

Are PFAS Really Parts-Per-Trillion Toxic? (Now-Parts-Per-Quadrillion Toxic?)

**Yuma Pacific – Southwest Section
YPSW 48th Annual Meeting**

January 20, 2023

What is a Part-Per-Trillion?

- US EPA Drinking Water Standards are in parts-per-million (ppm) .
 - A ppm is in units of milligrams of contaminant per liter of water (mg/L).
 - 1 PPM means that substance is one-millionth of the total amount of water. |
 - The Drinking Water Standard for lead (Pb) is 0.015 mg/L or ppm.
- 1 part-per-billion (ppb) is one thousand times smaller than 1 ppm.
 - A ppb is in units of micrograms of contaminant per liter of water (ug/L).
 - The Drinking Water Standard for lead (Pb) is thus 15 ug/L or ppb.
- 1 part-per-trillion (ppt) is one thousand times smaller than 1 ppb.
 - A ppt is in units of nanograms of contaminant per liter of water (ng/L).
 - A ppt is the equivalent to about thirty seconds out of every million years
- 1 part-per-quadrillion (ppq) is one thousand times smaller than 1 ppt.
 - A ppq is in units of picograms of contaminant per liter of water (pg/L).
 - A ppq is 1 penny in \$10,000,000,000,000 (10 trillion dollars)

A Part-Per-Trillion (ppt)

- 1 drop in 20 Olympic size pools



x 20 =



Take Away

- Is anything really toxic at a drop in a lake (a drop in 20 Olympic size pools)?

A Part-Per-Quadrillion (ppq)

- 1 drop in 20,000 Olympic size pools



x 20,000 =



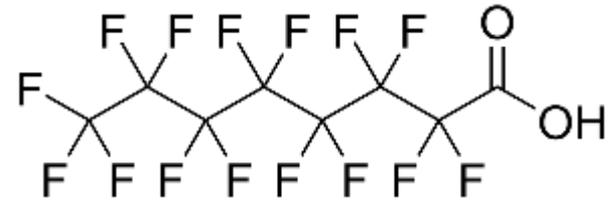
Take Away

- Is anything really toxic at a drop in an even larger lake (a drop in 20,000 Olympic size pools)?

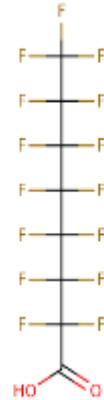
Objective of this presentation

- The objective of this presentation is to discuss the 2016 US EPA Drinking Water Health Advisory.
- The results of this discussion are simply intended to generate discussions on PFAS toxicity as a whole.
- It is not the objective of this presentation to discuss the new US EPA 2022 Drinking Water Health Advisories or the range of other Drinking Water Standards being developed by the US EPA, individual States, or other Countries.

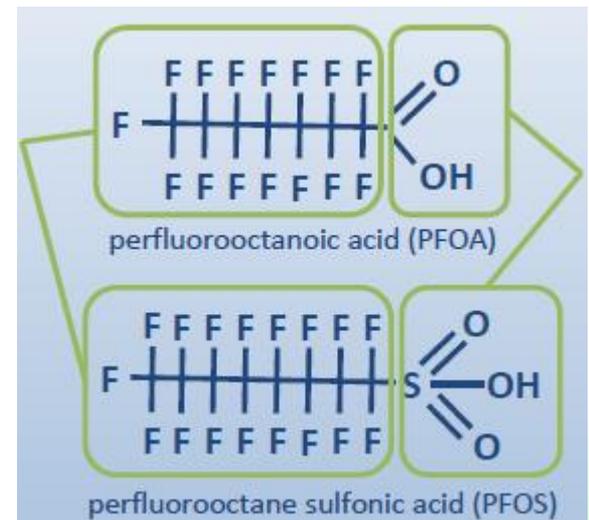
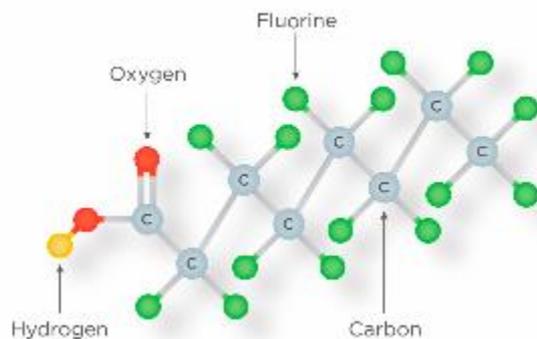
PFAS – What are they?



- PFAS (per- and polyfluoroalkyl substances) refers to a family of chemicals that were invented in the 1940s and entered mainstream production in the 1950s.
- Some estimates peg the number of chemicals in the PFAS family at more than 4,700.
- The widely known PFAS are Perfluorooctanoic acid (PFOA) and Perfluorooctane sulfonic acid (PFOS)



