NEW HAMPSHIRE DEPARTMENT OF Environmental Services

Summary of the Technical Background Report for the Proposed Maximum Contaminant Levels and Ambient Groundwater Quality Standards for PFOA, PFOS, PFNA and PFHxS.

Stakeholder Meeting
07/09/2019

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Presentation Overview

1. Health-Based Risk Assessment Process

2. Chemical-Specific Reference Doses for:
   PFOA PFOS
   PFNA PFHxS

3. Exposure Assumptions
   Use of the “Minnesota” Model
   Relative Source Contribution

4. Modeled Exposures & Proposed MCLs

5. Questions

image: medium.com

Acknowledgements

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- **residents and community stakeholders,**
- **academic institutions,**
- **community advocacy groups,**
- **representatives for the business community,**
- **and municipalities.**

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- **Connecticut Department of Public Health (CTDPH)**
- **Environmental Council of the States (ECOS) PFAS Caucus**
- **Federal-State Toxicology & Risk Analysis Committee (FSTRAC)**
- **Interstate Technology & Regulatory Council (ITRC) PFAS Working Group**
- **Massachusetts Department of Environmental Protection (MADEP)**
- **Michigan Department of Health & Human Services (MIDHHS)**
- **Minnesota Department of Health (MDH)**
- **New England Interstate Water Pollution Control Commission (NEIWPCC)**
- **New Jersey Department of Environmental Protection (NJDEP)**
- **Northeast Waste Management Officials' Association (NEWMOA)**

Health-Based Risk Assessment Process

1. **Identify the chemicals of concern**:

Perfluorooctanoic acid (PFOA)	Perfluorooctane sulfonic acid (PFOS)
Perfluorononanoic acid (PFNA)	Perfluorohexane sulfonic acid (PFHxS)

2. Identify sensitive and human-relevant health effects due to exposure to the chemical, and **derive a reference dose (RfD)** for the effects.
   - Is the chemical a carcinogen?
   - Are non-cancer health effects more protective than cancer endpoints?
   - Do epidemiological studies provide clear evidence?
   - Are there appropriate animal models for quantifying toxicity?

3. **Characterize an exposure scenario** using protective assumptions to determine an environmental concentration (*i.e.*, drinking water level) that will not exceed the RfD.

Health-Based Risk Assessment Process

Per the CDC's **Agency for Toxic Substances and Disease Registry** (ATSDR) draft toxicity profile on PFAS (ATSDR, 2018), suspected health outcomes include:

Rodent Experiments

- Immune system modulation
- Altered lipid metabolism
- Liver stress and inflammation
- Altered liver enzyme levels
- Thyroid disruption
- Reduced birth weight
- Fetal skeletal defects
- Fetal loss (death)
- Neurobehavioral defects
- Delayed mammary gland development
- Liver, testicular & kidney cancer

?

Human Epidemiology

Possible effects based on associations:

- Immune system modulation
- Altered lipid metabolism
- Altered liver enzyme levels
- Altered thyroid hormone levels
- Altered behavior in infants, children & adolescents
- Infertility in women
- Reduced birth weight
- Potentially testicular & kidney cancer

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Health-Based Risk Assessment Process

Proposed MCLs based on non-cancer endpoints

Specific PFAS	NHDES Revised MCLs	Animal Health Outcome
PFOA	12 ng/L	Liver toxicity & altered lipid metabolism
PFOS	15 ng/L	Suppressed immune response to vaccines
PFHxS	18 ng/L	Reduced female fertility
PFNA	11 ng/L	Liver toxicity & altered lipid metabolism

Chemical-Specific Reference Doses

A **reference dose (RfD)** is:
"An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." – EPA 2002

RfDs are not synonymous to ATSDR minimal risk levels (MRLs).

Measured internal dose from animal study

Estimated an external (oral) dose

Used for the calculation of a drinking water or other environmental standard

$$\frac{\textbf{Animal Serum (ng/mL)}}{\textbf{Total Uncertainty}} \times \textbf{Dosimetric Adjustment Factor (mL/kg–d)} = \textbf{Reference Dose (ng/kg–d)}$$

Accounts for animal-to-human differences and quality of studies

Chemical-Specific Reference Doses

Animal studies selected for RfDs in the Initial (January) MCL proposal.

Specific PFAS	Animal Study Health Effect	Notes & Corresponding Animal Serum Concentration
Perfluorooctanoic acid (PFOA)	Increased relative liver weight	Male mouse study Duration: 14 days 4,351 ng/mL $BMDL_{10}$; Loveless et al. 2006, NJDWQI 2017
Perfluorooctane sulfonic acid (PFOS)	Delayed pup growth & development	Reproductive & transgenerational rat study Duration: 2 generations 6,260 ng/mL Modeled; Luebker 2005ab, EPA 2016
Perfluorohexane sulfonic acid (PFHxS)	Reduced litter size	Reproductive & developmental CD-1 mouse study Duration: 14 days prior to & through gestation 27,200 ng/mL NOAEL; Chang et al. 2018
Perfluorononanoic acid (PFNA)	Increased relative liver weight	Reproductive & developmental CD-1 mouse study Duration: through gestation, 17 days 4,900 ng/mL $BMDL_{10}$; Das et al. 2015, NJDWQI 2018

Perfluorooctanoic acid (PFOA) RfD Derivation

Animal Starting Point (Internal Dose and Effect)

Animal Serum Level
(Benchmark Model, NJDWQI calculation)

Increased relative liver weight, or the onset of hepatotoxicity — 4,351 ng/mL

Uncertainty Factors

Human-to-Human Variation	10
Rodent versus Human Sensitivity (assumes humans are more sensitive than mice)	$10^{0.5}$
Database Uncertainty (suspected growth & immune effects)	$\times 10^{0.5}$
Total Uncertainty Factor	100

Internal Target Serum Level →

4,351 ng/mL
÷ 100
43.5 ng/mL

Estimation of Human External Dose

Dosimetric Adjustment Factor (DAF)

Converts the internal blood dose (above) to an external (oral) dose of the chemical.

$$DAF = Vd \times \left(\frac{Ln2}{Halflife\ (days)}\right)$$

$$DAF = 0.17\ L/kg \times \left(\frac{Ln2}{\mathbf{840\ days}}\right) = 1.40 \times 10^{-4}\ L/kg\text{-}d$$

