July 17, 2019 Reference No. 11178724

Elizabeth Callahan
MassDEP
One Winter Street
Boston, MA 02108
Address

Dear Ms. Callahan:

Re: Review of Massachusetts Department of Environmental Protection "Summary of Proposed MCP Method 1 Standards Revisions, March 2019, Proposed Method 1 Standards for PFAS"

As part of the proposed amendments to the Massachusetts Contingency Plan (MCP – 310 CMR 40.0000, the Massachusetts Department of Environmental Protection (MassDEP) has made several substantive modifications to the United States Environmental Protection Agency's (USEPA's) toxicity criteria for Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) in their "Proposed Method 1 Standards for PFAS." This comment package prepared by GHD addresses several areas of toxicology and public policy proposed in the new Method 1 Standards for PFAS.

Page 8, Basis of PFAS Reference Doses Used in the Derivation of the MCP Standards

MassDEP discusses the Minimum (sic) [Minimal] Risk Levels (MRLs) developed by the Agency for Toxic Substances and Disease Registry (ATSDR) and notes that they are lower than the USEPAs reference doses (RfDs) for PFOA/PFAS. This is not a fair comparison, since the "MRLs are not intended to define clean up or action levels for ATSDR or other Agencies"[1]). This is in contrast with the USEPAs RfDs, which are the toxicological basis used for developing cleanup standards for chemicals in various media. Developing criteria that are not intended to be used to define cleanup goals may result in unnecessary approaches to environmental site management. MassDEP has chosen to use the ASTDR MRLs to support PFAS criteria lower than the USEPA's criteria but without providing a sound technical basis for doing so or indicating that it is perhaps just based on a subjective policy decision.

GHD recommends that to provide balance and perspective on PFAS risk, criteria developed by other toxicology experts and authoritative bodies (e.g., Canada, Netherlands, Germany, Australia) that have concluded that some PFAS may be less toxic than the USEPA's estimates should also be mentioned in addition to those cited on page 9 (several of which, like ATSDR, are not developed or intended to be used for - regulatory decision making).

[1] https://www.atsdr.cdc.gov/mrls/index.asp

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Page 9, "Updated Approach" discussion:

First Paragraph, Relative Source Contribution (RSC): MassDEP makes a passing reference to the "likely conservativeness of the RSC" without detailed justification, background or discussion. Although not specifically cited in this document, an RSC of 0.2 is implied[2], which assumes a person only gets 20% of their PFAS exposure from drinking water and the other 80% from other exposure sources. In spite of the likely conservativeness of the RSC (and the 30 and 300 fold uncertainty factors [UF] that the USEPA used for PFOS and PFOA, respectively), MassDEP concluded that it was necessary to have an additional uncertainty factor without providing justification for its use.

GHD believes there are already sufficient UFs included in the PFAS toxicity analysis and drinking water calculations to make the existing criteria sufficiently protective. Adding an additional UF will increase site management costs without justifying the additional benefit received for this additional cost. Although adequate protectiveness of human health and the environment is of paramount importance, the cost-benefit of achieving potentially overly conservative cleanups should be evaluated to select appropriate criteria and with consideration to the relative cost-benefit to also appropriately manage other environment risks.

Second Paragraph, Toxicity Information Update: MassDEP seems to imply that the USEPA did not adequately consider potential PFAS effects on the human immune system in developing their RfD. USEPA specifically noted that one of the human health outcomes they assessed was immune function [3]. More specifically, MassDEP has not provided adequate justification for an additional database UF when in fact there were data available for the exact endpoint they have expressed concern over, and this endpoint was reviewed and considered by the USEPA as part of their RfD development process.

As their basis for this additional UF, MassDEP refers to uncited "animal bioassay data on a number of endpoints" that they believe were not adequately considered by the USEPA. In addition, they cite a National Toxicology Program (NTP) report that concluded both PFOA and PFOS should be presumed to pose immune hazards to humans. This NTP report did not provide a dose-response for human immune effects or recommend a protective concentration. This is a significant change to MassDEP's2018 toxicity assessment, when MassDEP concluded that the USEPA's RfDs were technically adequate.

It is neither sound science nor good policy to imply the USEPA's toxicological analysis is inadequate or outdated, but not provide sufficient information to support this conclusion. Merely adding an additional UF to the toxicity criteria due to poorly defined concerns about immune system effects is an additionally

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2 https://www.mass.gov/files/documents/2019/05/03/2019-04-24%20Proposed%20PFAS-Related%20MCP%20Revisions.pdf

3 USEPA. 2016. Health Effects Document for PFOS, Section 3.1.1.8; Health Effects Document for PFOA, Section 3.1.1.12.

conservative approach that should be properly supported. MassDEP should develop a quantitative toxicity assessment using the uncited data they reference. The toxicity factors for PFAS compounds will be crucial to state-wide decision making and should be scientifically robust; taking the work of another agency and adding a UF appears to be a convenient short cut.

Addition of New Uncertainty Factor: MassDEP has reduced the USEPA RfD for PFOS and PFOA by adding an additional uncertainty factor (UF) to account for data base uncertainties. An RfD is an "estimate (with uncertainties spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime" (see footnote 1).

