

Response to Public Comments on the Proposed PFAS-related Amendments to the Massachusetts Contingency Plan, 310 CMR 40.0000

This document summarizes the written comments received on proposed amendments to the Massachusetts Contingency Plan (MCP), as published in the public hearing draft on April 19, 2019, that pertain to notification thresholds and cleanup standards for perfluoroalkyl substances (PFAS) and MassDEP’s responses to those comments. A summary of comments received on the non-PFAS-related amendments will be provided in a separate document.

This document is organized by the topic(s) addressed by the comment. The topics include four questions MassDEP posed to reviewers in the public hearing draft (*see Note to Reviewer 65*). A general summary of the comments received and MassDEP's response to each of those four questions is provided, followed by the individual comments and corresponding responses. This document also summarizes comments and MassDEP's responses on a number of additional issues raised by commenters related to PFAS regulation and implementation issues. In many of its responses, MassDEP directs the reader to an accompanying Technical Support Document for additional information.

List of Commenters (abbreviation used in this document)		List of Acronyms	
3M Company (3M)	Massachusetts Water Resources Authority (MWRA)	AFFF	aqueous fire-fighting foam
American Chemistry Council (ACC)	Massachusetts Water Works Association (MWWA) (and specific MWWA member comments)	ATSDR	Agency for Toxic Substances and Disease Registry
Agresource Inc. (Agresource)	NAIOP Massachusetts (NAIOP)	AUC	area under the curve
Associated Industries of Massachusetts (AIM)	Nantucket Memorial Airport (Nantucket AP)	BW	body weight
CDM Smith	North East Biosolids and Residuals Association (NEBRA)	BMDL	benchmark dose lower confidence limit
Conservation Law Foundation (CLF)	OARS	DAF	dilution attenuation factor
Con-Test Analytical Laboratory	Precision Coating	DWI	drinking water intake
David Dow	Sanborn Head	GD	gestational day
Department of Defense (DoD)	Executive Committee of the Cape Cod Group-Sierra Club	HA	Health Advisory
GHD	(Sierra Club Cape Cod)	HDL	high-density lipoprotein
Green Toxicology LLC (Green & Crouch)	Sources, Transport, Exposure and Effects of PFASs (STEEP)	HED	human equivalent dose
GreenCAPE	(City/Town Water Officials)	IgM	immunoglobulin M
GZA	Eamon Twohig, Vermont Department of Environmental Conservation (Vt DEC)	LDL	low-density lipoprotein
Haley & Aldrich Inc. (Haley & Aldrich)	Weston & Sampson	LOAEL	lowest observed adverse effect level
LSP Association (LSPA)	Wood Environment & Infrastructure Solutions, Inc.	LSP	Licensed Site Professional
Massachusetts Department of Transportation (MassDOT)	(Wood)	MassDEP	Massachusetts Department of Environmental Protection
Massachusetts Coalition for Water Resources Stewardship (MCWRA)	Westfield Residents Advocating for Themselves (WRAFT)	MDHHS	Maine Department of Health and Human Services
		MDH	Minnesota Department of Health
		MISAW	Michigan Science Advisory Workgroup
		MOA	mode of action
		MRL	minimum risk level or minimum reporting limit
		mg/kg-day	milligrams per kilogram body weight per day
		mg/L	milligrams per liter
		ng/L	nanograms per liter
		NHANES	National Health and Nutrition Examination Survey
		NHDES	New Hampshire Department of Environmental Services
		NJDWQI	New Jersey Drinking Water Quality Institute
		NOAEL	no observed adverse effect level
		NTP	National Toxicology Program
		ORS	Office of Research and Standards
		ORSG	Office of Research and Standards guideline
		ppt	part per trillion
		PBPK	physiologically based pharmacokinetic model
		PFAS	per and polyfluoroalkyl substance
		PFDA	perfluorodecanoic acid
		PFHpA	perfluoroheptanoic acid
		PFHxS	perfluorohexanesulfonic acid
		PFNA	perfluorononanoic acid
		PFOA	perfluorooctanoic acid
		PFOS	perfluorooctanesulfonic acid
		PND	post-natal day
		POD	point of departure
		PPARα	peroxisome proliferator activated receptor alpha
		PRP	Potentially Responsible Party
		PXR	pregnane X receptor
		RfD	reference dose
		RSC	relative source contribution
		SRBC	sheep red blood cell
		SRF	State Revolving Fund
		TWA	time weighted average
		TWI	tolerable weekly intake
		UCMR 3	Third Unregulated Contaminant Monitoring Rule
		UF	uncertainty factor
		UF _A	interspecies uncertainty factor
		UF _H	intraindividual uncertainty factor
		UF _L	LOAEL to NOAEL uncertainty factor
		UF _S	subchronic to chronic uncertainty factor
		UF _D	database uncertainty factor
		UF _{total}	total (composite) uncertainty factor
		USEPA	United States Environmental Protection

