PFAS Health, Toxicology Regulatory Subgroup Meeting

Virginia Department of Health Office of Drinking Water
(Discuss exposure factors)
April 9, 2021
1:30pm – 3:30pm

Opening Remarks

Member Roll Call

Review of Previous Meeting Minutes

Presentation

Discussion

Public Comment

Closing items

PFAS Health, Toxicology Regulatory Subgroup Meeting

Virginia Department of Health Office of Drinking Water
April 9, 2021
1:30pm – 3:30pm
Meeting Minutes

1. **Opening Remarks**

VDH State Toxicologist, Dwight Flammia, Ph.D. called the meeting to order 1:33 p.m. The meeting was conducted by electronic communication means (WebEx) due to the ongoing public health emergency associated with the coronavirus pandemic. The meeting was recorded. Minutes and materials provided to Subgroup members will be posted on Town Hall.

2. **Subgroup Members Present**:
   Kelly Ryan (Va American Water)
   David Jurgens (City of Chesapeake)
   Erin Reilly (James River Association)
   Steve Risotto (ACC)
   Benjamin Holland (DEQ)
   Dwight Flammia (VDA, State Toxicologist)

   Guests:
   Anna Killius
   Bill Mann
   Amanda Waters
   Ellen Egan

   ODW Staff:
   Kris Latino

3. **Review of previous meeting**

The Subgroup determined that there were no changes to minutes from the March 12, 2021 meeting. The minutes and other meeting materials will be posted on Town Hall as "Final."

4. **Presentations**

The last couple of months this Subgroup focused on regulatory determinations other states made for PFOA and PFOS. The Subgroup noticed that the states used difference approaches and compared each state's MCLs. Dwight asked Subgroup members for comments:

Ben Holland stated that the EPA is starting to set MCLs. Some have concerns regarding the time involved in making recommendations.

The Subgroup will look at the relative source contribution (RSC) and body weight. Dwight's PowerPoint presentation provides a summary of data from the states, including what each state used to determine their MCL levels. The Subgroup also discussed the exposure decision tree:

Some of the important items evaluated in the Exposure Decision Tree are:

- Adequacy of data available for each relevant exposure source and pathway.
- Availability of information sufficient to characterize the likelihood of exposure to relevant sources.
- Whether there are significant known or potential uses/sources other than the source of concern.
- Whether information on each source is available to characterize exposure.
- In cases where environmental or exposure data are lacking, the Exposure Decision Tree approach results in a recommended RSC of 20%. This 20% RSC value may be replaced where sufficient data are available to develop a scientifically defensible alternative value. When appropriate, if scientific data demonstrative that sources and routes of exposure other than drinking water are no anticipated for the pollutant in question, the RSC may be raised to 80% based on the average data.

In summary, based on the physical properties and available exposure information for PFOA, there are many potential sources. Because there is no way to predict the actual percentage, for now we have chosen to use 20%, which is recommended. Most states have indicated that the decision method is the best method.

The subtraction method was used in a couple of states. The subtraction method results in a criterion allowing the maximum possible chemical concentration in water after subtracting other sources. The subtraction method generally results in criteria levels of a contaminant in a particular medium at significantly higher levels than the percentage method and, in this respect, is contradictory to such goals.

EPA Recommendations on Body Weights:

The EPA recommends maintaining the default body weight of 70 kg for calculating AWQC (ambient water quality criteria) as a representative average value for both male and female adults.

Pregnant women may represent a more appropriate population for which to assess risks for exposure to chemicals in ambient waters in some cases, because of the potential for developmental efforts in fetuses. EPA recommends using 67 kg.

EPA recommends 30kb as a default child's body weight.

In 2015, the EPA updated body weight to 80 kilograms.

Water consumption rate 2.4 liters per day (L/day)

Ingestion rate 2.4 L/day/80 kg = .03 L/kg-day

Old ingestion Rate 2 L/day/70 kg=.028 L/kg-day

The Subgroup went through the parameters each state used to develop MCLs. (The PowerPoint presentation is attached for your review)

5. **Discussion**

How do we look at relative source contribution with these different challenges?