Assumed a **2.3 year half-life**

43.5 ng/mL
1.40×10^{-4} L/kg-d
× 1,000 mL/L
6.1 ng/kg-d

PFOA RfD, 6.1 ng/kg-d

Perfluorooctane sulfonic acid (PFOS) RfD Derivation

Animal Starting Point (Internal Dose and Effect)

Animal Serum Level
(No Observed Adverse Effect Level, Agreed with MDH 2019 Assessment)

Decreased immunoglobulin production, Or reduced vaccine response — 2,360 ng/mL

Uncertainty Factors

Human-to-Human Variation	10
Rodent versus Human Sensitivity (assumes humans are more sensitive than mice)	$10^{0.5}$
Database Uncertainty (suspected growth & fetal thyroid effects)	$\times 10^{0.5}$
Total Uncertainty Factor	100

Internal Target Serum Level →

2,360 ng/mL
÷ 100
23.6 ng/mL

Estimation of Human External Dose

Dosimetric Adjustment Factor (DAF)

Converts the internal blood dose (above) to an external (oral) dose of the chemical.

$$DAF = Vd \times \left(\frac{Ln2}{Halflife\ (days)}\right)$$

$$DAF = 0.23\ L/kg \times \left(\frac{Ln2}{1{,}241\ days}\right) = 1.28 \times 10^{-4}\ L/kg\text{-}d$$

Assumed a 3.4 year half-life

23.6 ng/mL
1.28×10^{-4} L/kg-d
× 1,000 mL/L
3.0 ng/kg-d

PFOS RfD, 3.0 ng/kg-d

Perfluorononanoic acid (PFNA) RfD Derivation

Animal Starting Point (Internal Dose and Effect)

Animal Serum Level
(Benchmark Model, NJDWQI calculation)

Increased relative liver weight, or the onset of hepatotoxicity — 4,900 ng/mL

Uncertainty Factors

Human-to-Human Variation	10
Rodent versus Human Sensitivity (assumes humans are more sensitive than mice)	$10^{0.5}$
Database Uncertainty (lack of multigenerational studies)	$\times 10^{0.5}$
Total Uncertainty Factor	100

4,900 ng/mL
÷ 100
49.0 ng/mL

Internal Target Serum Level →

Estimation of Human External Dose

Dosimetric Adjustment Factor (DAF)

Converts the internal blood dose (above) to an external (oral) dose of the chemical.

$$DAF = Vd \times \left(\frac{Ln2}{Halflife\ (days)}\right)$$

$$DAF = 0.20\ L/kg \times \left(\frac{Ln2}{\mathbf{1{,}570\ days}}\right) = 8.83 \times 10^{-5}\ L/kg\text{-}d$$

Assumed a **4.3 year half-life**

49.0 ng/mL
8.83×10^{-5} L/kg-d
× 1,000 mL/L
4.3 ng/kg-d

PFNA RfD, 4.3 ng/kg-d

Perfluorohexane sulfonic acid (PFHxS) RfD Derivation

Animal Starting Point (Internal Dose and Effect)

Animal Serum Level
(Benchmark Model, *under peer-review*)

Reduced litter size in female mice, 13,900 ng/mL

Uncertainty Factors

Human-to-Human Variation	10
Rodent versus Human Sensitivity (assumes humans are more sensitive than mice)	$10^{0.5}$
Duration of Exposure (14-day effect)	$10^{0.5}$
Database Uncertainty (lack of studies, fetal thyroid effects)	$\times 10^{0.5}$
Total Uncertainty Factor	300

Internal Target Serum Level →

13,900 ng/mL
÷ 300
46.3 ng/mL

Estimation of Human External Dose

Dosimetric Adjustment Factor (DAF)

Converts the internal blood dose (above) to an external (oral) dose of the chemical.

$$DAF = Vd \times \left(\frac{Ln2}{Halflife\ (days)}\right)$$

$$DAF = 0.213\ L/kg \times \left(\frac{Ln2}{\mathbf{1{,}716\ days}}\right) = 8.61 \times 10^{-5}\ L/kg\text{-}d$$

Assumed a **4.7 year half-life**

46.3 ng/mL
8.61×10^{-5} L/kg-d
× 1,000 mL/L
4.0 ng/kg-d

PFHxS RfD, 4.0 ng/kg-d

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Comparison of Reference Doses

RfDs for the four evaluated PFAS in comparison to values from other agencies.
All values below are presented in **ng/kg-d**

Specific PFAS	NHDES (01/2019) (RfD)	NHDES (06/2019) (RfD)	US EPA 2016 (RfD)	ATSDR 2018 (MRL)	EFSA 2019 (RfD)
PFOA	5.2	**6.1**	20	3.0	0.8
PFOS	8.0	**3.0**	20	2.0	1.8
PFHxS	9.3	**4.0**	-	20	-
PFNA	2.5	**4.3**	-	3.0	-

USEPA. 2016. Drinking Water Advisory for Perfluoroctanoic acid (PFOA).
USEPA. 2016. Drinking Water Advisory for Perfluorooctane sulfonic acid (PFOS).
ASTDR. 2018. Toxicological Profile for Perfluoroalkyls Draft for Public Comment. https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237
EFSA.

Exposure Assumptions

Exposure characterization considers how much PFAS is permissible given:

1. Protective assumptions about drinking water ingestion rates
2. Estimation of other non-drinking water sources of exposure.

The U.S. EPA (2016) assumed the drinking water ingestion rate of the 90th percentile of lactating women, and that 20% of exposure is permissible through drinking water (PFOA & PFOS at 70 ng/L).