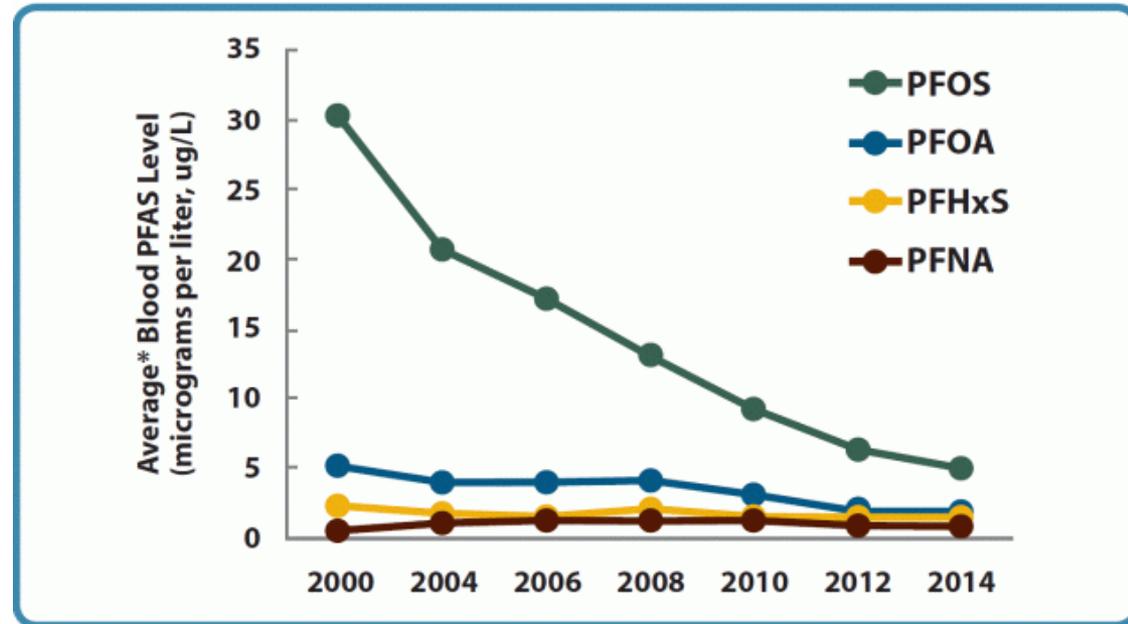
PFOA and PFOS are the “larger” PFAS compounds previously manufactured commercially and have 8 carbon atoms (C-8 PFAS) and associated fluorine atoms.



C-8 PFAS – Blood Levels (Half-Lives)

- Since 2002, production and use of the 8-carbon PFOS and PFOA in the United States have declined. Blood PFAS levels have gone down as well.

- From 1999 to 2014, blood PFOS levels have declined by more than 80%.
- From 1999 to 2014, blood PFOA levels have declined by more than 60%.



National Health and Nutrition Examination Survey (NHANES), blood PFAS in the U.S. population.

Take Away

- Use of the 8-Carbon (C-8) PFOA (and PFOS) was discontinued starting in 2002. Our blood PFOA & PFOS concentrations have radically decreased.

C-8 PFAS – Blood Levels (Half-Lives)

For comparison:

- The C-8 PFOA half-life in mice is 16 days
 - This means mice (and other animals?) eliminate PFOA very quickly from their bodies



How are we exposed to PFAS? Now the smaller C-4 & C-6 PFAS (like GenX)

Consumer Products

- Takeout containers e.g. pizza boxes & sandwich wrappers
- Fast-food wrappers
- Teflon, Non-stick pots, pans, and utensils
- Popcorn bags
- Outdoor clothing
- Camping tents
- Stain-repellant or water-repellant clothing
- Stain treatments for clothing and furniture
- Carpeting and carpet treatments
- Electrical wire insulation
- Shampoos
- Certain cosmetics, particularly eye shadow, foundation, facial powder, bronzer, and blush



How are we exposed to PFAS?

Environmental Contamination

- Contaminated water, fish, game
- Contaminated sites (soil, groundwater)

Industry

- Paints and adhesives
- Fluoro-elastomers (gaskets, O-rings, Hoses)
- Mining and oil surfactants
- Metal plating baths (chromium)

Fire Fighting

- Aqueous film-forming foams (AFFF) for fire fighting



Persistent Organic Pollutants (POPs) – Comparison to PCBs?

- PFAS and PCBs are POPs, but that is where the similarity ends
- PCBs like “fat”, they end up in the fat of our bodies and animal’s bodies
- Bioaccumulation – PCBs bio-magnify up the food chain in our fat tissues:
 - PCBs in fish fat, Bald Eagles eat fish, Polar Bears eat fish



- Unlike PCBs, **PFAS are water soluble**, PFAS stay in our blood and organs with a lot of blood (e.g., liver)

Take Away

- PFAS are not expected to bioaccumulate up the food chain like PCBs.

PFAS are in the blood of humans and animals

- “Data clearly show that albumin is the most important carrier protein for PFOS, PFOA, PFHxS, PFNA and PFDA in human plasma.”

“Albumin is the major carrier protein for PFOS, PFOA, PFHxS, PFNA and PFDA in human plasma”

Martin Forsthuber et al

Environment International

Volume 137, April 2020, 105324

- PFOA is primarily eliminated in the urine by humans and animals.

Take Away

- PFAS are not expected to bioaccumulate in or fat cells.

Persistent Organic Pollutants (POPs) – “Forever” Chemicals

- In summary, PFAS are POPs, they do not degrade in the environment
- Common sense says that their use in commercial products should be suspended except for essential uses (firefighting foams, saving lives)
- But, just because PFAS do not degrade, does not mean they bioaccumulate like PCBs and DDT

Comparison to other Drinking Water Standards

Comparison to other Drinking Water Standards (DWS)

	Start Amount fed to mice & rats (mg/kg-day)	End US EPA DWS (mg/L)	Michigan MCL	New 2020 US EPA DWHA
Petroleum / Gasoline				
Benzene	1.2	0.005 ppm		
Ethylbenzene		0.7		
Toluene	238	1.0		
Xylenes	179	10		
Dry Cleaner Solvents (and Industrial solvents)				
1,2,4-Trichlorobenzene	14.8	0.07		
1,1,1-Trichloroethane		0.2		
Common Pesticides & Herbicides				
Glyphosate (Roundup)	10	0.7		
Common Contaminants				
Styrene	200	0.1		
Dioxin	0.00000002	0.00000003		
Benzo(a)pyrene (soot in diesel exhaust)	0.092	0.0002		
PFAS (2016 US EPA Drinking Water Health Advisory)				
PFOA	1.0	0.00007 ppm (70 ppt)	0.000008 ppm	0.00000004 ppm

Comparison to other Drinking Water Standards

- With a low drinking water standard, logic says PFOA must be seriously (“uber”) toxic in animal studies.
- Question:
 - If “uber” toxic, how does amount of PFOA fed to mice (that results in a toxic effect) compare to the drinking water standards for other chemicals?

