DEPARTMENT OF THE NAVY
COMMANDER
NAVY REGION MID-ATLANTIC
1510 GILBERT ST.
NORFOLK, VA 23511-2737

IN REPLY REFER TO:
5090
N45R/14/RE408
JUL 19 2019

Elizabeth Callahan
Massachusetts Department of Environmental Protection
One Winter Street
Boston, MA 02108

Dear Ms. Callahan:

SUBJECT: DEPARTMENT OF DEFENSE COMMENTS ON PROPOSED PFAS-RELATED REVISIONS TO THE MASSACHUSETTS CONTIGENCY PLAN

As the Department of Defense (DoD) Regional Environmental Coordinator (REC) for U.S. Environmental Protection Agency (EPA) Region I and on behalf of the military services, the Commander, Navy Region Mid-Atlantic is responsible for coordinating responses to state environmental legislative and regulatory matters of interest. DoD appreciates the opportunity to provide the enclosed comments for your consideration in response to the proposed "PFAS-Related revisions to the Massachusetts Contingency Plan ("MCP", 310 CMR 40.0000)".

If you have any questions, you may contact Mark Hutchinson at Mark.r.hutchinson@navy.mil or (757) 341-0394 or me at Sharon.Baumann@navy.mil or (757) 341-0363.

Sincerely,

Sharon L Baumann

SHARON L. BAUMANN
Director for Regional
Environmental Coordination
By direction of the Commander

Enclosures: 1. DoD Comments on Massachusetts Contingency Plan PFAS-Related Revisions
2. DoD Technical Comments on Massachusetts Department of Environmental Protection Summary of Proposed MCP Method 1 Standards Revisions, March 2019

Copy to: U.S. Army REC, Region I (Mr. Kevin Kennedy)
U.S. Air Force REC, Region I (Mr. Michael Pattison)

Department of Defense Comments
Massachusetts Department of Environmental Protection
Massachusetts Contingency Plan
PFAS –Related Revisions

The Department of Defense (DoD) submits the attached technical comments on the proposed regulations under the Massachusetts Contingency Plan (MCP) that are related to perfluoroalkyl and polyfluoroalkyl substances ("PFAS"). The MassDEP proposes to "update MCP numerical cleanup standards and corresponding Reportable Concentration to reflect more recent scientific and technical information on chemical exposure and toxicity." As part of this effort MassDEP will set limits in the MCP for six PFAS compounds (PFOA, PFOS, PFNA, PFDA, PFHpA, & PFHxS), combined at 20 parts per trillion. In summary, DoD has significant concerns with the scientific defensibility of the assessments that formed the basis of the proposed requirements, and believes that the approach is based on incomplete toxicity information and in some cases, inappropriate application of toxicological principles. DoD thus believes it is premature to establish new and combined MCP proposed cleanup standards for soil and groundwater [Method 1], toxicity values for use in site-specific risk assessment [Method 2], and notification criteria for soil and groundwater [Method 3], for all six PFAS.

DoD follows the Federal cleanup law, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), in its cleanup investigations and response actions. This includes conducting CERCLA risk assessments to determine the need for remedial action, as well as evaluating State cleanup standards as "Applicable or Relevant and Appropriate Requirements" (ARARs) under section 121(d)(2) of CERCLA. DoD has proactively taken action to address PFOS and PFOA from DoD activities under the federal cleanup law, and remains committed to working collaboratively with MassDEP, and affected communities, on its cleanup responsibilities.

A. Combining Toxicological Reference Value

The DoD has concerns with the scientific defensibility of combining limits for more than one PFAS compound in a toxicity reference value. Currently, toxicological information exists at the federal level for three of the PFAS substances, providing the basis for the US EPA Office of Water's Lifetime Health Advisory Reference Dose (RfD) for PFOA and PFOS and the Provisional Peer-Reviewed Toxicity Value for PFBS. This information qualifies as Tier 2 and 3 toxicity values under US EPA Office of Land and Emergency Management directives (OSWER Directives 9285.7-53 and 9285.7-86). DoD utilizes toxicological reference values meeting Tier 1-3 criteria when conducting human health risk assessments under CERCLA, and to establish risk-based remedial goals in the absence of ARARs. In order for the DoD to utilize new toxicological information for PFHpA, PFHxS, and PFNA in a CERCLA risk assessment, the information must be based on the best available science utilizing scientifically accepted procedures that follow a transparent process with publicly available sources, and have undergone a scientific peer review (as also set out in the OSWER Directives 9285.7 .53 and 9285.7-86 and tl1e 2007 Environmental Council of the States' white paper, *Identification and Selection of Toxicity Values/Criteria for CERCLA and Hazardous Waste Site Risk Assessments in the Absence of IRIS Values).* It does not appear that the approach taken to establish toxicity criteria

for PFHpA, PFHxS, and PFNA would meet these requirements. Moreover, DoD finds the approach and justification for combining all six PFAS into one toxicity reference value is not technically defensible (see attached comments).