These assumptions vary by state agencies, sometimes resulting in different drinking water values despite similar RfDs.

image: medium.com

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Exposure Assumptions: Initial Proposal (January 4th, 2019)

$$\frac{\text{RfD (ng/kg–day)} \times \text{Relative Source Contribution (\%)}}{\text{Water Ingestion Rate (L/kg–day)}} = \text{Maximum Contaminant Level (ng/L)}$$

Specific PFAS	Reference Dose (ng/kg-day)	Water Ingestion Rate (L/kg-day)	Relative Source Contribution	Proposed MCL (ng/L)
PFOA	These values changed in response to technical comments	These values changed in the EPA Exposure Factor Handbook (Feb 2019)	These values changed in response to technical comments	38
PFOS				70
PFHxS				85
PFNA				23

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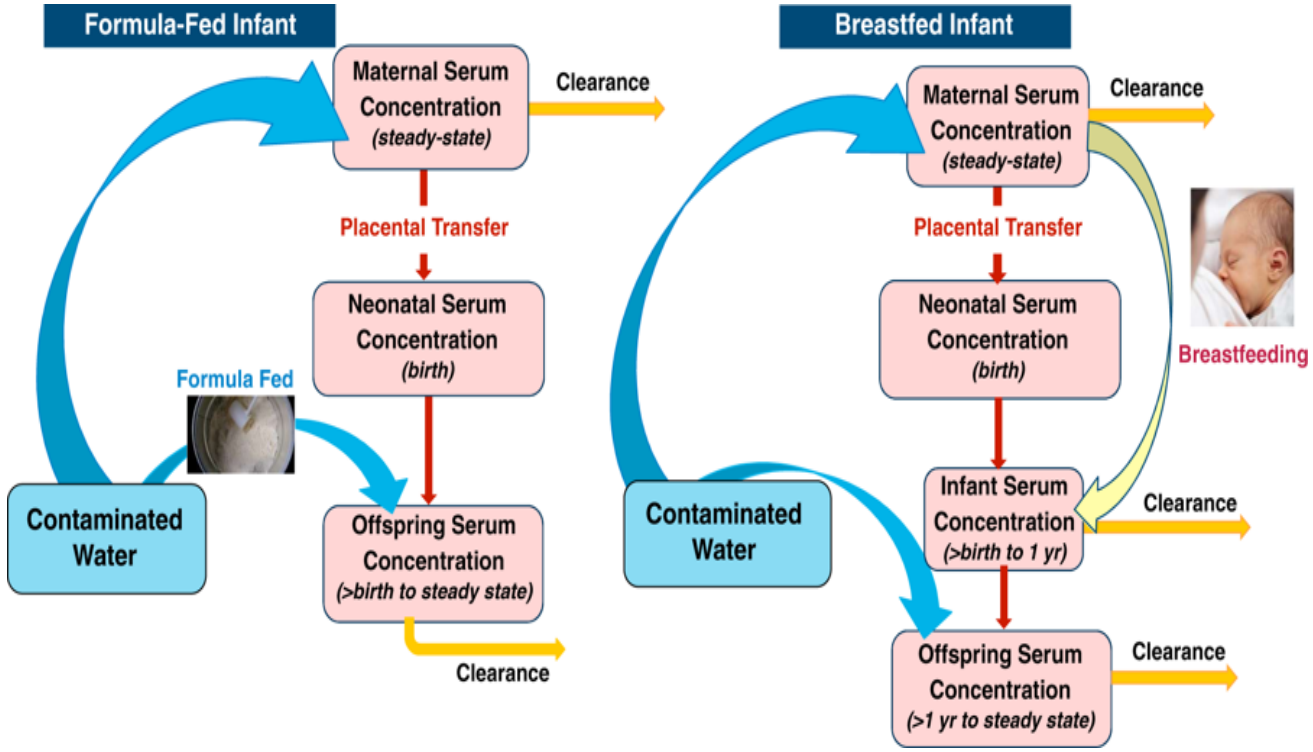
Exposure Assumptions: Example using June 2019 proposal

$$\frac{\text{RfD (ng/kg–day)} \times \text{Relative Source Contribution (\%)}}{\text{Water Ingestion Rate (L/kg–day)}} = \text{Maximum Contaminant Level (ng/L)}$$

Specific PFAS	Reference Dose (ng/kg-day)	Water Ingestion Rate (L/kg-day)	Relative Source Contribution	*Example* Drinking Water Value (ng/L)
PFOA	6.1	These values do not account for the transfer of PFAS across the placenta and into breastmilk.	50%	These values would result in unacceptable serum levels in breastfed infants.
PFOS	3.0		50%	
PFHxS	4.0		50%	
PFNA	4.3		50%	

Exposure Assumptions: Minnesota Model

What is the Transgenerational (or Minnesota) Model?



The conceptual diagram for the toxicokinetic model.
Image from: Goeden et al. (2019), *Journal of Exposure Science & Environmental Epidemiology* vol. 29, 183–195.

Excel-based model is available upon request from Minnesota Department of Health.

Human Half-life Assumptions

- NHDES applied **average** (**central tendency**) half-life estimates for PFOA (2.3 years), PFOS (3.4 years), PFNA (4.3 years) and PFHxS (4.7 years).
- NHDES did not apply the 95th percentile, or other high-end values derived from occupational exposures.

Placental & breastmilk transfer efficiencies

- NHDES applied **average** (**central tendency**) transfer efficiencies, similar to MDH and MIDHHS.

Duration of *exclusive* breastfeeding

- NHDES applied a **conservative** **12-month exclusive breastfeeding duration** for the modeled exposure scenarios.