The Technical Support Document and copies of written public comments are posted here:
<https://www.mass.gov/lists/final-pfas-related-revisions-to-the-mcp-2019>

Question 1

Is the proposed revision of the USEPA RfD through the inclusion of an additional Uncertainty Factor to account for more sensitive toxicity endpoints appropriate in light of the ATSDR draft MRLs and other data? Are reviewers aware of other critical data not addressed in the USEPA; ATSDR; NJ; and NTP evaluations that MassDEP should consider in making these determinations?

Summary of written comments received in response to Question 1--A number of comments were received relating to this issue. In summary these ranged from:

- The MassDEP RfD is not sufficiently protective; the most sensitive endpoint should be used.
- The MassDEP RfD is not sufficiently protective of potential carcinogenicity.
- The MassDEP RfD is overly conservative; the USEPA RfDs should be used and no additional uncertainty factor is warranted.
- The MassDEP and USEPA RfDs are both overly conservative and should be raised.

MassDEP's general response to written comments on Question 1--MassDEP has concluded that the proposed application of an additional uncertainty factor equal to the square root of 10, in the RfD derivation for the subgroup of PFAS addressed is appropriate. This approach is supported by the available toxicity data, which demonstrates effects at doses below those selected as points of departure by USEPA in its RfD derivation for PFOA and PFOS. This approach is also consistent with standard practice and guidance regarding the application of these factors. MassDEP believes its choice of an UF of the square root of 10 rather than 10 is appropriate and protective of non-cancer risks.