- *POD is the Point of Departure or PoD, the amount fed to laboratory mice and rats - in milligrams of contaminant, per kg of body weight, per day or mg/kg-day*
- *MCL is USEPA Maximum Contaminant Level or USEPA Primary Drinking Water Standard*

Sage Advise



- University of Illinois
- 1976, Before Chemistry 101 Final
- Professor's Advice:
 - If your answer does not make (common) sense, it is probably incorrect.
 - e.g., answer of 0.83482743 or answer of 0.1

Comparison to other Drinking Water Standards

- Answers:
 - PFAS are not uber toxic.
 - The **starting point** is the similar, if not higher, less toxic (e.g., the amount fed to mice)
 - But, the **end point**, the calculated drinking water health advisory, is radically lower than other chemicals

Take Away

- Something is not quite right compared to other chemicals
 - The methodology used by the US EPA seems to be a **radical departure** from typical calculated drinking water standards

Toxicity

Mice Fed PFOA

Study used in the US EPA 2016 DW Health Advisory Calculations



Toxicol Sci. 2006 Apr;90(2):510-8. Epub 2006 Jan 16.

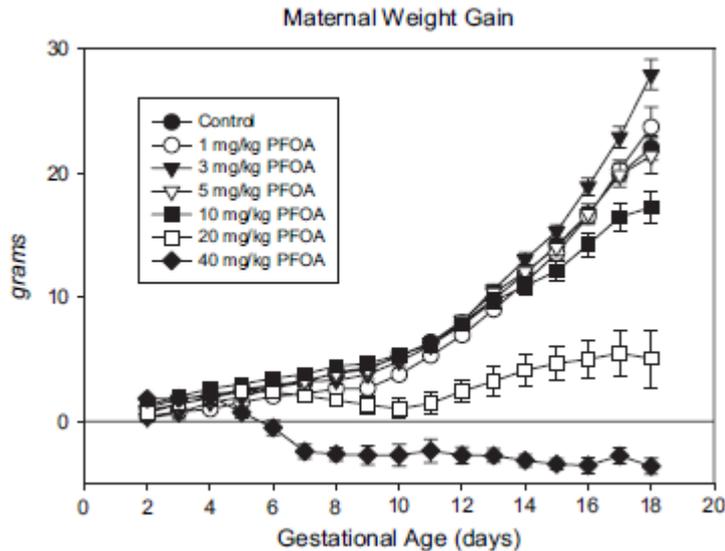
Effects of perfluorooctanoic acid exposure during pregnancy in the mouse.

Lau C, Thibodeaux JR, Hanson RG, Narotsky MG, Rogers JM, Lindstrom AB, Strynar MJ.

- Timed-pregnant CD-1 mice were given 1, 3, 5, 10, 20, or 40 mg/kg PFOA by oral gavage daily from gestational day (GD) 1 to 17; controls received an equivalent volume (10 ml/kg) of water.

<https://www.ncbi.nlm.nih.gov/pubmed/16415327>

Mice Fed PFOA



- Female mice were administered PFOA during pregnancy: 1, 3, 5, 10, 20, or 40 mg/kg-day:
 - 40 mg/kg, the mothers could not maintain pregnancy
 - > 5 mg/kg, significant increase in the incidence of full-litter resorptions
 - 20-40 mg/kg, mothers lost considerable weight (seriously sick).
 - 10-20 mg/kg, most pups did not survive the first day of life.

Mice Fed PFOA

- A Human Equivalent Dose:
 $40 \text{ mg/kg-day} * 70 \text{ kg} = 2,800 \text{ mg/day}$



Take Away

- Eat or drink a teaspoon of practically anything, and drug or household chemical, and bad things happen.....

Mice Fed PFOA – Acute Dose? – Teaspoon of PFOA per Day

Why? (Eat or drink a teaspoon of practically anything, and drug or household chemical, and bad things happen.....)

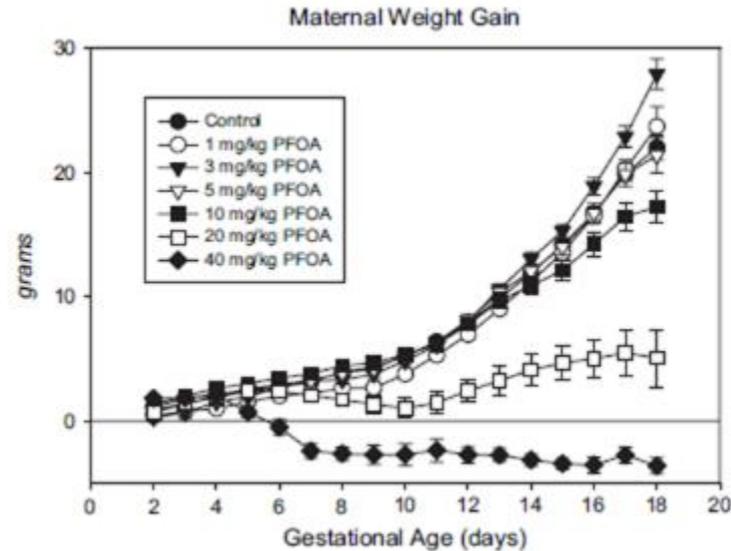
- Glass represents all of our body's defenses (repair of cells, breakdown chemicals in our liver, excretion in our urine, etc.).
- The overflowing glass is what happens at high doses, our defenses are overwhelmed.



