersey Department of Environmental Protection, Trenton, New Jersey, United States of America, **2** New Jersey Department of Health, Trenton, New Jersey, United States of America, **3** Rutgers University, New Brunswick, New Jersey, United States of America

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Review article

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

Brian Pachkowski*, Gloria B. Post, Alan H. Stern

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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*: Small groundwater systems; nontransient noncommunity systems (e.g. schools, factories).
    - Most are also voluntarily reporting PFOA & PFOS.
    - 1st quarter, 2019: ~10% of systems detected 1 or more PFAS above 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.

The Philadelphia Inquirer

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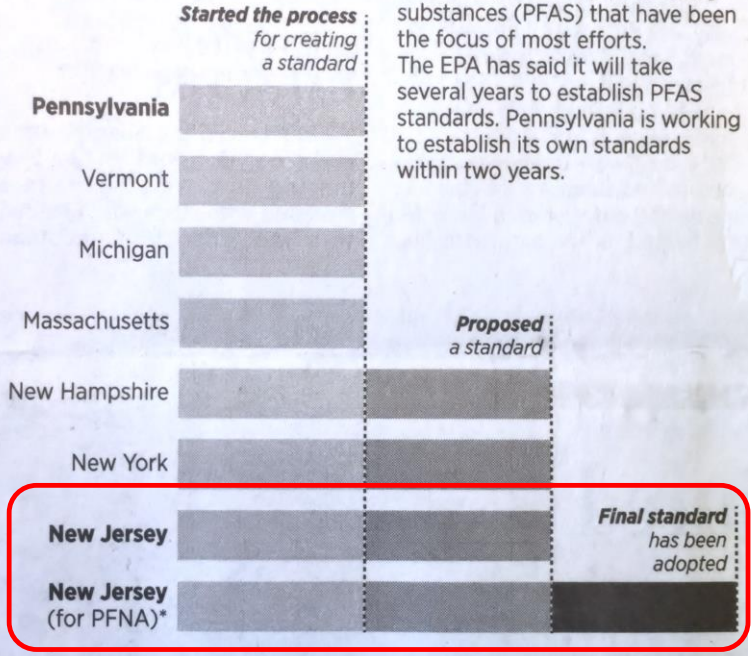
Setting Their Own Drinking-Water Standards

Seven states, including Pennsylvania and New Jersey, are at different stages of a multiyear process for setting their own drinking-water standards for PFOA and PFOS, the two perfluoroalkyl substances (PFAS) that have been the focus of most efforts. The EPA has said it will take several years to establish PFAS standards. Pennsylvania is working to establish its own standards within two years.



*In 2018, New Jersey became the first state to establish a drinking-water standard for PFNA, another type of PFAS. It is the only enforceable standard in the country to date.

SOURCE: Inquirer research

JOHN DUCHNESKIE / Staff Artist

CHEMICAL EXPOSURE

States act as water safety at EPA lags

Unhappy with feds, Pa., N.J., and others move toward their own drinking-water limits.

By Justine McDaniel and Laura McCrystal
STAFF WRITERS

When Maria Collett began knocking on doors as a Pennsylvania state Senate candidate in 2018, she heard one thing over and over: Do something about the drinking water.

Collett, a registered nurse and attorney from Lower Gwynedd Township, heard it from mothers who reminded her of herself. From a man who struggled with what to tell his children about the tap water they drank. From a woman who required life-altering surgery to treat a condition that could be linked to the chemicals that had been widely discovered in the local water supply.

Residents in the Horsham, Warrington, and Warminster Township areas were more than frustrated with government responses to the water-contamination crisis that has affected 90,000 in Bucks and Montgomery Counties and an estimated 39 million

See WATER STANDARDS on A10

Factors Considered in Developing New Jersey PFAS MCLs

- **Health-based MCL**
  - *Non-carcinogens:* No health effects from lifetime exposure (Reference Dose).
  - *Carcinogens:* 1-in-1 million lifetime cancer risk, specified in NJ law.
- **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**

Human Health Basis for NJ PFAS MCLs

- Primary basis is animal toxicity data.
  - Human data was not used because co-exposure to multiple PFAS precludes determination of dose-response for each individual PFAS.
- Multiple human health effects associated with low blood serum PFAS levels were also considered.
  - *Justify concern about exposures from drinking water.*
- Animal-to-human comparison based on internal dose (blood serum PFAS levels).
  - Blood serum level in humans is much higher than in animals from the same dose.
- Non-cancer effects:
  - Well established, adverse/progress to adverse, relevant to humans
  - ***More sensitive than those used for USEPA Health Advisories***.
- Carcinogenicity:
  - PFOA and PFOS: "Suggestive evidence"
  - PFNA: No studies of cancer effects.