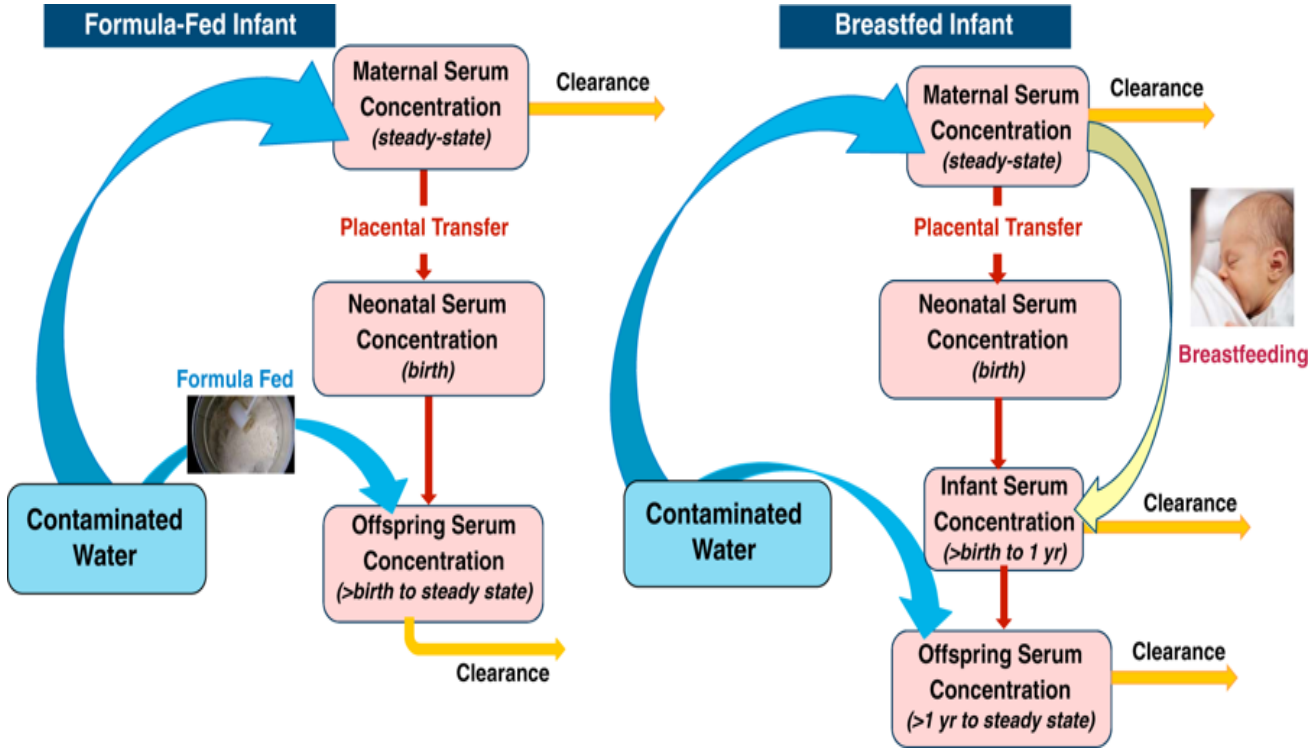
Breastmilk & water ingestion rates

- NHDES applied the **95th percentile** (**conservative**) ingestion rates for water and breastmilk across life.

Values are summarized in Table 3 of the June Report.

Exposure Assumptions: Minnesota Model

What is the Transgenerational (or Minnesota) Model?



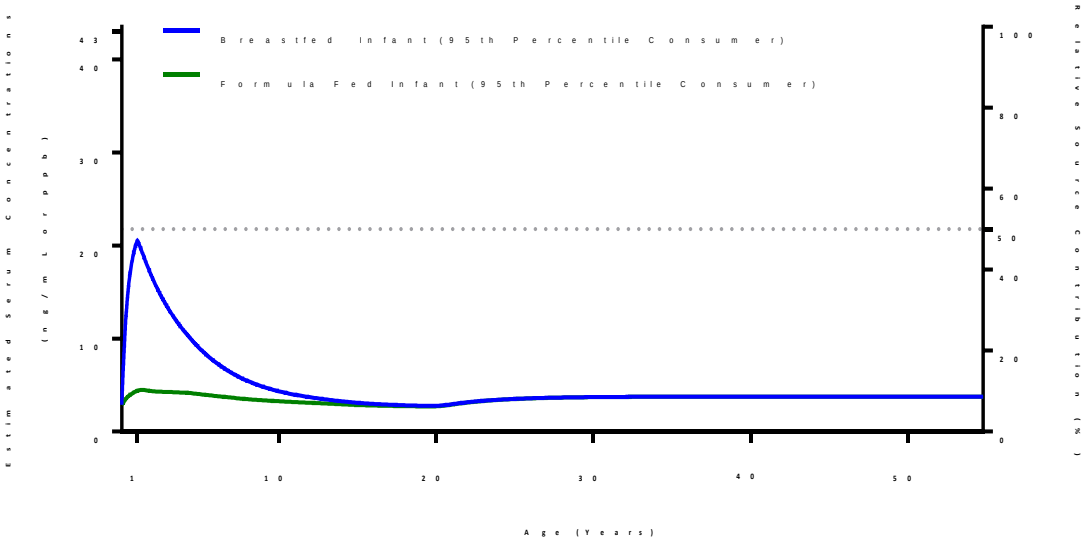
The conceptual diagram for the toxicokinetic model.
Image from: Goeden et al. (2019), *Journal of Exposure Science & Environmental Epidemiology* vol. 29, 183–195.

Excel-based model is available upon request from Minnesota Department of Health.

The model allows for the comparison of:

- **predicted blood levels (left y-axis) to**
- **the % of allowable maximum dose (right y-axis).**

Example model output for a PFOA MCL of 12 ng/L using NHDES's risk assessment assumptions.

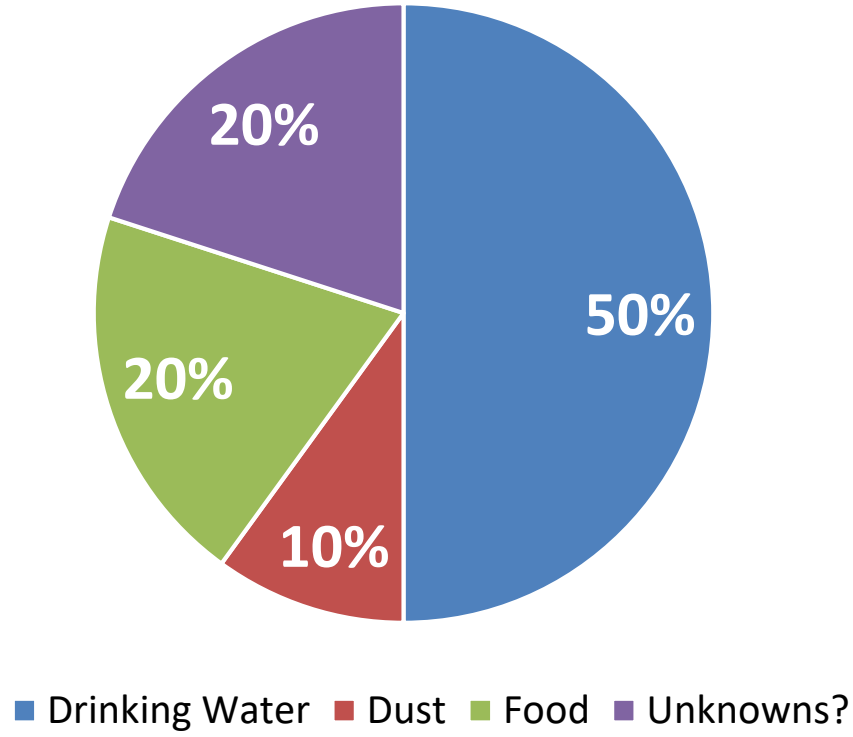


Exposure Assumptions: Relative Source Contribution

This is **how we "budget" the daily dose (RfD)** for water versus non-drinking water sources of exposure.