Take Away

- At a human equivalent of a teaspoon of PFAS a day, the laboratory mice were seriously sick.

Mice Fed PFOA



- Female mice were administered PFOA during pregnancy: 1, 3, 5, 10, 20, or 40 mg/kg-day:
 - No significant increase in malformations was noted in any treatment group.
 - Other observations:
 - Dose-dependent growth deficits were detected in all PFOA-treated litters except the 1-mg/kg group.
 - Significant delays in eye-opening (up to 2-3 days) were noted at 5 mg/kg and higher dosages.

Sage Advise



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Mice Fed PFOA

- Mice were fed the human equivalent of **1 teaspoon (start)** of PFAS per day or **2,800 mg (start) of PFOA/day**.
 - The mice were dying, no malformations were observed in the pups.
- The Drinking Water Health Advisory of 70 parts-per-trillion (or 0.000070 mg of PFOA per liter of water, or ppm) was calculated from this data.
- That results in an acceptable daily exposure to humans of 0.000070 mg/L x 2 liters of water/day = **0.00014 mg of PFOA/day (end)**



Take Aways

- Should we be feeding mice such high doses?
- Does it make sense to generate such a low DW Health Advisory from such a high dose?



x 20 =



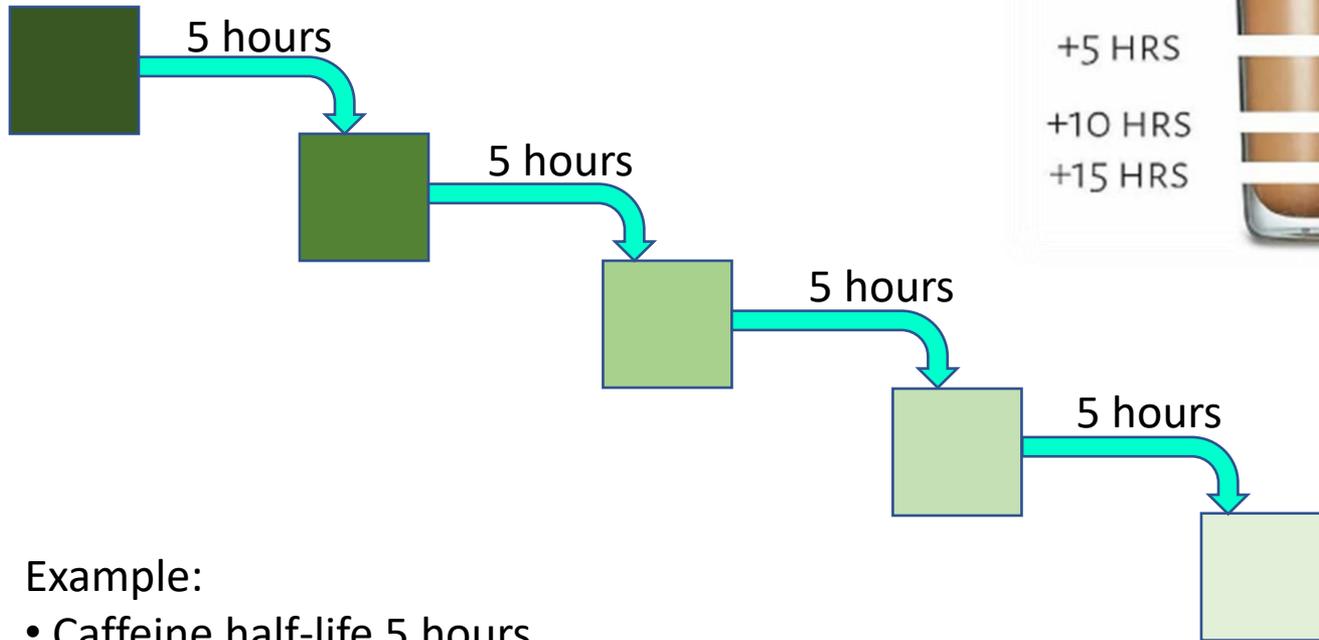
(1 ppt is a drop in 20 Olympic size pools?)

Half Life

- Why then are the US EPA Drinking Water Health Advisory calculations so low:
 - Why are the drinking water calculations so low?
 - US EPA used an approximately **500 fold uncertainty factor** to calculate a **Human Equivalent Dose (HED)**, to account for the half life from mice (15 days) to men (2.3 years)

What Does Half-Life Mean?

- For caffeine, our bodies degrade half of the caffeine from that cup of coffee, then excretes it in urine.



Example:

- Caffeine half-life 5 hours

Another example:

- PCBs half-lives of 4.6 to 41 years

CAFFEINE

HOW LONG DOES IT TAKE TO METABOLISE ONE COFFEE?

0 HRS		3.00 PM
+5 HRS		8.00 PM
+10 HRS		1.00 AM
+15 HRS		6.00 AM

C-8 PFOA Half-Life – Actual Human Clinical Study

- US EPA has estimated the **PFOA half-life to be 2.3 years** or more by back-calculations from human blood serum PFOA monitoring data.
 - Mice have a PFOA half-life of ~15 days
 - **US EPA then used a 500 fold uncertainty factor to to calculate a Human Equivalent Dose (HED), to account for the half life from mice (15 days) to men (2.3 years)**
 - Dourson et. al. identified an actual **PFOA clinical study**. PFOA was administered to humans as a potential cancer treatment drug (clinical trial for cancer chemotherapy).
 - This study was **Patented**, not available at the time the USEPA produced the DW Health Advisory.
 - Dourson et. al. has estimated the actual PFOA half-life in humans at **6 months** (from the clinical study) to **1.5 years** (back-calculated from blood serum levels).
 - This actual human half life data would raise the calculated PFOA drinking water health advisory 10 to 100 fold.
- Take Aways**
- A Re-Calculated Drinking Water Health Advisory would be in the 700 to 7,000 ppt range.