Specific comments and responses related to Question 1 are summarized below.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
1	ACC	<p>The application of a database uncertainty factor is inappropriate. MassDEP has proposed the addition of a 10-fold uncertainty factor to the reference doses (RfD) for PFOS and PFOA “to account for more sensitive toxicity endpoints.” According to the proposal, the addition of a database uncertainty factor (UF_D) is suggested for potential immunotoxicity effects for PFOS and liver and mammary gland effects for PFOA. According to MassDEP, the proposals to add additional uncertainty factors are based on draft documents from the federal Agency for Toxic Substances and Disease Registry (ATSDR) and the New Jersey Department of Environmental Protection – neither of which have been finalized.</p> <p>The reproductive and development data bases for PFOS and PFOA are robust, however, and do not suggest the need to account for an incomplete characterization of toxicity. Similarly, the potential immunotoxic effects of PFOS have been studied in both laboratory animals and humans. The results of these studies are inconsistent and both EPA5 and Health Canada have questioned the relevance of immune system effects observed in mice and the small antibody variations seen in epidemiology studies to adverse health effects in humans. It is inappropriate, therefore, to conclude that immunotoxic effects represent a more sensitive health effect such that a modifying factor of 10 should be included in the assessment of PFOS.</p>	<p>MassDEP has not proposed adding an UF of 10 at this time. Instead, based on an assessment of the available science MassDEP concluded that it is appropriate to add an UF equal to the square root of 10 to ensure protection of public health. This is discussed in the accompanying Technical Support Document. The additional UF is not based on any single endpoint, study or assessment, but instead reflects MassDEP’s evaluation of the weight of the evidence.</p>
1	ACC	<p>Both the liver and mammary gland effects reported in animal studies of PFOA are associated with activation of the PPARα and are of questionable relevance to humans. This conclusion is supported by the conclusions of the C8 Health Project and recent human data reported by Convertino et al. (2018) which provide strong evidence that the liver effects are a rodent-specific adaptive response. Alterations in mammary gland development were not observed in a study of offspring of wild type, PPARα-null, or PPARα humanized mice following in utero exposure to PFOA. In a multi-generational study in CD-1 mice, moreover, the investigators noted that the delay in mammary gland development did not appear to affect lactational support based on normal survival and growth of the second generation (F2) offspring.</p>	<p>PFAS cause adverse effects in genetically engineered PPARα knockout animals. This demonstrates that this mechanism cannot be the sole one responsible for all PFAS toxicity.</p> <p>The significance of the mammary gland effects, and some of the reported liver effects, is a matter of ongoing scientific debate and not all scientists agree on how this data should be interpreted. MassDEP finds the noted effects to be concerning but has not relied on the cited studies or these effect classes to derive a POD for RfD derivation.</p> <p>The cited Convertino study involved a limited number of very ill cancer patients and is thus not generalizable to the general population.</p>
1	CDM Smith	<p>Robust toxicological studies that investigate the health effects of individual compounds at low levels and the difference in the way animals (e.g. mice) and humans react to chemical influence should serve as the basis for setting a standard that may serve as a foundation for drinking water MCL.</p>	<p>MassDEP’s approach, as discussed in the accompanying Technical Support Document, does consider studies on individual compounds. It also accounts for differences in animal and human responses, kinetics and sensitivity.</p>
1	CDM Smith	<p>More research could support higher standards, such as those developed in Canada, the European Union, or other States. MassDEP should consider adopting higher interim standards and participating in collaborative efforts to identify more consistent and appropriate standards as part of those collective efforts.</p>	<p>It is MassDEP’s judgment that the proposed standards are supported by the data.</p>
1	City/Town water officials	<p>It is important to acknowledge that the profiles are not yet final and are subject to change based on comments received. MassDEP should not rely on the ASTDR information until has been finalized</p>	<p>MassDEP has noted that the ATSDR document is a draft. The ATSDR document, along with other information, prompted MassDEP to reassess PFAS toxicity and was considered in this assessment, but it was not used as the basis for the proposed standards.</p>
1	City/Town water officials	<p>MassDEP should not adopt an excessively conservative factor to the EPA’s reference dose, as it is not supported by sound science.</p>	<p>As discussed in the accompanying Technical Support Document, MassDEP’s proposed standards are not excessively conservative and are well supported by the science.</p>

