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

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Northeastern University
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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 (> 20 ng/L) in NJ much more often than nationally.

<table>
<thead>
<tr>
<th></th>
<th>New Jersey</th>
<th>U.S. (other than NJ)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PFOA</strong></td>
<td>10.9% (at sites throughout NJ)</td>
<td>2.1%</td>
</tr>
<tr>
<td><strong>PFNA</strong></td>
<td>2.3% (near industrial source)</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

- **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

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

Gloria B. Post, Judith B. Louis, Keith R. Cooper, Betty Jane Bobos-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 Biotechnology 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 420, Trenton, New Jersey 08625

The U.S. population is at greatest risk when consuming drinking water containing PFOA. The U.S. Department of Health and Human Services (DHHS) has a half-life of 10 years and adverse effects on the immune system (S). In some studies, population levels were in the other measures of I not find these effects in other studies or measures. However, the effectiveness was not found. The authors suggest that PFOA is not associated with sputum and there were negative (S), 70,000 people exposed association with sputum. Blood, including a source of exposure, is house dust. Exposure also occurs transformation of

**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

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

Nicholas A. Procopio, Robert Kart, Sandra M. Goodrow, Joseph Maggio, Judith B. Louis, Thomas A. Atherhold

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

Brian Pachkowski, Gloria B. Post, Alan H. Stern
Bureau for Risk Analysis, Division of Science, Research and Environmental Health, New Jersey Department of Environmental Protection, Trenton, NJ, USA

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

Gloria B. Post, Perry D. Cohn, Keith R. Cooper

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

†Consumer Environmental, and Occupational Health Service, New Jersey Department of Health and Senior Services, P.O. Box 309, Trenton, NJ 08625, USA

‡Department of Microbiology and Molecular Biology, Rutgers University, 76 Lipman Drive, New Brunswick, NJ 08901, USA

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

Jessie A. Gleason, Gloria B. Post, Jerald A. Fagiliano

*Office of Science, New Jersey Department of Environmental Protection, 428 East State Street, Trenton, NJ 08625, USA

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

Gloria B. Post, Jessie A. Gleason, Keith R. Cooper

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
Current Status of NJDEP PFAS Regulations

PFNA:
• 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.
Seven states, including Pennsylvania and New Jersey, are at different stages of a multyear 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.

<table>
<thead>
<tr>
<th>State</th>
<th>Process Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pennsylvania</td>
<td>Proposed a standard</td>
</tr>
<tr>
<td>Vermont</td>
<td>Proposed a standard</td>
</tr>
<tr>
<td>Michigan</td>
<td>Proposed a standard</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Proposed a standard</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>Final standard</td>
</tr>
<tr>
<td>New York</td>
<td>Final standard</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Final standard</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Final standard</td>
</tr>
</tbody>
</table>

*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
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.

<table>
<thead>
<tr>
<th>(Units: ng/L)</th>
<th>Health-based MCL</th>
<th>Analytical PQL</th>
<th>Treatment Removal</th>
<th>Recommended MCL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PFOA</strong></td>
<td>14</td>
<td>6</td>
<td>Not limiting</td>
<td>14</td>
</tr>
<tr>
<td><strong>PFOS</strong></td>
<td>13</td>
<td>4.2</td>
<td>Not limiting</td>
<td>13</td>
</tr>
<tr>
<td><strong>PFNA</strong></td>
<td>13</td>
<td>5</td>
<td>Not limiting</td>
<td>13</td>
</tr>
</tbody>
</table>
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**

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

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

** Applies to total of PFOA & PFOS.
# PFOS: NJ, Federal & EFSA Toxicity Factors & Drinking Water Guidelines

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


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

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

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

• **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

• **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).
NJDEP PFAS Publications


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

Ossification of Phalanges in Offspring (Lau et al., 2006)

- Forelimb Phalanges
- Hindlimb Phalanges

* p < 0.05 compared to control

Day of Puberty in Male Offspring (Lau et al., 2006)

* p < 0.05 compared to control

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

Exponential 4 Model used for BMD and BMDL. The Equations and Equations for the BMDL.
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.