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Dourson et al 2019 & 2021 , Analysis of Human Clinical Study Half-Life

The analysis of the PFOA human clinical study half-life by Dr. Dourson / Toxicology Excellence for Risk Assessment (TERA) received the Regulatory and Safety Evaluation Specialty Section of the Society of Toxicology (SOT) Paper of the Year in 2020.

- There is a lone clinical study by Elcombe et al. 67 (2013) who administered PFOA to 42 adult humans, both male and female, in a phase 1, range finding, clinical trial for cancer chemotherapy.
- Doses were given once weekly as an oral tablet from 50 to 1200 mg for up to 6 weeks.
- Blood concentrations of PFOA over time were closely monitored.
- Adequate kidney and liver function and physical integrity of the gastrointestinal tract were important criteria for acceptance of patients into the trial.
- The daily mg/kg-day doses were estimated by Dourson et al. (2019) as 0.1 to 2.3 mg/kg-day
 - This approximates exposures in the experimental animal studies that caused toxicity.

Dourson et al 2019 & 2021, Analysis of Human Clinical Study Half-Life

- Clinical study of Elcombe et al. (2013) was used to estimate PFOA half-life of ~200 day (~0.5 years) in a second paper by Dourson and Gadagbui, 2021.
- PFOA half-life of ~1.5 years by Xu et al. (2020) appears to be most reliable estimate from human observational studies (blood monitoring of human populations) since background exposures were subtracted.
- Thus, a range in the PFOA half-life appears to lie between 0.5 and 1.5 years.
- The Elcombe et al. (2013) study is a patent application, so was not used in the 2016 US EPA Drinking Water Health Advisory calculations.
- *Note, although participants had good liver and kidney function, the Elcombe et al. (2013) study participants were ill and may have had different kinetics when compared with healthy individuals.*

C-4 and C-6 Replacement PFAS – Half-Lives

- These are commonly referred to as GenX, ADONA and F53B, respectively. Replacement chemicals, like GenX, tend to have fewer carbon atoms in the chain, but have many similar physical and chemical properties as their predecessors PFOS and PFOA.
- The 8-carbon PFAS are being replaced by C-4 and C-6 PFAS.
- The C-4 and C-6 PFAS are thought to generally have **elimination half-lives in weeks or months**, not years.
- Again, the half life of PFOA in lab animals is in days.
- Thus, the C-8 PFOA 500-fold uncertainty factor would not directly apply to the C-4 and C-6 PFAS.

Recalculation

Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020

Report Prepared For:
Michigan Manufacturers Association
620 S. Capitol Ave.
Lansing, MI 48933

Report Prepared By:
Dr. Michael L. Dourson, TERA
Dr. Edward J. Calabrese, UMass
Mr. Richard J. Welsh, ASTI

Independent Technical Review of the Health-Based Drinking
Water Value Recommendations for PFAS in Michigan