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1	City/Town water officials	There needs to be a better understanding of the real potential human health impacts at the low levels that are being detected and potentially regulated in drinking water within Massachusetts.	MassDEP standards are designed to address potential human health impacts. Concern over the potential human health impacts of PFAS is well supported by the available science.
1	Clean Water Action	Clean Water Action agrees with CLF that the UF used for the proposed MCP changes does not make sense. The UF should be adjusted to prioritize the safety of children and fetuses.	CLF commented that an additional uncertainty factor of 10 should be applied in order to account for fetal and infant exposures. However, USEPA’s guidance on using such a factor applies to RfDs that are based on adult effects. Considering that the RfDs derived by MassDEP are based on developmental effects and did take effects on infants and fetuses into account, the suggested uncertainty factor is not warranted. MassDEP applied an additional UF of equal to the square root of 10 in deriving revised RfDs to account for data indicating effects at lower levels of exposure than those that USEPA used as the POD in its RfD derivations for PFOS and PFOA.
1	CLF	The standards should protect against immune system effects.	Data on potential immune system effects are part of the scientific rationale for revising the RfD values downward through the inclusion of an additional uncertainty factor of the square root of 10, consistent with standard RfD derivation methods and guidance. MassDEP has concluded that this approach is appropriate and protective in consideration of the available data and associated uncertainties. See the accompanying Technical Support Document for additional information.
1	CLF	As a model for a more protective approach, the authors cite work by Grandjean and Budtz-Jorgensen. These investigators identified serum BMDLs of 1.3 ng/ml PFOS and 0.3 ng/ml PFOA by relating concentrations in children’s serum to immune system effects in those children. They then identified a drinking water limit by relating serum concentrations measured in Ohio and West Virginia residents to concentrations in their drinking water, which indicated a drinking water to serum ratio of 1:100.	The cited study supports a more protective value than the USEPA RfD and Health Advisory. However, MassDEP has concluded that the study, while informative and concerning, does not alone provide a sufficient basis for regulatory decisions. The BMDLs from this study are based on a relatively small number of human subjects; do not fully account for exposures to other PFAS; and the functional significance of the reported effects has been questioned. Like most regulatory agencies to date, MassDEP views this study (and other epidemiological studies) as supporting evidence in RfD and drinking water value derivations and have relied on animal bioassay data in the quantitative derivations of drinking water guidance values.
1	CLF	The proposed standard ignores a growing body of scientific evidence that there is no safe level of PFAS.	It is a matter of ongoing scientific discussion as to whether thresholds exist for various adverse effects associated with a variety of chemicals, not just PFAS. Conventional regulatory toxicology practice involves treating non-carcinogenic effects as threshold effects. In this case, MassDEP has concluded that the proposed standards, which take into account the available studies, are sufficient to protect against significant non-cancer risks attributable to exposures from consumption of groundwater and are supported by the science.
1	CLF	MassDEP’s proposal relies upon a reference dose that is higher than the reference doses identified for individual PFAS by ATSDR, NRDC, and other States.	MassDEP RfD values are within the range of those derived by other agencies. See the accompanying Technical Support Document for a comparison of these values. MassDEP notes that the range of values for RfDs developed by different organizations is indicative of experimental variability associated with the data and differing interpretations of the data.
1	CLF	MassDEP failed to apply an additional UF of 10 to protect infants, developing fetuses, and children as recommended by the National Academy of Sciences.	Developmental effects are the PODs used in the RfD derivations. MassDEP applied an additional UF to account for data indicating effects at lower levels for a number of endpoints. MassDEP does not agree that an additional UF is warranted by current data.
1	CLF	In recognition of the significant toxicity of PFAS, the vulnerability of the most sensitive subpopulations to PFAS, and the numerous uncertainties regarding the toxicology of PFAS, MassDEP should use only the most conservative assumptions to protect public health. Specifically, MassDEP should align its approach to regulating PFAS compounds with the “more protective choices” set forth in Tables 4, 5, 6, and 7 of the [attached] NRDC report.	Adopting only the most conservative options for all toxicological and exposure parameters is inconsistent with toxicology and risk assessment practice as implemented by USEPA, MassDEP and other regulatory agencies. With respect to PFAS, no agency has adopted the most conservative option for all parameters in deriving drinking water guidance or standards. The options selected by MassDEP for the various parameters are summarized in the accompanying Technical Support Document. These are all within the range of scientifically appropriate values selected by one or more regulatory agencies.