PFOA: NJ, Federal & European Food Safety Authority Toxicity Factors & Drinking Water Guidelines

Agency	*Species*	*Basis*	*Toxicity Factor* (ng/kg/day)	*Drinking Water Guideline* (ng/L)*
New Jersey DEP	Animal	Delayed mammary gland development (mouse)	0.11	*(0.77)*
		Not recommended due to lack of precedent as basis for risk assessment.		
		↑ liver weight (rat): • With uncertainty factor of 10 for more sensitive effects (e.g. mammary gland)	2	14
		Cancer (rat testicular tumors)	---	14
USEPA		Developmental: Delayed bone development & earlier puberty in males (mouse)	20	70**
Draft ATSDR		Developmental: Behavioral & skeletal changes (mouse)	3	--
EFSA	Human	↑ cholesterol (also ↑ liver enzyme ALT, ↓ birth weight)	0.8	---

* **Exposure Assumptions:** NJ – default adult; USEPA – lactating woman.

** *Applies to total of PFOA & PFOS.*

PFOS: NJ, Federal & EFSA Toxicity Factors & Drinking Water Guidelines

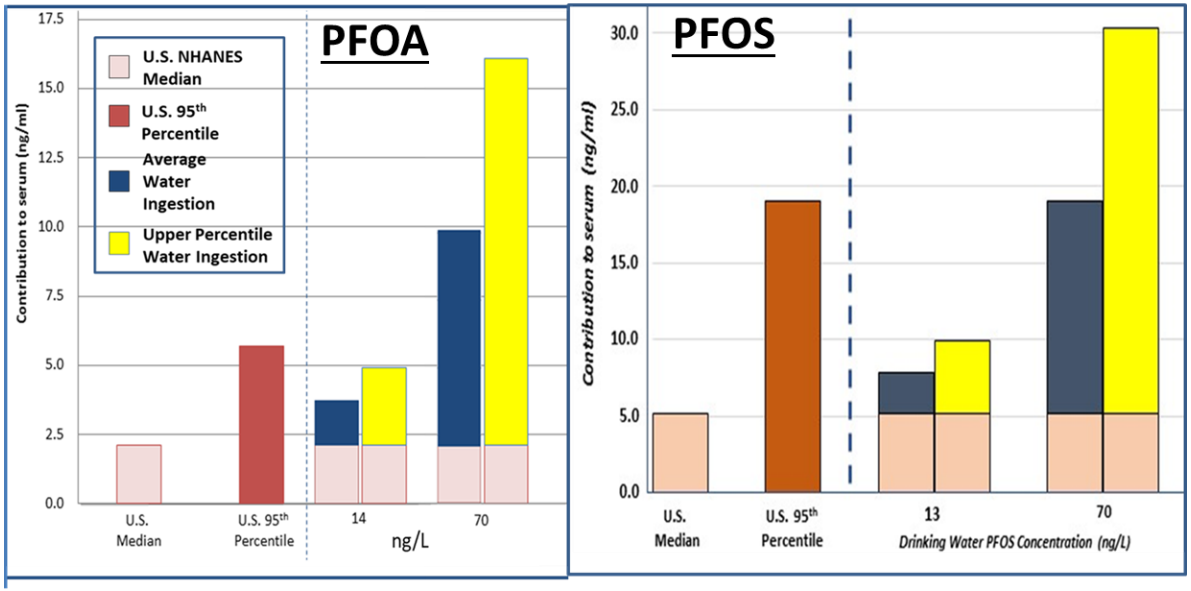
Agency	*Species*	*Basis*	*Toxicity Factor* (ng/kg/day)	*Drinking Water Guideline* (ng/L)*
NJDEP	Animal	Immune system suppression (mouse)	1.8	13
USEPA		Developmental: ↓ offspring body weight (rat)	20	70**
Draft ATSDR		↓ offspring body weight; immune system suppression	2	--
EFSA	Human	↑ cholesterol; ↓ vaccine response; ↓ birth weight	1.8	---