January 30, 2020

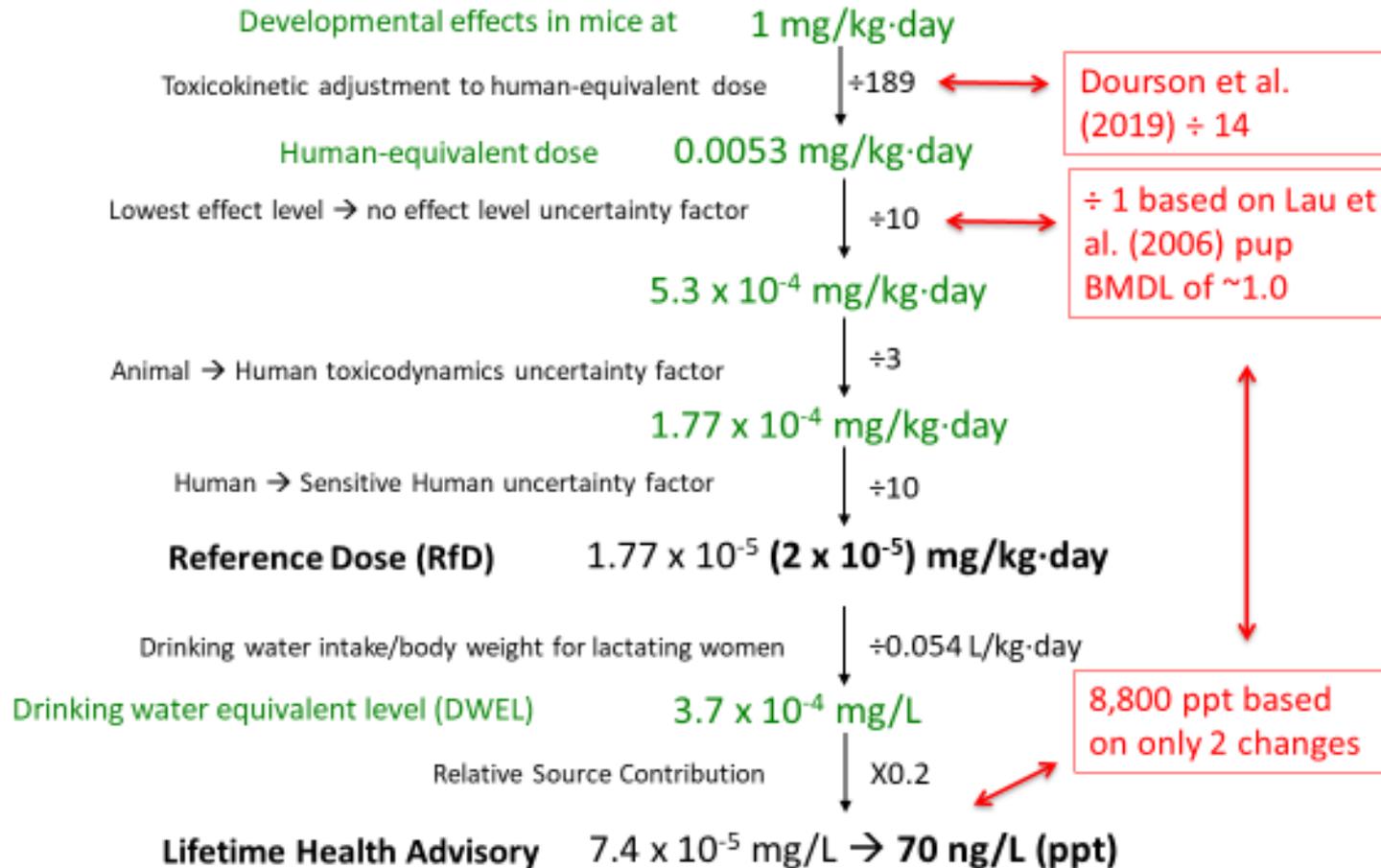


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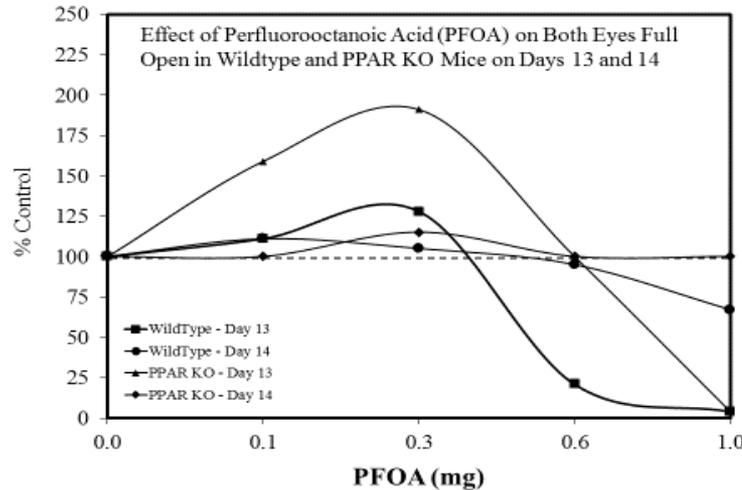
Dourson et. al. – Example Calculations for Alternate Health Advisory Level for PFOA



Note: 0.0000070 ppm or mg/L = 0.0070 ppb or ug/L = 70 ppt or ng/L

Perspective – Hormesis, Dr Edward Calabrese

- A study by Abbott et al., 2007 with PFOA, using a broad range of exposures, reported that eye opening in the low dose groups occurred earlier than in the control group. This indicated not only a threshold response but also a potentially enhanced performance at doses below the threshold.



Take Away

- Low PFAS (environmental) exposures show hormesis, thus lower drinking water exposures would not demonstrate toxicity.

Abbott BD, Wolf CJ, Schmid JE, Das KP, Zehr RD, Helfant L, Nakayama S, Lindstrom AB, Strynar MJ, Lau C. (2007). Perfluorooctanoic acid-induced developmental toxicity in the mouse is dependent on expression of peroxisome proliferator-activated receptor- α . *Toxic Sci* 98(2):571-581.

Perspective – What other Countries Have Concluded

Australian National University

- The Australian National University review of over 200 studies found a possible small cholesterol effect and some others, but it stated:
- “The majority of studies we included in this review were evaluated to have a moderate to high risk of bias that could have influenced published findings.”
- “While there have been many studies into the health effects of PFAS it is uncertain whether or not PFAS are harmful to human health. In the few areas in which there is evidence for a possibly causal association of PFAS with an effect on human health the association is either uncertain or apparently weak.”

Take Away

- Other countries have conducted comprehensive PFAS reviews and concluded PFAS toxicity in ppb, not ppt range.

Reference:

PFAS in Drinking Water by Joseph A. Cotruvo

EM, The Magazine for Environmental Managers, Air & Waste Management Association (A&WMA), May 2020

PFAS levels in Michigan Deer and Eat Safe Wild Game Guidelines, January 2018

- The State of Michigan collected tissue samples from 128 white-tailed deer across Michigan to test for per- and polyfluoroalkyl substances (PFAS).
 - White-tailed deer in Michigan are exposed to PFAS, however, information on routes of deer exposure to PFAS and duration of exposure is not available at this time.
 - Most of the deer included in this dataset do not appear to have PFAS exposures that will lead to elevated, or even detectable levels in muscle tissue.
 - DHHS and MDNR issued a 'Do Not Eat' advisory for deer taken within five miles of Clark's Marsh in Oscoda Township due to one deer having very high PFOS levels in the muscle, liver, and kidney.

Take Aways

- PFAS generally not detected in Deer populations. This is consistent with shorter half-lives of C-8 PFAS in lab animals. This is consistent with high water solubility of all PFAS.
- PFAS would not be expected to bioconcentrated (bio-magnify up the food chain) in animal fat like PCBs.

Take Away #1

- A part-per-trillion (ppt) is a drop in 20 Olympic size pools.
- A part-per-quadrillion (ppq) is a drop in 20,000 Olympic size pools.