The Subgroup needs to determine

- What our receptors are;
- Who are receptors are;
- What the critical effect is on mammary gland;
- The immune system and how it effects the development;
- If PFAS has an effect on the immune system is it an adverse effect;
- Breast feeding mothers; and
- The percentage that should be considered for the infant as it grows older and requires less milk.

Dwight suggest starting with the current standard of 80 kg, 2.4 liters –

The Subgroup believes that the study should be based on the science.

Subgroup Deliverables

To help guide future meetings, Subgroup members broadly discussed the findings, recommendations, and/or conclusions they are considering reaching or making as part of the process for creating recommendations as necessary for maximum contaminant levels (MCLs) for per- and polyfluoroalkyl substances (PFAS) in drinking water.

Additional information:

The Subgroup would like to encourage an additional toxicologist to join - if members know of any toxicologist who might be interested in assisting, please let Dwight know

Dwight also encouraged Subgroup members to go to the SharePoint site and explore all of the new articles located by ODU. He is working with ODU to come up with some tables to identify specific items.

6. **Assignments**

Dwight is asking ODU to summarize some of the documents. He is requesting ODU assist him with tables with uncertainty factors.

If there is any other information for May meeting, please let Dwight know.

He may ask Minnesota to speak at the next meeting. Is there interest in having someone talk about how Minnesota did their calculations? Please let him know your thoughts.

7. **Public Comments**

There were not any public comments.

8. **Next Meeting**

Friday, May 14, 2021. After May, meetings will move from the second Friday of the month to the second Wednesday, starting on June 9 at 1:30 p.m.

Establishing Regulatory Limits for PFAS in Virginia Drinking Water

PFAS Toxicology Regulatory Workgroup

Dwight Flammia, Ph.D.
State Public Health Toxicologist
Virginia Department of Health
April 9, 2021

PFAS Workgroup Meeting Overview

Meeting Overview

- Opening Remarks
- Workgroup Members Introductions
- Review of previous meeting
- Presentation
- Discussion
- Assignments
- Public Comment
- Next Meeting

Introductions

Jillian Terhune (City of Norfolk)
Kelly Ryan (VA American Water)
Mark Estes (Halifax County Service Authority)
David Jurgens (City of Chesapeake)
Erin Reilly (James River Association)
Chris Leyen (VCLV)
Steve Risotto (ACC)
Benjamin Holland (DEQ)*
Dwight Flammia (VDH, State Toxicologist)
Andrea Wortzel (Mission H2O)
Steve Herzog (Hanover County)
Paul Nyffeler (Chem Law)

State MCLs

State	PFOS	PFOA
Massachusetts	20*	20*
Michigan	16	8
New Hampshire	15	12
New Jersey	13	14
New York	10	10
Vermont	20*	20*
*Sum of 5 PFAS not to exceed		

State Drinking Water Ingestion and RSC

TABLE 4: Toxicity factors and exposure assumptions used in state and US Environmental Protection Agency drinking water guidelines for perfluorooctanoic acid

	USEPA	MA	VT	NJ	MN	MI	WA	NH	NY	CA
Reference Dose[a] (ng/kg/d)	20	5	20	2	18	3.9	3	6.1	1.5	0.7[b]
Drinking water ingestion	0.054 L/kg/d Lactating woman (80th percentile)		0.175 L/kg/d Infant, 0–1 yr (95th percentile)	0.029 L/kg/d Default adult (upper percentile)	Modeled: –Prenatal exposure –Breast milk (1 yr) –Lifetime drinking water exposure				Not specified (0.034–0.151 L/kg/d considered)	0.053 L/kg/d Lifetime daily average
Relative source contribution	20%				50% for infant				60%	NA
Guideline (ng/L)	70	20	20	14	35	8	10	12	10	10

[a]All values shown are Reference Doses except for California. See footnote b.
[b]California guideline is based on a cancer potency factor at the 1-in-10 000 risk level rather than a Reference Dose. Value shown is daily dose (nanograms per kilogram per day) estimated to result in 1-in-10 000 lifetime cancer risk.
USEPA = US Environmental Protection Agency; NA = not applicable (Relative Source Contribution is not considered in guidelines based on cancer risk); MA = Massachusetts; VT = Vermont; NJ = New Jersey; MN = Minnesota; MI = Michigan; WA = Washington; NH = New Hampshire; NY = New York; CA = California.