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1	DoD	MassDEP is proposing cleanup regulations based on draft and incomplete toxicological information that is not intended to inform regulatory determinations.	MassDEP considered a wide range of available toxicological data and assessments, including peer-reviewed scientific studies and final and draft documents published by other regulatory agencies (e.g. the ATSDR Draft document and publications by other states) in its deliberations. MassDEP did not use the draft values as the basis of its standards.
1	DoD	MassDEP should justify the reliance on the draft ATSDR Toxicity Profile, and should address the reliance on some draft documents and not others (e.g. USEPA’s draft assessment of GENX and PFBS).	The ATSDR draft document, along with many other sources, was considered by MassDEP. The ATSDR document was not the basis of the proposed standards. MassDEP has not proposed standards for GenX or PFBS. Hence documents pertaining to those compounds were not assessed at this time.
1	DoD	MassDEP should address the decision not to pursue a more critical approach to the evaluation of published toxicity studies (e.g., like that MassDEP used for TCE).	MassDEP has evaluated key published studies. MassDEP’s reviews and conclusions regarding these can be found in the accompanying Technical Support Document.
1	DoD	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 values to establishing drinking water standards for PFOS PFOA and/or total PFAS.	<p>As described in the Technical Support Document accompanying these responses, MassDEP has not relied on the ATSDR MRL values as the basis of its PFAS standards.</p> <p>MassDEP does concur that the ATSDR and USEPA may apply their respective toxicity values differently. However, toxicologically these values are very similar. Both MRLs and RfDs are estimates of average daily exposure to a chemical that is likely to be without appreciable risk of adverse non-cancer health effects. Both are based on exposure levels that have been associated with the occurrence (or absence) of toxic effects, adjusted to estimate exposure levels unlikely to result in adverse health effects in a population exposed over a specified time period. MRLs are derived by ATSDR and meant to be used as a screening tool. They are derived by dividing a No Observed Adverse Effect Level (NOAEL), a Lowest Observed Adverse Effect Level (LOAEL) or a Benchmark Dose (BMD) by an appropriate uncertainty factors to account for such factors as extrapolation from an animal study to humans, interindividual variability in sensitivity in the human population, and data base uncertainties). MRLs are typically in units of mg/kg/day or ppm. MRLs can be acute (14 days or less), intermediate (15-365 days), or chronic (>365 days). USEPA RfDs are used in evaluating non-carcinogenic effects resulting from environmental exposures, for example from a Superfund site. The RfD is generally expressed in units of milligrams per kilogram of body weight per day (mg/kg/day).</p>
1	DoD	It is unclear what specific toxicological studies aligned with the new RfD 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.	<p>These issues are addressed in the accompanying Technical Support Document.</p> <p>MassDEP is aware of the strengths and weaknesses of different approaches to identifying a POD for developing an RfD. Uncertainty Factors are applied, as warranted, to PODs that may be established based on experimentally derived LOAEL, NOAEL or benchmark dose (BMD) values. BMDs can take into account the full dose response curve but often cannot be derived due to a lack of statistically acceptable dose response model fits. Even when acceptable statistically based fits can be achieved, BMD comparisons across compounds can be limited due to a lack of comparable dose group spacing in the lower portions of the dose response that are typically of most relevance to environmental exposures.</p>
1	DoD	MassDEP specifies that the lower RfD is supported on the basis of a number of epidemiology studies. Additional references, details of how supporting data was used, and which was excluded are needed to fully assess the validity of the document.	Similar to USEPA and many other regulatory agencies that have assessed PFAS toxicity, MassDEP did not use the epidemiology data as a basis of its revised RfD. Therefore, as discussed in the accompanying Technical Support Document, MassDEP did not replicate the extensive reviews of the epidemiology studies that have been completed by other agencies, which have identified associations between exposures to PFAS and a range of health effects.