- **20%** - Low and the default EPA recommendation when "we don't know". Results in the most restrictive MCL.
- **50%** - Consistent with values derived from NHANES to estimate background
- **80%** -Results in a higher MCL value and assumes that other sources are not contributing to exposure (20% or less).

Relative Source Contribution
(example below for visualization purposes)



Exposure Assumptions: Relative Source Contribution

20%

U.S. EPA (2016)
- **20% RSC for PFOA & PFOS** for the lifetime health advisory of 70 ng/L, based on RfDs of 20 ng/kg-d.

Vermont - VTDOH (2016-2017)
- **20% RSC across all** for health-based screening values (HBSVs).

New Jersey - NJDWQI (2017-2018)
- **20% RSC for PFOA & PFOS** because of insufficient serum data (proposed MCL).
- **50% RSC for PFNA** because of sufficient serum data from NHANES and a NJ community (MCL).

New York - NYDWQC (2018)
- **≤60% RSC for PFOA & PFOS** recommendation based on serum data (proposed MCL).

Minnesota - MDH (2017-2019)
- **50% RSC for PFOA, PFOS & PFHxS** in their model for (HBSVs).

50-60%

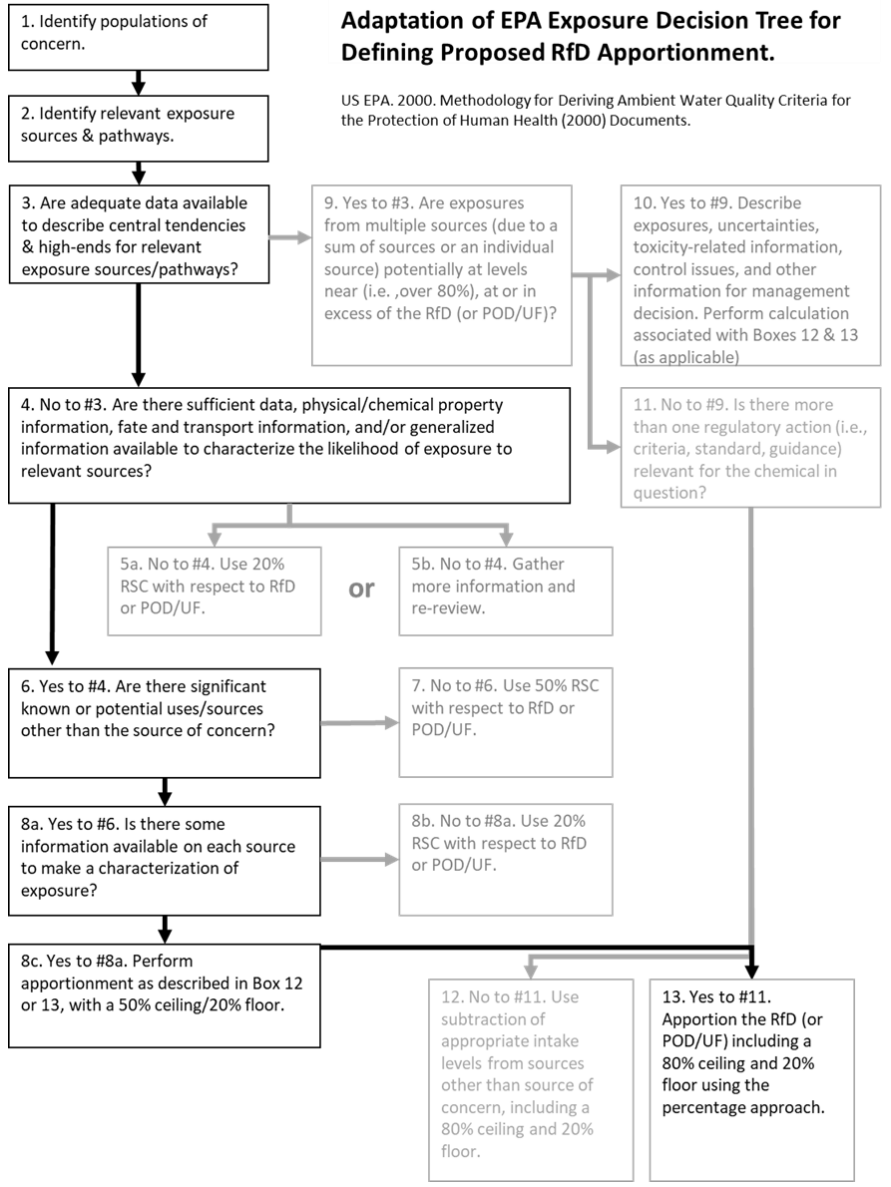
Michigan - MIDHHS (2019)
- **50% RSC for PFOA, PFOS, PFNA & PFHxS** in MDH's transgenerational model (HBSVs).

How did the NHDES MCLs arrive at a 50% RSC?

Exposure Assumptions: Relative Source Contribution

NHDES referred to the EPA Decision Tree for determining the relative source contribution.

Arrived at a **50% ceiling** combined with apportionment (**subtraction method**) to derive chemical specific RSCs.



US EPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000) Documents.

Accessed online at: https://www.epa.gov/wqc/methodology-deriving-ambient-water-quality-criteria-protection-human-health-2000-documents

Exposure Assumptions: Relative Source Contribution

In the initial proposal, NHDES estimated "background" using existing blood data. However, this value should reflect the typical non-drinking water exposures.

Used the EPA subtraction method:

$$\frac{\text{Target serum level (ng/mL)} - \text{Population background (ng/mL)}}{\text{Target serum level (ng/mL)}} = \text{RSC}$$

Using the NHANES (average) for PFOA:

$$\frac{43.5\ \text{ng/L} - 1.8\ \text{ng/L}}{43.5\ \text{ng/L}} = 0.96 \text{ or } 96\%$$

Using Adults from Southern NH (95th percentile) for PFOA:

$$\frac{43.5\ \text{ng/L} - 26.6\ \text{ng/L}}{43.5\ \text{ng/L}} = 0.39 \text{ or } 39\%$$

The use of the *NH-specific data likely overestimates* the background (non-drinking water) exposure.