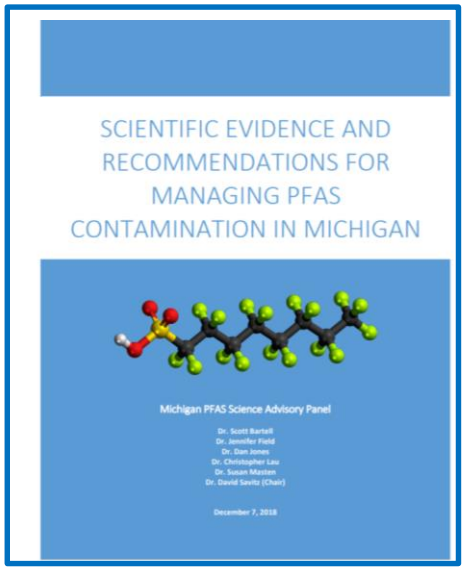
* **Exposure Assumptions:** NJ – default adult; USEPA – lactating woman.

** *Applies to total of PFOA & PFOS.*

Increases in Serum PFOA & PFOS Predicted from NJ 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."**





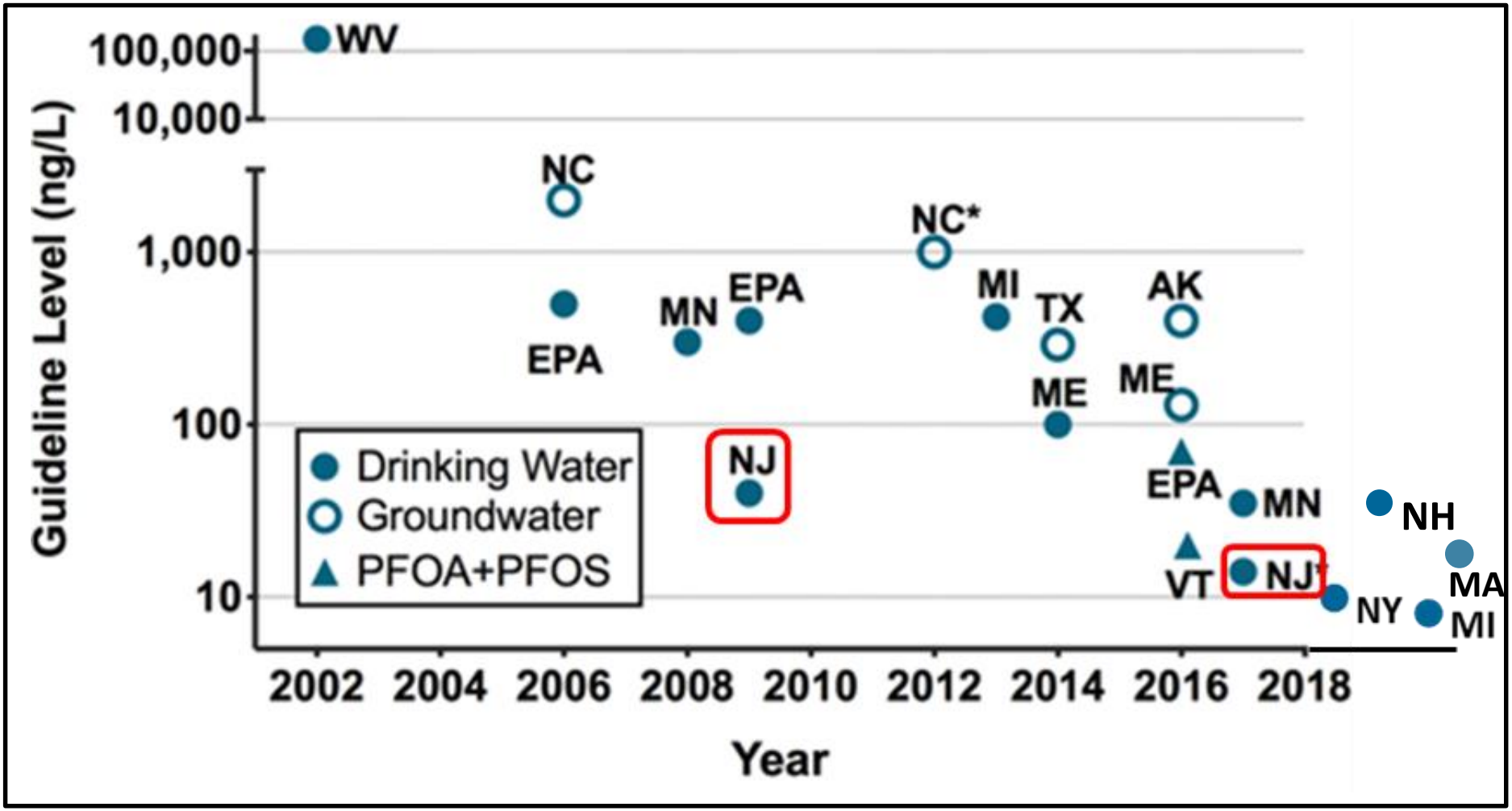
Michigan PFAS Science Advisory Panel Report (Dec. 2018) supports these New Jersey conclusions:

"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."**

New Jersey MCL for PFNA (9 Carbons)

- Found **more frequently in NJ** drinking water than nationally.
  - *In vicinity of industrial source.*
- Adverse effects are generally **similar to PFOA** but more toxic and bioaccumulative.
- Risk assessment based on **increased liver weight.**
- Much more sensitive effect - **liver damage (necrosis):**
  - *Could not be used because lacked numerical serum PFNA data needed for risk assessment. These data were requested, from study sponsors but not provided.*
  - *Uncertainty factor of 3 for more sensitive effects.*
- **Health-based MCL and MCL are 13 ng/L.**

USEPA & State PFOA Drinking Water Guidelines Over Time



(Updated from Cordner et al., 2019. Includes both **final** & **proposed/recommended** values. *Note logarithmic scale.*)

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.

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.

EXTRA SLIDES

PFOA - Delayed Mammary Gland Development as Basis for NJ RfD

- **Sensitive** – Occurs in offspring at doses/serum levels **below those that increase offspring liver weight.**
- **Well established** - 9 mouse studies; from gestational and/or lactational exposure.
  - *Only one negative study, which has problematic issues.*
  - *Differing mouse strain susceptibility consistent with toxicokinetic differences.*
- **Adverse** - Structural changes persist until adulthood.
- **Human relevance** – No reason to discount based on mode of action.
- Insufficient data to make conclusions about effects on lactational function.
  - *Evaluated in only one mouse study.*
  - *Several **human studies** associate PFOA with ↓ duration of breastfeeding.*

PFOA: Increased Liver Weight as Basis for NJ RfD

- **Well established** effect in non-human primates and rodents.
- Most **sensitive effect** with serum data needed for dose-response analysis, except mammary gland delay.
- Increased liver weight and/or hepatocellular hypertrophy **co-occurred with and/or progressed** to more severe hepatic effects:

  Example: *Chronic rat study suggests "progression of lesions… from hepatocellular hypertrophy to fatty degeneration to necrosis followed by regenerative hyperplasia" (Butenhoff et al., 2012).*

- From Hall et al. (2012) criteria (cited by USEPA):

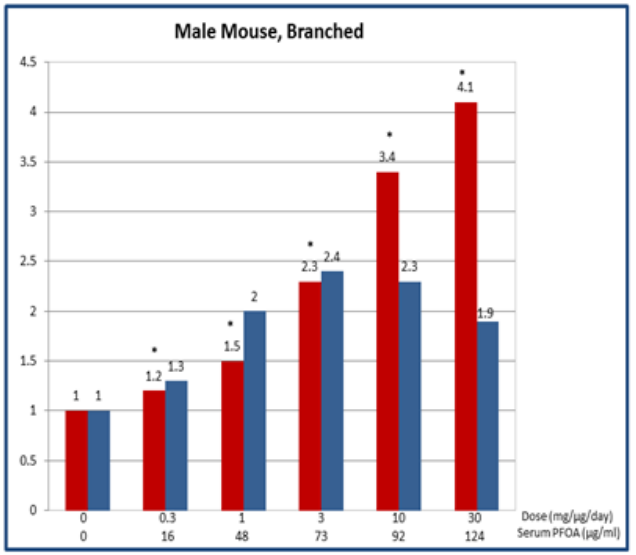
  "[Increased liver weight and hepatocellular hypertrophy] may be reversible if the anticipated duration of exposure is short, while ***progression to more severe hepatic effects*** *may occur from* ***longer exposures to the same dose****…. In this case, the* ***combination of dose level and duration of exposure****….. would now be considered* ***adverse****."*

- Reversibility is **not relevant** to chronic exposure duration of MCLs.