The specific UF used by MassDEP is not stated in the text. The proposed MassDEP RfD is 5x10-6 mg/kg-d vs the USEPA value of 2 x 10-5 mg/kg-d. MassDEP has noted this additional UF is needed to account for "effects on development and the immune system, in laboratory animals at dose levels below those used in the USEPA RfD calculations".

This is a crux argument for the proposed criteria and should be explained and supported in greater detail. It is critical that MassDEP provide the data supporting their conclusion that the USEPAs RfD calculations are not adequately protective so the reasoning can be understood. The USEPA provided documents on PFOA and PFOS toxicity that were several hundred pages in length and provided extensive discussion on each assumption. MassDEP is apparently inferring that the USEPA's evaluation was inadequate by suggesting they included data that the USEPA did not use. If MassDEP has additional data that support their contention, they should be presented and their reasoning for use discussed.

It is recommended that MassDEP consider removing the additional data base UF they used to modify the USEPA's RfD, unless adequate justification is provided for including it. In their toxicity assessments for both PFOA and PFOS, the USEPA used a database UF of one, noting that there is substantive human data as well as extensive data from short term, subchronic, chronic, reproductive, developmental, and mechanistic studies in animals. The overall UF used by the USEPA was 300 for PFOA and 30 for PFOS. GHD believes that based on current science and community understanding these UFs are adequate for determining appropriate cleanup goals.

A more meaningful explanation should at least be provided by MassDEP in support of their proposed PFAS toxicity assessment approaches. Like other states, MassDEP is using the same studies and data used by the USEPA to develop toxicity criteria for PFOA and PFOS, but is adding an extra UF and assuming other PFAS chemicals are equi-potent. This actually increases the overall uncertainty associated with PFAS management, since several additional assumptions are being made.

Toxicokinetic Modeling: The MassDEP toxicology discussion does not specifically mention the impact of the USEPA's toxicokinetic modeling between animals and humans for PFOA and PFOS. This approach is intended to account for the differences in excretion rates and biological half-lives of PFOA/PFAS between animals and humans by normalizing long-term blood levels. One consequence is that the animal "no observed adverse effects level" (NOAEL) gets reduced by 2-3 orders of magnitude when calculating an equivalent human NOAEL. This modeling is still somewhat controversial among toxicologists, as it relies solely on animal studies while bypassing consideration of more relevant human epidemiology data and blood level studies.

The toxicokinetic modeling is discussed in these comments in regards to the overall level of uncertainty factors included in the PFAS toxicity assessment. It is important to acknowledge that the animal NOAEL is reduced by 2-3 orders of magnitude when developing a human NOAEL through the toxicokinetic modeling. While intended to account for metabolic differences between species and be protective, the modeling is also conservative and adds several orders of magnitude to the overall uncertainty.

Multiple PFAS Toxicity: MassDEP is proposing to apply their modified RfD for PFOS and PFOA to an additional four PFAS compounds (PFHxS, PFNA, PFHpA, and PFDA; pg 8 of the guidance), in essence creating an RfD that would include the total concentration of six PFAS.

MassDEP recommends assuming that four additional PFAS compounds are equi-toxic as PFOA and PFOS. These additional four compounds lack an adequate toxicity database to derive their own values, so MassDEP drew the conclusion – without presenting any data – that the structural and biological properties were similar enough to PFOA and PFOS that all six compounds could be regulated as one PFAS group.

This is a significant step towards regulating PFAS as groups, which may indeed eventually be the way to proceed. But at this stage to just assume these additional compounds are equi-toxic because of some similar but non-toxicological properties is not consistent with good science. It is only a short jump from here to say that we should regulate all PFAS on the basis of PFOA and PFOS, rather than actually conduct the studies necessary to support that decision.

An alternate approach could be modeled after the relative potency factors developed by the USEPA for carcinogenic polycyclic aromatic hydrocarbons (cPAHs). This approach provides relative potency estimates ranging from 0.001 to 1.0 for other cPAHs relative to benzo(a)pyrene, based on findings from mouse skin carcinogenesis tests. Something similar could be developed for PFAS to provide a scientific basis for potency estimation, rather than just assuming others are equi-potent with PFOA/PFOS (such as has been done by the Dutch National Institute for Public Health and the Environment [4]. GHD recommends

[4] "Mixture exposure to PFAS: A Relative Potency Factor Approach"; RIVM Report 2018-0070; https://www.rivm.nl/bibliotheek/rapporten/2018-0070.pdf)

that language be included that notes that the proposed standards will be revisited as additional understanding of the toxicology of PFAS is developed.

Summary

In summary, GHD believes that Mass DEP should provide further technical support and reasoning for their rationale for including an additional UF to lower the USEPA USPFOA/PFOS toxicity criteria. Increasing the overall UF suggests that existing PFAS criteria are not sufficiently protective, although they are in fact already at or below widely accepted national and international standards.

Assuming that an additional four PFAS compounds are as toxic as PFOA and PFOS based on supposition rather than science is not good public policy. GHD recommends that MassDEP develop a science-based approach that considers a larger group of compounds than just four. Making toxicology assumptions without any meaningful support is not good public policy.

Sincerely,

GHD

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Vice President

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