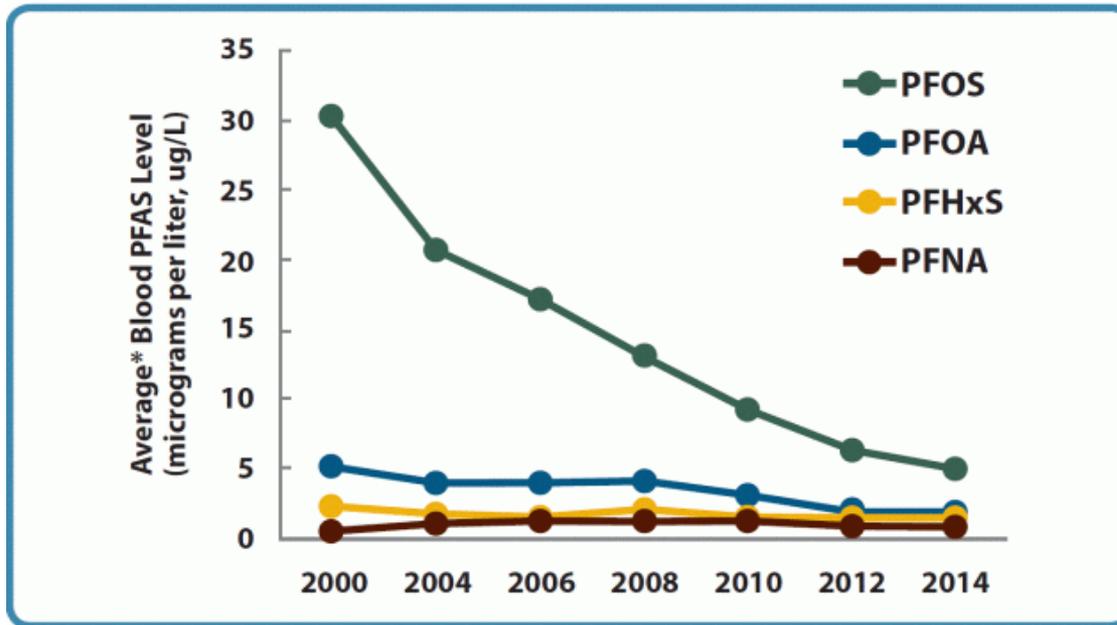
x 20,000 =



Take Aways

- Comment sense: Is anything really toxic (e.g., cause cancer, birth defects, etc.) at a drop in a lake?
- Also consider Calabrese et. al., hormesis, chemicals (including PFAS) show lower responses (toxicity) at low concentrations.

Take Away #2



Take Aways

- Use of the 8-Carbon (C-8) PFOA (and PFOS) was discontinued starting in 2002.
- Our blood PFOA & PFOS concentrations have drop dramatically.
- The new replacement C-4 and C-6 PFAS are eliminated from our bodies even quicker (weeks or months).

Take Away #3

Persistent Organic Pollutants (POPs)

- Unlike PCBs, **PFAS are water soluble**, PFAS stay in our blood and organs with a lot of blood (e.g., liver)
- Albumin (common protein in people's blood) is the most important carrier protein for PFOA in human plasma



Take Away

- PFAS are not expected to bioconcentrate in people's fat, and would not be expected to bio-magnify up the food chain like PCBs.

Take Away #4

Half-Lives

- PFOA – US EPA – Based on Blood Plasma Levels in People
 - 2.3 or more years in people
- PFOA Clinical Study
 - 6 months
- PFOA in Mice
 - 15 Days
- Replacement C-4 and C-6 PFAS
 - Weeks or months, not years



Take Aways

- Half-Life from clinical study is 6 months
- Half-Lives are relatively short for lab animals.
- Half-Lives of replacement PFAS are relatively short.

Take Away #5

	Start Amount fed to mice & rats (mg/kg-day)	End US EPA DWS (mg/L)	Michigan MCL	New 2020 US EPA DWHA
Petroleum / Gasoline				
Benzene	1.2	0.005 ppm		
Ethylbenzene		0.7		
Toluene	238	1.0		
Xylenes	179	10		
Dry Cleaner Solvents (and Industrial solvents)				
1,2,4-Trichlorobenzene	14.8	0.07		
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Common Pesticides & Herbicides				
Glyphosate (Roundup)	10	0.7		
Common Contaminants				
Styrene	200	0.1		
Dioxin	0.00000002	0.00000003		
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PFAS (2016 US EPA Drinking Water Health Advisory)				
PFOA	1.0	0.00007 ppm (70 ppt)	0.000008 ppm	0.00000004 ppm

Take Aways

- Something is not quite right for the PFAS Drinking Water Health Advisory compared to Drinking Water Standards for other chemicals?
 - The methodology used by the US EPA seems to be a **radical departure** from typical calculated drinking water standards

Take Away #5 (continued)

	Start Amount fed to mice & rats (mg/kg-day)	End US EPA DWS (mg/L)	Michigan MCL	New 2020 US EPA DWHA
Petroleum / Gasoline				
Benzene	1.2	0.005 ppm		
Ethylbenzene		0.7		
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PFAS (2016 US EPA Drinking Water Health Advisory)				
PFOA	1.0	0.00007 ppm (70 ppt)	0.000008 ppm	0.00000004 ppm

Take Aways

- The common sense expectations for part-per-trillion (ppt) drinking water standards would be that PFAS are extremely toxic to lab animals compared to other chemicals.
 - Expect PFOA to be “methyl-ethyl-death” in lab animals.
- But, PFOA has a toxicity (in lab animals) similar to other chemicals with ppm standards.