EPA Relative Source Contribution Tree

EPA emphasizes that the purpose of the **RSC is to ensure that the level of a chemical** allowed by a criterion or multiple criteria, **when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD** or the POD/UF.

EPA Relative Source Contribution Tree

Some of the important items evaluated in the Exposure Decision Tree are:

- Adequacy of data available for each relevant exposure source and pathway.
- Availability of information sufficient to characterize the likelihood of exposure to relevant sources.
- **Whether there are significant known or potential uses/sources other than the source of concern** (i.e., ambient water and fish/seafood from those waters).
- **Whether information on each source is available to characterize exposure**.

In cases where environmental or exposure data are lacking, the Exposure Decision Tree approach results in a recommended RSC of 20%. This 20% RSC value may be replaced where sufficient data are available to develop a scientifically defensible alternative value. **When appropriate, if scientific data demonstrating that sources and routes of exposure other than drinking water *are not anticipated* for the pollutant in question, the RSC may be raised to 80%** based on the available data (USEPA 2000).

EPA Relative Source Contribution PFOA

In summary, based on the physical properties and available exposure information for PFOA, **there are many are potential sources**. Following EPA's Exposure Decision Tree in its 2000 methodology (USEPA 2000), **significant potential sources other than drinking water ingestion exist**; **however, information is not available to quantitatively characterize exposure from all of these different sources** (Box 8B in the Decision Tree). Therefore, EPA recommends an **RSC of 20%** (0.20) for PFOA.

EPA Relative Source Contribution Tree

The **percentage method is recommended** in the context of the above goals when multiple media criteria are at issue. **The percentage method does not simply depend on the amount of a contaminant in the prospective criterion source only. It is intended to reflect health considerations, the relative portions of other sources, and the likelihood for ever-changing levels in each of those multiple sources (due to ever-changing sources of emissions and discharges).** Rather than simply defaulting in every instance, the Agency attempts to compare multiple source exposures with one another to estimate their relative contribution to the total–given that understanding the degree to which their concentrations vary, or making any distributional analysis, is often not possible. The criteria levels, when multiple criteria are at issue, are based on the actual levels, with an assumption that there may be enough relative variability such that an apportionment (relating that percentage to the RfD) is a reasonable way of accounting for the uncertainty regarding that variability.

EPA Relative Source Contribution Tree

EPA cautions States and Tribes when using the subtraction method in these circumstances. **The subtraction method results in a criterion allowing the maximum possible chemical concentration in water after subtracting other sources**. As such, it removes any cushion between pre-criteria levels (i.e., actual "current" levels) and the RfD, thereby setting criteria at the highest levels short of exceeding the RfD. It is somewhat counter to the goals of the CWA for maintaining and restoring the nation's waters. It is also directly counter to Agency policies, explicitly stated in numerous programs, regarding pollution prevention. EPA has advocated that it is good health policy to set criteria such that exposures are kept low when current levels are already low. **The subtraction method generally results in criteria levels of a contaminant in a particular medium at significantly higher levels than the percentage method and, in this respect, is contradictory to such goals.** In fact, many chemicals have pre-criteria levels in environmental media substantially lower (compared to the RfD) than the resulting criteria allow.

EPA Body Weight (2000)

EPA recommends maintaining the default body weight of 70 kg for calculating AWQC as a representative average value for both male and female adults.

The value of 70 kg is based on the following information.

NHANES III

The mean body weight value for men and women ages 18 to 74 years old from this survey is 75.6 kg.

National Cancer Institute Study

The mean value adults ages 20-64 years old is 70.5 kg

The value from the NHANES III database is also higher than the value given in the revised EPA Exposure Factors Handbook (USEPA, 1997b), which recommends 71.8 kg for adults, based on the older NHANES II data. The Handbook also acknowledges the commonly used 70 kg value and encourages risk assessors to use values which most accurately reflect the exposed population.