But, the current lack of regulations on PFAS means an 80% RSC, especially for adults, is inadequately protective.

US EPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000) Documents.
Accessed online at: https://www.epa.gov/wqc/methodology-deriving-ambient-water-quality-criteria-protection-human-health-2000-documents

Exposure Assumptions: Relative Source Contribution

Estimation of RSC by Subtraction Method Using NH-specific data

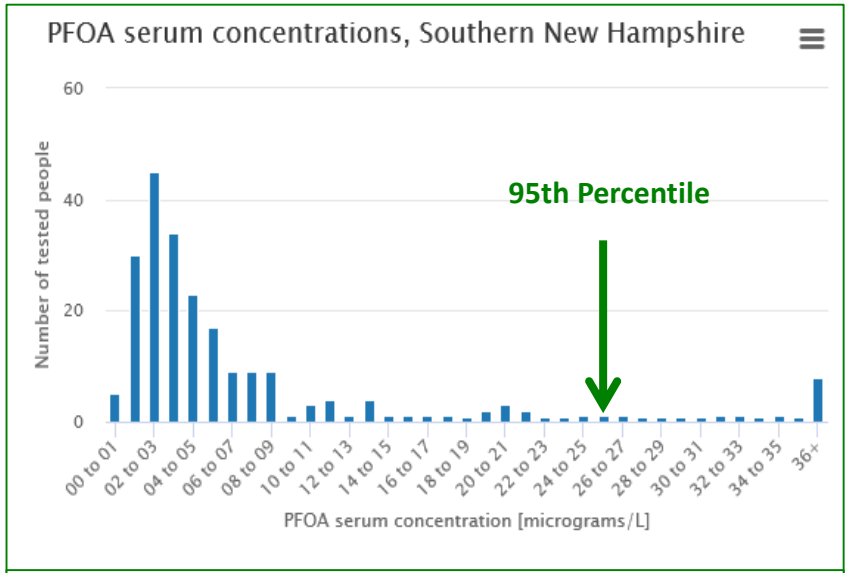
Subtraction method applied to all 4 PFAS using blood data collected by NH Dept. Health & Human Services from highest exposed populations.

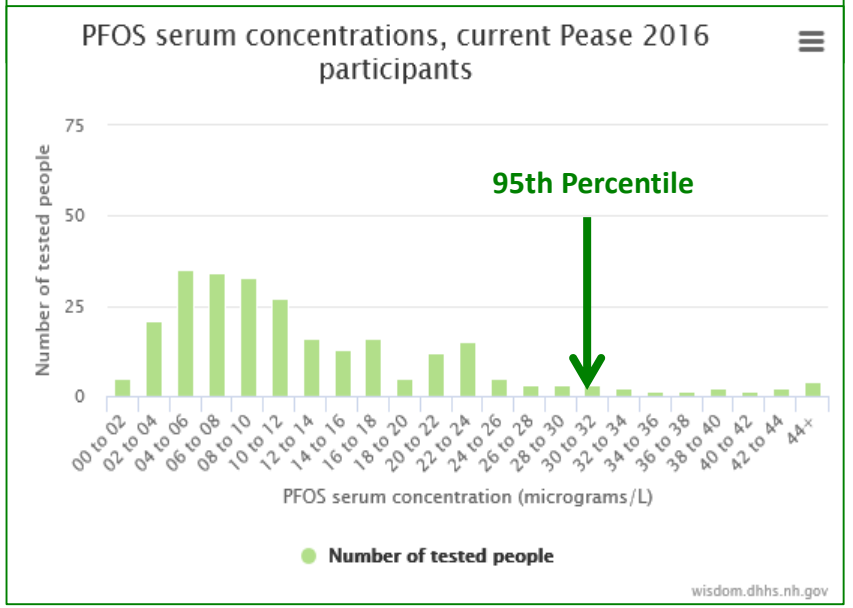
Used NH-specific PFAS blood concentrations:

	Geometric mean	95th Percentile
PFOA*	4.40 ng/mL	**26.6 ng/mL**
PFOS**	10.2 ng/mL	**31.7 ng/mL**
PFHxS**	4.50 ng/mL	**26.0 ng/mL**
PFNA	0.66 ng/mL	**1.70 ng/mL**

* **PFOA** concentrations from exposed population in Merrimack (217 participants) & Southern NH (219 participants).

** **PFOS** & **PFHxS** concentrations from exposed population in Pease, NH (256 participants).





NH Wisdom Portal, Per- and Polyfluoroalkyl Substances (PFAS) Blood Testing and Community Exposure: https://wisdom.dhhs.nh.gov/wisdom/#TopicGroup_8203D9F1281247419C5C417B8E591CE7

Exposure Assumptions: Relative Source Contribution

Estimation of RSC Using NHANES data

RSC estimates using the NHANES 2013-2014 dataset (summarized by Daly et al. 2018):

- **geometric mean (GM) and**
- **95th percentile.**

NHANES data more likely to reflect background exposure levels from non-drinking water sources.

Reference Population	Reference Serum level (ng/mL)	Target Serum Level (ng/mL)	Resulting RSC Allotment for Drinking Water (%)
PFOA			
3-5 year olds (GM)	2.00	43.5	**95.4**
6-11 year olds (GM)	1.89	43.5	**95.7**
12-19 year olds (GM)	1.66	43.5	**96.2**
3-5 year olds (95th percentile)	5.58	43.5	**87.2**
6-11 year olds (95th percentile)	3.84	43.5	**91.2**
12-19 year olds (95th percentile)	3.47	43.5	**92.0**
PFOS			
3-5 year olds (GM)	3.38	24.0	**85.9**
6-11 year olds (GM)	4.15	24.0	**82.7**
12-19 year olds (GM)	3.54	24.0	**85.3**
3-5 year olds (95th percentile)	8.82	24.0	**63.3**
6-11 year olds (95th percentile)	12.40	24.0	**48.3**
12-19 year olds (95th percentile)	9.30	24.0	**61.3**
PFNA			
3-5 year olds (GM)	0.76	49.0	**98.4**
6-11 year olds (GM)	0.81	49.0	**98.3**
12-19 year olds (GM)	0.60	49.0	**98.8**
3-5 year olds (95th percentile)	3.49	49.0	**92.9**
6-11 year olds (95th percentile)	3.19	49.0	**93.5**
12-19 year olds (95th percentile)	2.00	49.0	**95.9**
PFHxS			
3-5 year olds (GM)	0.72	46.3	**98.4**
6-11 year olds (GM)	0.91	46.3	**98.0**
12-19 year olds (GM)	1.27	46.3	**97.3**
3-5 year olds (95th percentile)	1.62	46.3	**96.5**
6-11 year olds (95th percentile)	4.14	46.3	**91.1**
12-19 year olds (95th percentile)	6.30	46.3	**86.4**