B. Derivation of Toxicity Criteria Based on Draft Assessments and Uncertain or Weak Toxicological Information

MassDEP is proposing cleanup regulations based on draft and incomplete toxicological information that is not intended to inform regulatory determinations. The Agency for Toxic Substances and Disease Registry (ATSDR) recently released the Draft Toxicological Profile for Perfluoroalkyls for 14 different PFAS compounds, and clearly stated that they do not intend the Minimum Risk Levels to define cleanup levels. The EPA Health Advisories for PFOA and PFOS are non-enforceable and non-regulatory. *See* EPA Office of Ground Water and Drinking Water's memorandum *Clarification about the Appropriate Application of the PFOA and PFOS Drinking Water Advisories*, dated November 15, 2016. MassDEP justified toxicity reference values for PFHpA, PFHxS, and PFNA based on structurally similar compounds. This lacks a scientifically accepted procedure that follows a transparent process with publicly available sources that have undergone a scientific peer review.

The premise that structurally similar compounds are sufficient to justify a cumulative cleanup level for PFHpA, PFHxS, PFNA, PFOS, PFOA, and PFDA is not consistent with acceptable toxicological practice per EPA Risk Assessment Guidance for Superfund (RAGS) Part A, Section 8.2.2. Specifically, PFHpA has a shorter half-life in humans than PFOA and PFOS (days vs. years); PFHxS is less toxic than PFOA and PFOS by approximately 10 fold, and PFNA has lower solubility and protein binding than PFOA. The use of a cumulative cleanup level approach should be founded on clear evidence of similar mechanism of action and same affected target organs. These PFAS compounds neither exhibit toxicological effects by a similar mechanism nor cause the same adverse effects on target organs. Therefore, DoD has significant concerns with combined clean-up limits for more than one PFAS compound based solely on structural similarities.

C. Lack of Sampling Methods

There is no final validated standard EPA method for analyzing these six PFAS in surface water, non-potable groundwater, wastewater or solids. Although EPA SW-846 Method 8327 has been released for public comment, it has not been finalized. EPA has also stated that use of modified methods based on EPA Method 537 for non-drinking water samples provides no consistent sample collection or analytical guidelines and have not been validated or systematically assessed for data quality. Data collected for PFAS at this time may have limited usefulness and lack comparability and reproducibility that may lead to inconsistent site characterizations and risk assessments of PFAS contamination.

Comment #	Section	Page#	Comment	Suggested Action, Revision and References (if necessary)
1	Proposed Method 1 Standards for PFAS	8	What is the rationale for the selection of the 6 PFAS compounds MassDEP selects for Method 1 Standard development?	MassDEP should justify their reliance on the DRAFT ATSDR Toxicity Profile of Perfluoroalkyls, US EPA's Lifetime Health Advisory for Drinking water and New Jersey Drinking Water Quality Institute documents for toxicity information. This justification should clearly address MassDEP reliance on some DRAFT documents and not others (e.g., U.S. EPA's DRAFT assessment of GenX and PFBS). And MassDEP's decision not to pursue a more critical approach to the evaluation of published toxicity studies (e.g., like that MassDEP used for TCE). Such a critical approach would provide a more robust and supportable Method 1 Standard for PFAS.
2	Basis of PFAS Reference Doses...	8	A major error in this document is equating MRLs with RfDs. ATSDR defines MRLs as screening levels and emphasizes that "*MRLs are not intended to define clean up or action levels for ATSDR or other Agencies.*" When ATSDR released the DRAFT of their MRLs, some were concerned that state regulators would inappropriately apply these value to establishing drinking water standards for PFOS/PFOA and/or total PFAS.	The new MassDEP standards under review misinterpret the intended uses of two different types of toxicity values. The text should be clarified to present the correct distinction between the two types of toxicity values in this section.

Comment #	Section	Page#	Comment	Suggested Action, Revision and References (if necessary)
3	Proposed method 1 standards for PFAS	9	Use of the RfD in Risk Assessment and adjusting down the MassDEP ORS RfD values for PFOS and PFOA from $2x10^{-5}$ to $5x10^{-6}$ has not been empirically justified nor validated. In the absence of identifying additional database uncertainty factors, and justifying the values employed in arriving at this more conservative value ($5x10^{-6}$), it is unclear what specific toxicological studies aligned with this new value or the processes involved to derive this new value. In addition, the point of departure (POD) is the human equivalent dose (HED), which is derived from the modeled serological concentrations that represent either an NOAEL or LOAEL experimental dose when incorporating uncertainty factors. However, considerable scientific debate in the field of risk assessment has challenged use of NOAELs and LOAELs, calling into question their utility in this Methods Revision - particularly since the process for derivation of the RfD has not been logically or formally defined in this report. One of the key issues with NOAELs/LOAELs is the failure to adequately appreciate and take into account the full dose response curve or treatment group variability.	An appropriate dose-response analyses should be performed where the data is sufficient to do so - this approach would assist in decreasing the extent of the uncertainty - particularly since there are recommendations in the report for a near arbitrary dose revision of the RfD values for PFOS/PFOA from $2x10^{-5}$ to $5x10^{-6}$. It is recommended then, that the report's authors consider Benchmark Dose (BMD) analysis as opposed to relying on a point estimate like the RfD. This will also remove any uncertainty or concern with arbitrarily adjusting the RfD down to $5x10^{-6}$ and provide a near empirically determined dose that is protective of human health. Instead of selecting one particular treatment level (e.g., the NOAEL), BMD analysis permits an evaluation of the whole dose-response curve for all the available treatment groups. An effect level - the Benchmark Response, can then be examined to derive the effect doses (EDs) or effect concentrations (ECs) for PFOS and PFOA. Indeed, BMD has more or less replaced the use of NOAELs/LOAELs for human health risk assessments, and for many PFASs, there is a sufficient volume of data to permit the use of BMD approaches. For these assessments, "*dose-response analysis*" refers to an evaluation of the exposure and effect relationship.