EPA Pregnant Women Weight (2000)

Pregnant women may represent a more appropriate population for which to assess risks from exposure to chemicals in ambient waters in some cases, because of the potential for developmental effects in fetuses.

NHANES III data for women 15 to 44 had a **mean weight of 67.3 kg**.

Ershow and Cantor study (1989) present body weight values specifically for pregnant women with a **mean weight of 65.8 kilograms**.

EPA recommends use of a body weight value of 67 kg in cases where pregnant women are the specific population of concern and the chemical of concern exhibits reproductive and/or developmental effects (i.e., the critical effect upon which the RfD or POD/UF is based). **Using the 67 kg assumption would result in lower (more protective) criteria than criteria based on 70 kg.**

EPA Child Weight (2000)

EPA recommends 30 kg as a default child's body.

The value is based on the **mean body weight value of 29.9 kg** for children ages 1 to14 years old (NHANES III).

A **mean body weight of 28 kg** is obtained using body weight values from Ershow and Cantor (1989) for five age groups within this range of 0-14 years.

EPA Human Health Ambient Water Quality Criteria (**2015 Update**)

Body weight: **80 kilograms** (represents those 21 years and older)

Water consumption rate: **2.4 L/day**

Ingestion Rate 2.4 L/day/80 kg = 0.03 L/kg-day

Old
Ingestion Rate 2 L/day/70 kg = 0.028 L/kg-day

Massachussetts

All parameters selected by MassDEP are the same as those used by USEPA in deriving the drinking water Health Advisories for PFOA and PFOS. These options are neither the most, nor least, conservative of the alternatives.

The water ingestion rate for a lactating woman was applied, which equals 54 ml per kilogram body weight.

- This is the USEPA **consumers-only estimate** of the combined direct and indirect community water ingestion at the 90th percentile for this subpopulation. Basing exposure on a lactating woman is also protective of other groups.

A relative source contribution factor (RSC) of 20% was selected. Again, this is consistent with the RSC applied by USEPA in the Health Advisory derivations for PFOA and PFOS.

- Although higher RSCs have been derived by other state agencies for these longer-chain compounds based on serum concentrations from the NHANES data for the individual compounds (CDC 2019), MassDEP elected to use a 20% value. MassDEP concluded that this more conservative value is warranted to account for other exposures, including in utero and nursing exposures that recent modeling has indicated are significant, and to account for other non-drinking water exposures to the compounds across the subgroup of PFAS being addressed, as well uncharacterized exposures to related compounds.

Michigan

Breast-fed infant, which is also protective of a formula-fed infant
Placental transfer of 87% (MDH 2017)
Breastmilk transfer of 5.2% (MDH 2017)
Human Serum half-life of 840 days (Bartell et al. 2010)
Volume of distribution of 0.17 L/kg (Thompson et al. [2010])

95th percentile drinking water intake, consumers only, from birth to more than 21 years old (Goeden et al. [2019])
Upper percentile (mean plus two standard deviations) breast milk intake rate (Goeden et al. [2019])
Time-weighted average water ingestion rate from birth to 30-35 years of age (to calculate maternal serum concentration at delivery) (Goeden et al. [2019])

Relative Source Contribution of 50% (0.5)
Based on NHANES 95th percentiles for 3-11 (2013-2014) and over 12 years old (2015-2016) participants (CDC 2019)

Michigan

PFNA 50% RSC

PFOA 50% RSC

PFOS 50% RSC

PFHxA

- As no human serum data were available to assess the population's exposure to PFHxA from sources other than drinking water, a default Relative Source Contribution of 20% was selected consistent with USEPA (2000) guidance.