Modeled Exposures & Proposed MCLs

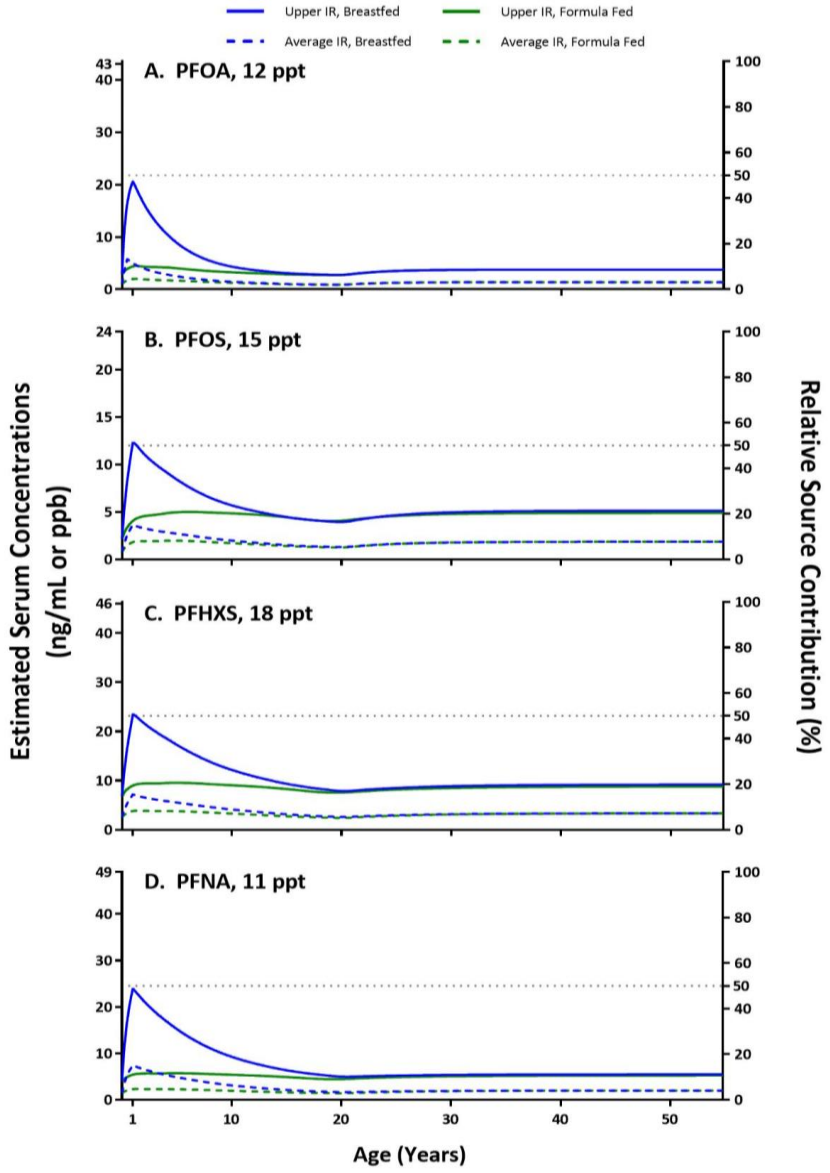
Given these **reference doses** and **exposure assumptions**, the proposed MCLs/AGQS are:

PFOA	**12 ng/L**
PFOS	**15 ng/L**
PFHxS	**18 ng/L**
PFNA	**11 ng/L**

Because of the unique properties of PFAS, accounting for breastmilk transfer is necessary.

The 50% RSC (upper limit) protects children from additional exposures to from other non-drinking water sources of PFAS.

Thus, these proposed MCLs are protective across all life stages for associated chronic health outcomes.



Modeled Exposures & Proposed MCLs

Where was NHDES conservative in its health-based risk assessment?

Central Tendency Assumptions	Conservative (High-End) Assumptions
1. Application of Uncertainty Factors (see page 23 of the June Technical Report)	1. Accounting for breastmilk & placental transfer in a drinking water standard (MDH model)
2. Human half-life estimates (average values)	2. 95th percentile water consumptions rates, *throughout life*
3. Placental & breastmilk transfer estimates (average values)	3. Assumed 12-month exclusive breastfeeding period
4. Individual MCLs specific to each compound instead of a class-based MCL.	4. Assuming 100% absorption in GI tract
5. Relative Source Contribution cap of 50%*	5. Relative Source Contribution cap of 50%*