PFOA: Mode of Action for Hepatic Effects

- Primary issues:
  - *Human relevance of rodent effects.*
  - *Role of PPAR-α in **non-carcinogenic** hepatic effects.*
- Extensive review of data from:
  - *Non-human primates (monkeys),*
  - *Standard rodent strains.*
  - *PPAR-alpha null ("knockout") mice.*
  - *Mice with humanized PPAR-alpha.*
  - *Human tissues.*
  - *In vitro studies.*
- ***Overall conclusion:*** **Non-carcinogenic hepatic effects of PFOA are relevant to humans for the purposes of risk assessment.**

Example of Approach Used

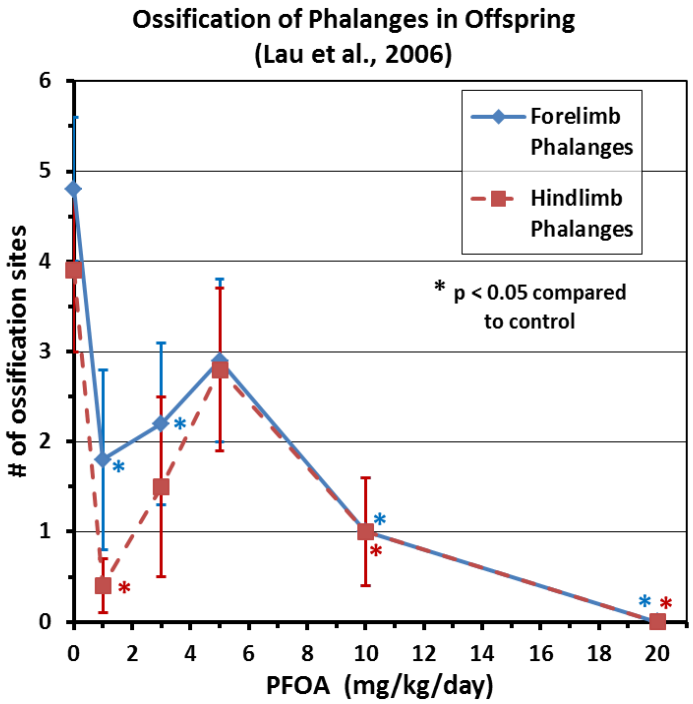


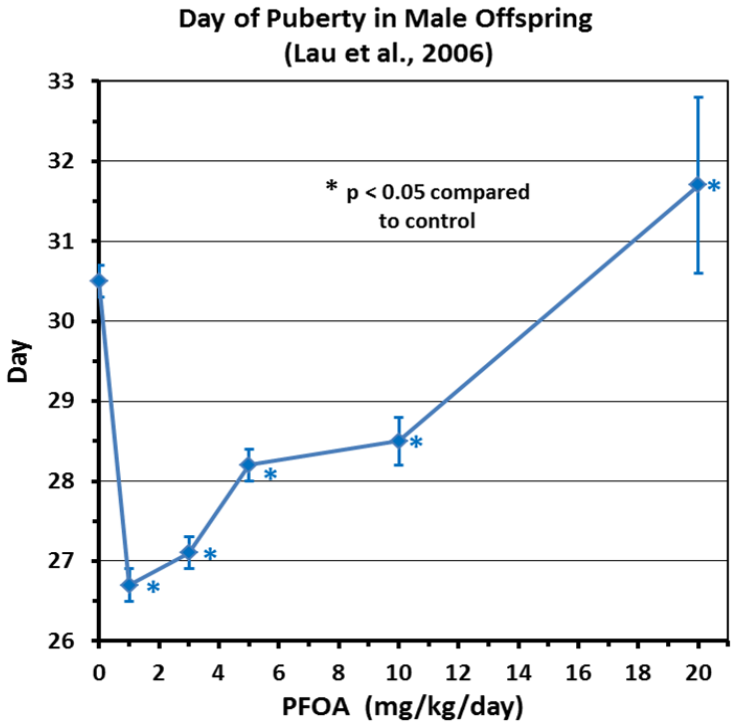
Relative Liver Weight

Relative Peroxisomal beta-oxidation

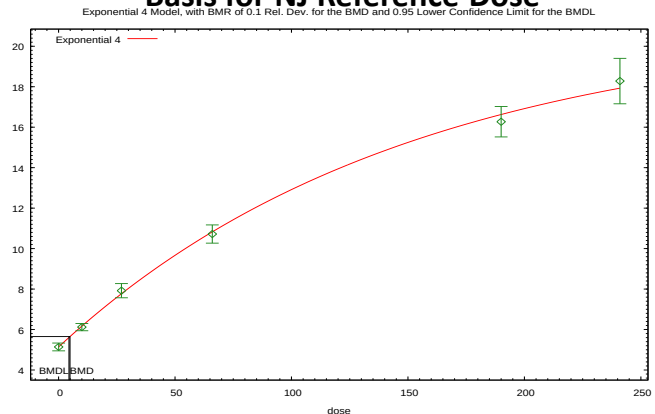
NJ DWQI, 2017

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





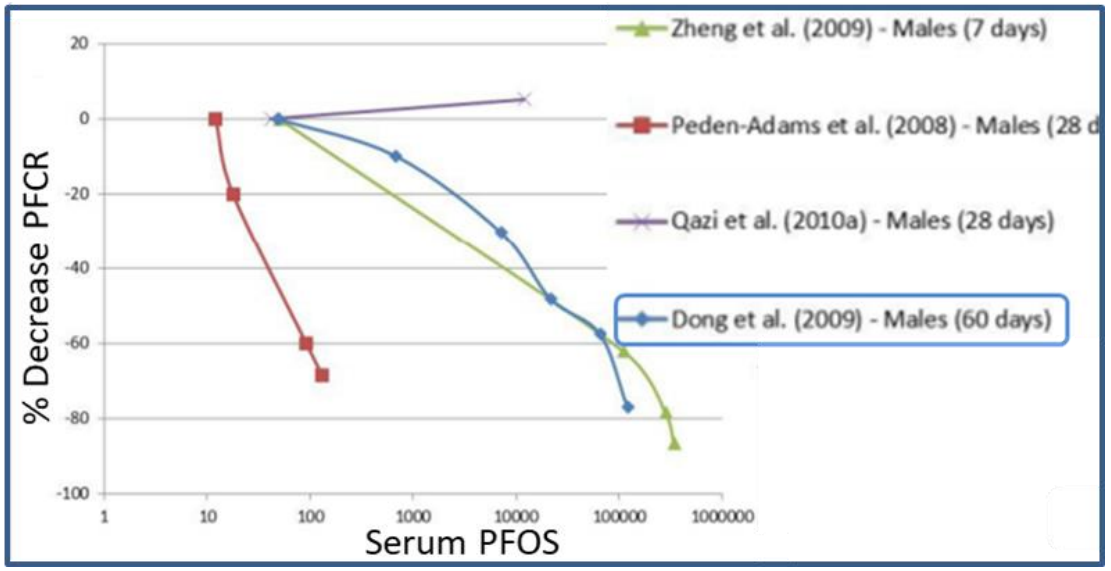
BMD Modeling for Increased Liver Weight – Basis for NJ Reference Dose



PFOS: Decreased Plaque Forming Cell Response as Basis for NJ RfD

(Pachkowski et al., Env. Research, 2019)

- NJ Reference Dose (RfD) of 1.8 ng/kg/day based on **decreased plaque forming cell response** in male mice exposed for 60 days (Dong et al., 2009).
  - Measures antibody response to foreign antigen.
  - More sensitive than ↓ rat pup weight used for USEPA RfD (20 ng/kg/day).
- **Well established** – 4 positive studies; only 1 negative study.
  - Study with lowest LOAEL was not used for RfD.