New Hamshire Decision Tree Process

The subtraction method (EPA 2000) estimates an apportionment of the RSC is based on assumed knowledge of the background exposure. For PFAS, the subtraction method has been mathematically applied as follows (NJDWQI 2018; MDH 2018, 2019ab):

$$\text{Relative Source Contribution} = \frac{\text{Target serum level } \left(\frac{ng}{mL}\right) - \text{Reference or background population level } \left(\frac{ng}{mL}\right)}{\text{Target serum level } \left(\frac{ng}{mL}\right)} \times 100\%$$

The difference between the target serum level and the RfD is that the former is an internal blood concentration while the latter is the external amount of the chemical that could come from multiple sources. For each of the compounds, the target serum levels were: PFOA – 43.5 ng/mL, PFOS – 23.6 ng/mL, PFNA – 49.0 ng/mL and PFHxS – 46.3 ng/mL. The reference population serum level is meant to reflect a background level of exposure from the general population, not one that is highly exposed due to a specific environmental source such as drinking water. Using the NHANES average serum values, subtracting this background level from the target serum level (the maximum allowable level) results in a proportion that is presumably permissible for drinking water alone. Other sources including food, dust, treated consumer products (e.g., carpeting, cookware, food packaging, etc.) are assumed to be included in the reference or background population blood concentrations.

Using this approach with the NHANES 2013-2014 data for children ranging in age from 3 to 19 years (as reported in Daly et al., 2018), NHDES arrived at RSCs of 50% for PFOA, PFOS, PFNA and PFHxS. Unlike its

New Jersey

Relative Source Contribution factor

A Relative Source Contribution (RSC) factor that accounts for non-drinking water sources including food, soil, air, water, and consumer products is used by USEPA, NJDEP, and the DWQI in the development of health-based drinking water concentrations based on noncarcinogenic effects. The default value for the RSC is 20%, meaning **that 20% of total exposure is assumed to come from drinking water and 80% from non-drinking water sources. If supported by available data, a higher chemical-specific value (up to 80%) can be used** (i.e. the percent exposure from non-drinking water sources is lower than the default assumption of 80%). The Health Effects Subcommittee concluded that there are insufficient data to develop a chemical-specific RSC for PFOA. **USEPA UCMR3 monitoring shows that PFOA occurs (at concentrations greater than 20 ng/L) more frequently in PWS located throughout New Jersey (10.5%) than nationwide (1.9%).** There are no New Jersey-specific biomonitoring data for PFOA, and the more frequent occurrence in NJ PWS suggests that New Jersey residents may also have higher exposures from non-drinking sources, such as contaminated soils, house dust, or other environmental media, than the U.S. general population. Additionally, the default RSC of 20%, while not explicitly

Vermont

Body weight adjusted intake rate

BWAIR = 0.175 L/kgBW-d

The 2016 EPA Drinking Water Health Advisories for PFOA1 and PFOS4 state that “the developing fetus and newborn are particularly sensitive to PFOA- and PFOS-induced toxicity.” EPA has recommended that fine age groupings be used in the assessment of potential exposure to children. A series of ten ranges between birth and 21 years of age is recommended for consideration as appropriate. The 95th percentile Body Weight Adjusted Water Intake Rate for the first year of life based on combined direct and indirect water intake from community water supplies for consumers only is 0.175 L/kgBW-d.

Vermont

RSC = 0.2 (20%)

Consistent with EPA guidance an RSC is incorporated in the development of DWHAs that are based upon a threshold type, primarily noncarcinogenic, health effect. The RSC represents the portion of an individual's total daily exposure to a specific chemical that is attributed to or allocated to drinking water. **An RSC of 20% is incorporated to account for exposure to PFOA and PFOS from other sources. This follows EPA's recommendation to use an RSC of 20% when quantitative data on other sources of exposure are not available.** The 2016 PFOA Health Advisory states "**In cases where environmental or exposure data are lacking, the Exposure Decision Tree approach results in a recommended RSC of 20%.** This 20% RSC value may be replaced where sufficient data are available to develop a scientifically defensible alternative value.

New York

Video

Relative Source Contribution 60%

Subtraction method approach

Ingestion rates (L/kg-day)

Adult 0.034

Lactating woman 0.054

Infant 0.151

Discussion

Comments on work-group document

Public Comment

Next Meeting – Friday May 14, 2021

- Note: Second Wednesday beginning June