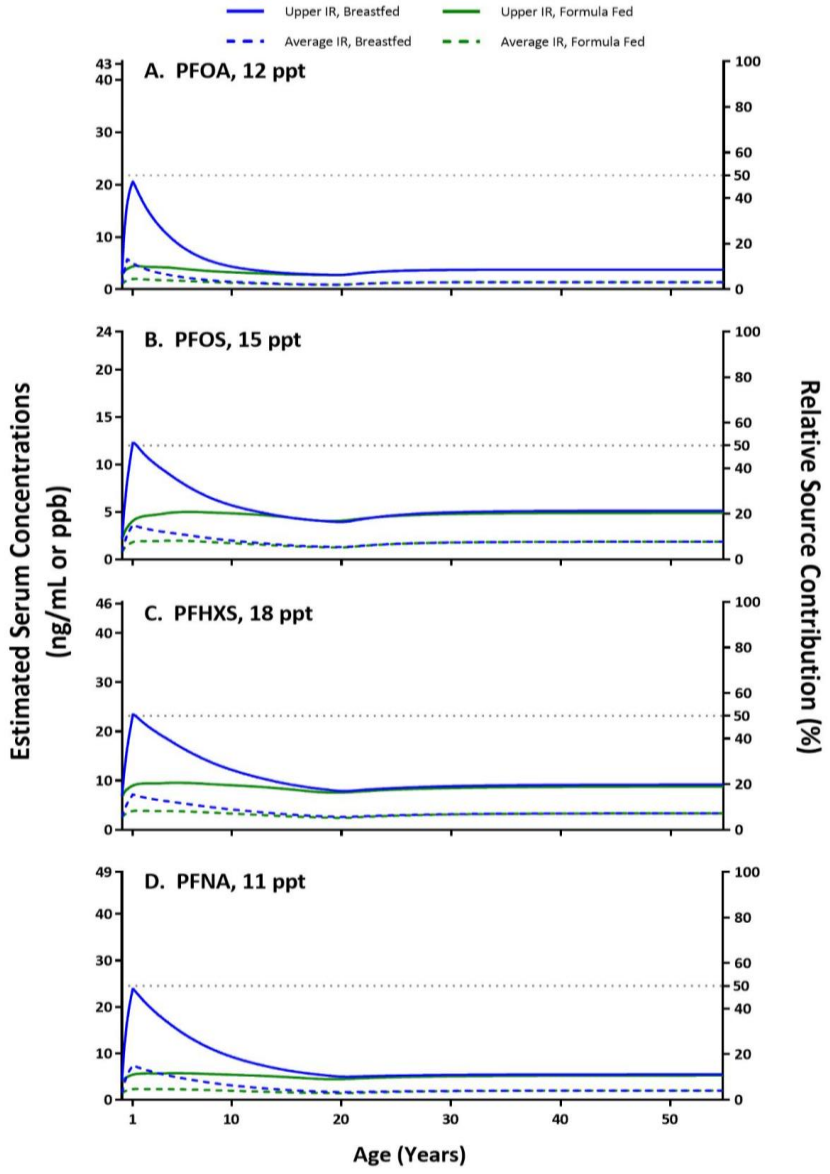
Modeled Exposures & Proposed MCLs

Given these **reference doses** and **exposure assumptions**, the proposed MCLs/AGQS are:

PFOA	**12 ng/L**
PFOS	**15 ng/L**
PFHxS	**18 ng/L**
PFNA	**11 ng/L**

NHDES is *currently* not recommending a class- or subclass-based approach to regulating PFAS.

NHDES is committed to continuing to review the scientific literature for advances in risk assessment for these and other PFAS.



Questions

References and Supporting Documents can be found in the Reference List of the June 2019 Technical Report:
https://www.des.nh.gov/organization/commissioner/legal/rulemaking/documents/pfas-scr-attch-1-w-ltr.pdf

Technical Questions about this presentation can be submitted to the **NHDES Permitting & Environmental Health Bureau**:

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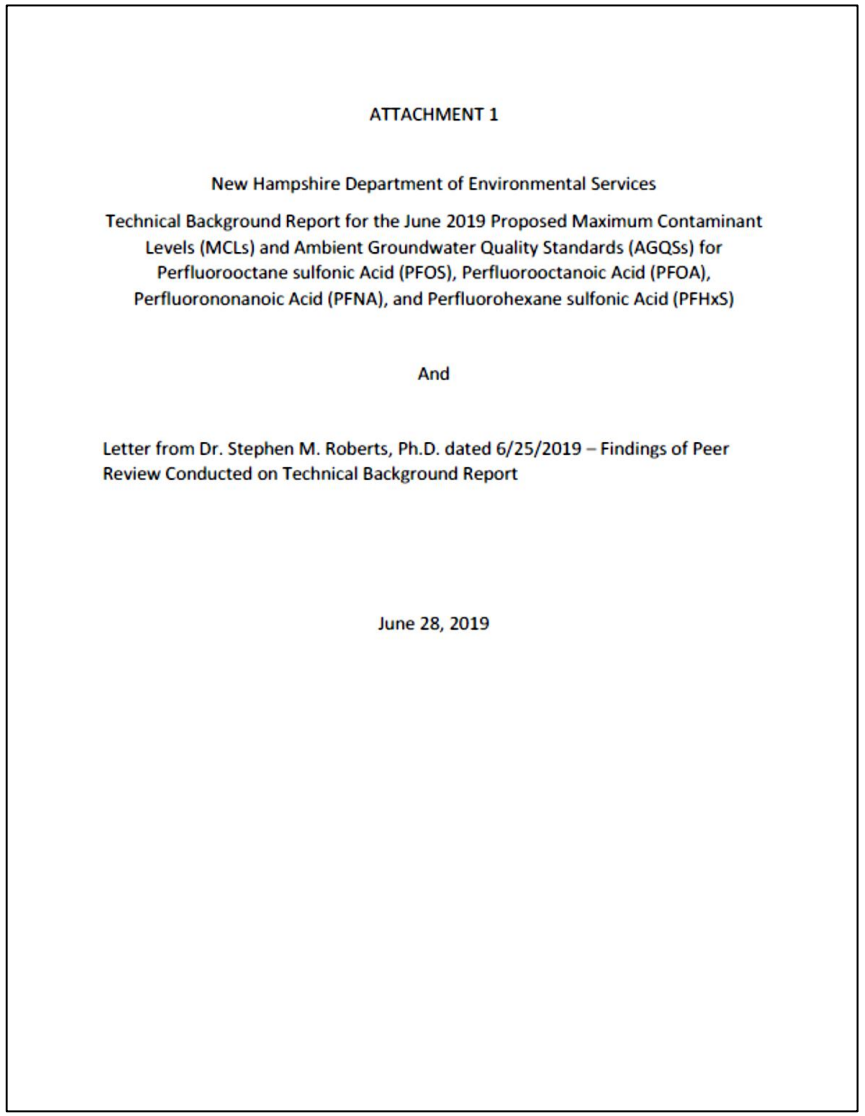

ATTACHMENT 1

New Hampshire Department of Environmental Services

Technical Background Report for the June 2019 Proposed Maximum Contaminant Levels (MCLs) and Ambient Groundwater Quality Standards (AGQSs) for Perfluorooctane sulfonic Acid (PFOS), Perfluorooctanoic Acid (PFOA), Perfluorononanoic Acid (PFNA), and Perfluorohexane sulfonic Acid (PFHxS)

And

Letter from Dr. Stephen M. Roberts, Ph.D. dated 6/25/2019 – Findings of Peer Review Conducted on Technical Background Report

June 28, 2019