- No reason to discount human relevance.
- Supported by **human associations:**
  - Decreased **antibody response to vaccines:** analogous human effect.
  - Increased incidence of **infectious disease**.



PFOS – Support for Immune System Toxicity as Basis for RfD

- **Well-established** risk assessment endpoint**:**
  - Recent **USEPA Integrated Risk Information System (IRIS) RfDs** for other contaminants are based on ↓ **plaque forming cell response** in mice.
- **Recent PFOS evaluations:**
  - **National Toxicology Program (2016) systematic review:** Presumed human immune hazard.
    - *High level of evidence for **suppressed antibody response in animals**.*
    - *Moderate level of evidence from human studies.*
  - **Minnesota Department of Health (2019) Reference Dose:**
    - *Primary based of RfD is immunotoxicity in mice.*
  - **Draft Agency for Toxic Substances & Disease Registry (2018) Intermediate Minimum Risk Level (MRL) - 2 ng/kg/day**:
    - *Immunotoxicity - most sensitive endpoint.*
    - *Not used as basis because no toxicokinetic model for time weighted average serum PFOS concentrations in relevant mouse strains.*
    - *MRL based on ↓ rat pup weight includes UF of 10 for immunotoxicity.*
  - **Peer reviewed publications** (Lilienthal et al., 2017; Dong et al., 2017):
    - *Immunotoxicity more sensitive than developmental effects.*