July 26, 2023

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Attn: Docket ID No. EPA-HQ-OLEM-2022-0922

The Coalition for Responsible Waste Incineration (CRWI) appreciates the opportunity to submit a response to the *Addressing PFAS in the Environment*; Advanced notice of proposed rulemaking, FR 22,399 (April 13, 2023). CRWI is a trade association comprised of 27 members representing companies that own and operate hazardous waste combustors and companies that provide equipment and services to the combustion industry.

Attached are our comments on two issues.

Thank you for the opportunity to comment. If you have any questions, please contact me at (703-431-7343 or mel@crwi.org).

Sincerely yours,

Melvin E. Keener, Ph.D.
Executive Director

cc: M. Schutz, EPA

1. Should EPA consider whether analytical methods are available when designating these compounds as hazardous substances?

   Yes. There are two primary reasons why EPA should have an approved analytical method before designating any compound as a hazardous substance under CERCLA. Without an approved analytical method, one would not know the accuracy and precision of the laboratory data and the test results cannot be compared to a standard. For example, if one were to take a water sample and send it to four different laboratories to be analyzed for dioxin contents, each laboratory is going to use the same analysis methods and should come up with comparable results (within a range of uncertainty). If each laboratory were to use a different analytical technique, they may or may not come up with the same results (within range) and you would have no way of knowing which answer is correct. CRWI would like to point out that it is not just the laboratory analytical method that must be standardized but also the sampling method. If different sampling methods were to be used, additional variability would be introduced and the uncertainty of the accuracy of the data would increase. These are the reasons the Agency requires the use of approved sampling and analytical methods and multi-laboratory validation for those methods.

   A second reason is that the Agency should use same analytical methodology in developing standards as it uses to demonstrate compliance with those standards unless it can be shown that methods give comparable results. Thus, the first step in developing regulations must be the development of a standardized sampling and analytical method. Otherwise, comparisons are likely to be meaningless. While certain regulations allow the use of suitable methods where no analytical method has been approved, at this point in time there is no way to determine what is a suitable method for PFAS.

   EPA currently has approved methods for the nine PFAS compounds mentioned in the ANPRM. However, without an approved sampling and analytical method for that compound, the Agency should not designate any other compound as a hazardous substance under CERCLA.

2. Should EPA develop categories of PFAS compounds based on chemical structure, carbon chain length, functional groups, physical and/or chemical properties, or mode of action?

   No. EPA has faced this problem before when regulating dioxins and dioxin-like compounds. In this case, the Agency recognized that just being similar did not equate to similar levels of toxicity and essentially developed regulations based on the relative toxicity of each dioxin/furan congener. To develop those standards, the Agency recognized that different source categories would have a different mix of dioxin/furan congeners and what mattered was the overall toxicity of the mix.

Currently, there is very little data on the toxicity of various PFAS compounds. To date, EPA has released a final IRIS determination for perfluorobutanoic acid (PFBA)[1] and perfluoropropanioc acid (PFPrA)[2]. EPA set reference doses (RfD) for PFBA of 1 X 10^{-3} mg/kg/day and 1 X 10^{-4} mg/kg/day for PFPrA. The Agency is in the process of developing IRIS assessments for perfluorodecanoic acid (PFDA), perfluorohexanoic acid (PFHxA), perfluorohexanesulfonic acid (PFHxS), and perfluorononanoic acid (PFNA). The draft reference dose for PFHxA (based on the February 2022 proposal) is 5 X 10^{-4} mg/kg/day. The Agency plans to release draft assessment for the other three in 2023.

In addition, the Agency has released draft health advisory levels for perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS), perfluorobutanesulfonoc acid (PFBS), and hexafluoropropylene oxide-dimer acid (HPFO-DA)[3]. Based on draft health advisory levels, EPA set draft chronic reference doses as follows.

PFOA	1.5 x 10^{-9} mg/kg/day
PFOS	7.9 x 10^{-9} mg/kg/day
HPFO-DA	3 x 10^{-6} mg/kg/day
PFBS	3 x 10^{-4} mg/kg/day

At this time, EPA has final or draft reference doses for seven PFAS compounds. To make the comparisons easier, we put all the data above into a single table below and grouping them by structure.

PFOA	1.5 x 10^{-9} mg/kg/day
PFOS	7.9 x 10^{-9} mg/kg/day
PFHxA	5 X 10^{-4} mg/kg/day
PFBS	3 x 10^{-4} mg/kg/day
PFBA	1 X 10^{-3} mg/kg/day
PFPrA	1 X 10^{-4} mg/kg/day
HPFO-DA	3 x 10^{-6} mg/kg/day

This is a very limited dataset and only two are final. While CRWI does not necessarily agree with the values developed, it allows one to examine how structure, chain length, and functional groups may be related to toxicity. The first six in the above table are all linear chain compounds. The RfD for the first six vary by six orders of magnitude. The last compound in the table is an ether. This could lead one to the conclusion that the structure is not a major indicator of toxicity.

[1] https://iris.epa.gov/ChemicalLanding/&substance_nmbr=701#organ)
[2] https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=358291&Lab=CPHEA
[3] https://www.epa.gov/system/files/documents/2022-06/technical-factsheet-four-PFAS.pdf

Five of the compounds in the above list have a carboxylic acid functional group, two have a sulfonic acid group. For the compounds with carboxylic acid functional groups, the RfD's vary by six orders of magnitude while the RfD's for the compounds with sulfonic acid vary by five orders of magnitude. This could lead one to the conclusion that the functional group is not a major indicator of toxicity.

If the above table is rearranged based on the number of carbons (lowest to highest, number of carbons in parentheses) in the compound (see table below), it seems possible that carbon chain length might be worth further examination.

PFPrA (3)	1×10^{-4} mg/kg/day
PFBS (4)	3×10^{-4} mg/kg/day
PFBA (4)	1×10^{-3} mg/kg/day
PFHxA (6)	5×10^{-4} mg/kg/day
HPFO-DA (6)	3×10^{-6} mg/kg/day
PFOA (8)	1.5×10^{-9} mg/kg/day
PFOS (8)	7.9×10^{-9} mg/kg/day

For the most part, the reference dose decreases as chain length increases. The exception is that the reference dose for the three carbon carboxylic acid compound is one order of magnitude lower than the four carbon carboxylic acid compound. There is a one order of magnitude difference between the two four-carbon compounds. It should be pointed out that these two have different functional groups. There are two orders of magnitude difference between the two six-carbon compounds. While these two compounds have the same functional group, one has a linear structure while the other is an ether. There is less than an order of magnitude difference between the two eight-carbon compounds and, like the four-carbon compounds, these two compounds have different functional groups.

CWRI would like to repeat that this analysis is based on very limited data. As additional data becomes available or current draft values change, different conclusions may be reached. Given the current information, it would seem unscientific to regulate PFAS compounds based on structure, carbon chain length, or functional group. Overall, the reference dose appears to decrease with carbon chain length. In addition, functional groups seem to have a smaller impact on toxicity when compared within the same length of carbon chain and it is possible that structure may also play a part. Additional data will be needed before that determination can be made. Perhaps the only conclusion that can be made from this discussion is there is a potential for a complex relationship between toxicity and carbon chain length, functional group, and structure. Based on current data, this suggests that developing any grouping would be unscientific and that each should be regulated as in individual compound.