Take Away #6

- Mice were fed a Human Equivalent Dose of a teaspoon per day:

$$40 \text{ mg/kg-day} * 70 \text{ kg} = 2,800 \text{ mg/day}$$



Take Away

- Acute dose?
- Eat or drink a teaspoon of practically anything, and drug or household chemical, and bad things happen.....

Take Away #6 (continued)

- Glass represents all of our body's normal defenses (repair of cells, breakdown chemicals in our liver, excretion in our urine, etc.).
- The overflowing glass is what happens at high doses, our defenses are overwhelmed.

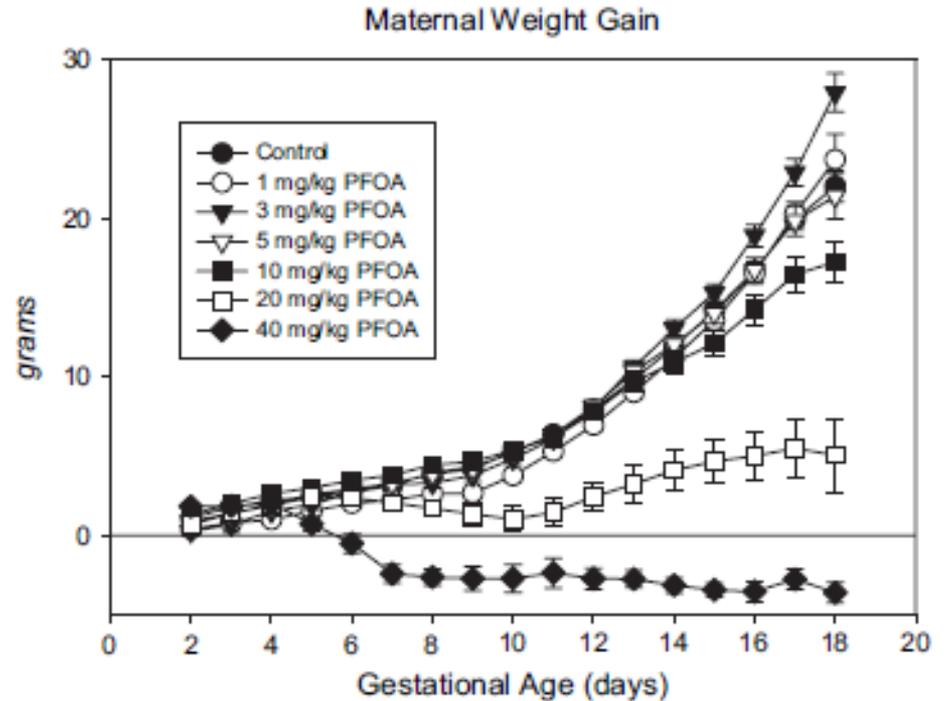


Take Aways

- Mice fed a human equivalent of a teaspoon of PFAS a day.
- Acute dose? Overwhelm our bodies normal defenses?

Take Away #7

- Mice mothers were losing weight, likely sick or dying at all but lowest doses.



Take Away

- Eat or drink a teaspoon of practically anything, and drug or household chemical, and bad things happen.....

Take Away #8

- Mice were fed the human equivalent of **1 teaspoon (start)** of PFAS per day or **2,800 mg (start) of PFOA/day**.
 - The mice were sick.
- The Drinking Water Health Advisory of 70 parts-per-trillion (or 0.000070 mg of PFOA per liter of water, or ppm) was calculated from this data.
- That results in an acceptable daily exposure to humans of 0.000070 mg/L x 2 liters of water/day = **0.00014 mg of PFOA/day (end)**



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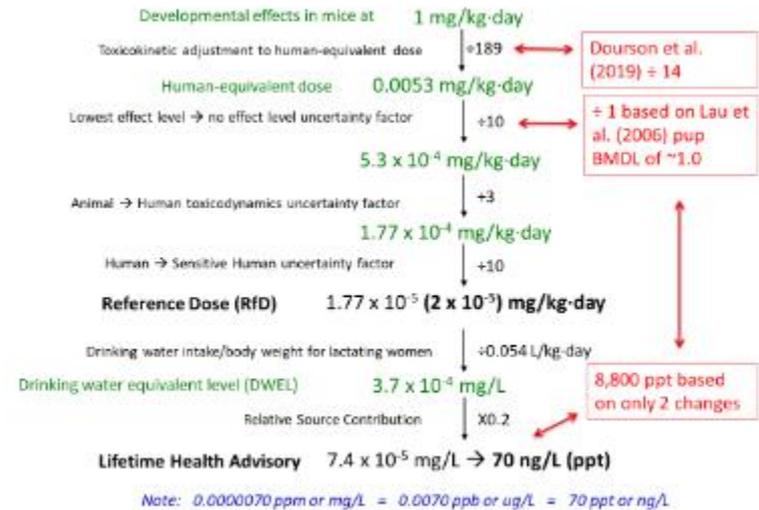
Take Aways

- Can mice be fed almost a teaspoon of PFOA per day, then **confidently** calculate, using uncertainty factors, a part-per-trillion (ppt) Drinking Water Health Advisory?
- Should a drop of PFAS in a lake really be calculated to be ppt toxic?

Take Away #9

Clinical Trial and PFOA Half-Life

- PFOA as a potential cancer treatment drug in people (clinical trial for cancer chemotherapy).
- This study was Patented, not available at the time of the USEPA DW Health Advisory.
- Using the clinical study in people, Dourson et. al. estimated the actual PFOA **half-life in humans at 6 months**.



Take Away

- Calculated alternative Drinking Water Health Advisory is **8,800 ppt versus 70 ppt**.

Note, US EPA guidelines recommend the use of the Benchmark Dose (related to calculation for No/Lowest Observable Effect Level (NOEL) in Lab Mice).



More Information

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