Comment #	Section	Page#	Comment	Suggested Action, Revision and References (if necessary)
4	Proposed method 1 standards for PFAS	9	Final Paragraph. Report states that "*MassDEP ORS is applying the revised RfD for PFOS and PFOA (5 x 10^{-6} mg/kg-day) to PFNA, PFHxS, and PFHpA following the approach previously described.*" Given the arguments provided above for issues identified in using NOAELs/LOAELs for derivation of RfD in risk assessment, extrapolation of the revised RfD for PFOS and PFOA to PFNA, PFHxS, and PFHpA is questionable. Reasons for this include 1) the arbitrary derivation of the revised RfD; and 2) Broad criticism of the use of NOAELs/LOAELs in risk assessment decision-making.	It is recognized that quality dose-response data-sets might not be available for all PFASs. However, for several; including PFOS and PFOA, BMD analysis has been used by other Agencies and should be considered and encouraged here. For others; including PFHpA and PFHxS, the data might not be available yet to permit BMD analysis. However, best practices currently available should be followed. It seems unacceptable scientific practice to broadly align the revised RfD to all PFASs under consideration. At this time, the report poorly justifies the reasoning for such an alignment, and given the availability of BMD for making informed risk assessment decisions, the approach using NOAELs/LOAELs appears to be flawed. It is recommended that Benchmark dose (BMD) analysis be employed to derive a value that is protective of human health.
5	Basis of PFAS Reference Doses Used in the Derivation of the MCP Standards	9	Dose additivity, though recommended in ORS 2018a, is not supported within that document. Dose additivity requires the same MOA, as well as parallel log(dose)-response curves. As ORS states, the developmental effects of PFOA and PFOS differ and therefore are likely to have different MOAs. Also, The National Academies (in "*A Class Approach to Hazard Assessment of Organohalogen Flame Retardants*", 2019) recognizes the "*diversity of the broader PFAS class*" in trying to support "*read-across within structure-based subgroups*". Not only do PFOA and PFOS have different structures, but the larger PFAS group also includes both perfluoroalkyl and polyfluoroalkyl substances that can differ substantially from each other in functional chemical structures as well as chain length. These differences indicate it is unlikely that all of the compounds "*are structurally closely related*" and are similar "*in potencies and mechanisms of action*".	Consider revisions to the document that state that data are not currently available for most PFASs and that, until such data are available, and as such, the assessment made assumptions of additivity and add concentrations of all PFASs as a default. However, also consider chemical-specific analyses that justify not adding concentrations and/or the use of chemical-specific potency assessments.

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6	Basis of PFAS Reference Doses…	9	This document specifies that the lower RfD is supported on the basis of a number of epidemiology studies (none referenced). Most of the epidemiology studies are cross-sectional in design and only establish associations. Additionally, it is poorly understood why controlled animal data are not always reflective in humans.	Rigorous methodology process should be used when screening studies for the derivation of toxicity values, and should included balanced interpretation of data from controlled animal studies and epidemiology studies. Additional references, details of how supporting data was used, and which were excluded, would lend needed crediblity to the validity of the RfD. These additional details are needed to fully assess the validity of the document.
7	Soil Standards for PFAS	12	The fact that "*… non-GW-1 soil standards apply to individual PFAS.*" is inconsistent with prior MassDEP assumptions regarding PFAS additivity. This should be discussed and justified.	Either PFAS can be grouped together or they should not. Regardless, the assumption of dose and/or response additivity for PFAS should be clearly defined and applied in a consistent fashion.
8	Soil Standards for PFAS	12	The basis for suggesting that the leaching-based soil concentration for PFAS is lower than the PFAS reporting limit of 0.2 ug/kg should be justified and the appropriate references cited.	Please explain why a Method 1 S-3 Soil standard can not be derived for the protection of groundwater. Please note that Method 1 S-2 Standards may be required in the future for the volatile fluorotelomer alcohols.