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1	DoD	It is recommended that Benchmark dose (BMD) analysis be employed to derive a value that is protective of human health.	In MassDEP’s assessment as detailed in the accompanying Technical Support Document, BMD analysis has been relied upon where the available data is sufficient and the application is appropriate.
1	GHD	MassDEP discusses the Minimum 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.	<p>As described in the Technical Support Document accompanying these responses, MassDEP has not relied on the ATSDR MRL values as the basis of its PFAS standards.</p> <p>MassDEP does concur that the ATSDR and USEPA may apply their respective toxicity values differently. However, toxicologically these values are very similar. Both MRLs and RfDs are estimates of average daily exposure to a chemical that is likely to be without appreciable risk of adverse non-cancer health effects. Both are based on exposure levels that have been associated with the occurrence (or absence) of toxic effects, adjusted to estimate exposure levels unlikely to result in adverse health effects in a population exposed over a specified time period. MRLs are derived by ATSDR and meant to be used as a screening tool. They are derived by dividing a No Observed Adverse Effect Level (NOAEL), a Lowest Observed Adverse Effect Level (LOAEL) or a Benchmark Dose (BMD) by an appropriate uncertainty factors to account for such factors as extrapolation from an animal study to humans, interindividual variability in sensitivity in the human population, and data base uncertainties). MRLs are typically in units of mg/kg/day or ppm. MRLs can be acute (14 days or less), intermediate (15-365 days), or chronic (>365 days). USEPA RfDs are used in evaluating non-carcinogenic effects resulting from environmental exposures, for example from a Superfund site. The RfD is generally expressed in units of milligrams per kilogram of body weight per day (mg/kg/day).</p>
1	GHD	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.	The ATSDR draft document, along with many other sources, was considered by MassDEP. However, the ATSDR document was not the basis of the proposed standards. The accompanying Technical Support Document discusses consideration of information from different sources.
1	GHD	<p>MassDEP concluded that it was necessary to have an additional uncertainty factor without providing justification for its use.</p> <p>GHD believes there are already sufficient UFs included in the PFAS toxicity analysis and drinking water calculations to make the existing criteria sufficiently protective.</p> <p>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.</p> <p>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 an UF appears to be a convenient short cut.</p> <p>MassDEP should provide further technical support and reasoning for their rationale for including an additional UF to lower the USEPA USPFOA/PFOS toxicity criteria.</p> <p>It is recommended that MassDEP consider removing the additional data base UF.</p>	Detailed justification is presented in the accompanying Technical Support Document. Briefly, MassDEP is applying an additional database UF equal to the square root of 10. The resulting values, when rounded, yield the proposed RfD. This decision is consistent with longstanding USEPA UF selection practice and guidance. This decision is well supported based on a review of existing data that indicate a lower reference value would likely result if additional data on various endpoints were available. It accounts for a significant potential that the existing USEPA RfD is under-protective.

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1	GHD	<p>The MassDEP toxicology discussion does not specifically mention the impact of the USEPA’s toxicokinetic modeling between animals and humans for PFOA and PFOS. 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.</p> <p>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.</p>	<p>This comment is unclear. The referenced model does not depend solely on animal studies as it in fact included parameters derived from human data (e.g. serum clearance values). The model is applied to account for the fact that humans clear these compounds from the body much more slowly than the test animals, resulting in prolonged internal exposures and higher steady state levels. This does not reduce the animal NOAELs but adjusts them to humans and reduces, rather than contributes to, uncertainty.</p>
1	Green & Crouch	<p>MassDEP’s currently proposed standards are based almost entirely on only two studies in rodents: One study of PFOA in laboratory mice (Lau et al., 2006), in which minor, transient, developmental effects were reported; One study of PFOS in laboratory rats (Luebker et al., 2005) that reported “delayed eye opening” and reduced birth weights in neonates;</p>	<p>MassDEP does not agree with the statement that its toxicity values for PFOA and PFOS are based on only two studies in rodents. As stated previously, MassDEP reviewed the available data on PFAS and opted to revise the RfDs for PFOA and PFOS. The RfDs are based on the available toxicity information for a number of endpoints, with similar candidate RfDs based on several studies.</p>
1	Green & Crouch	<p>MassDEP toxicity values do not reflect well-established, marked differences in sensitivities to PFOA and other PFAS between and among laboratory rats, mice, monkeys, and humans.</p> <p>Abundant evidence indicates that rats and mice are highly susceptible to the effects (both adverse and beneficial) of chemicals (both endogenous and exogenous) that act via PPARα, while humans and other mammals—including guinea pigs, hamsters, rabbits, and monkeys—are relatively resistant to these effects.</p>	<p>The differences in species sensitivities are implied to involve a PPARα mediated mechanism of action. This issue is discussed in all of the federal and state toxicity documents on PFAS and in the open literature. There are now several experimental studies showing PPARα dependent and PPARα independent pathways of PFAS toxicity and neither is well characterized in either humans or animals.</p> <p>The comparison between animal and human sensitivity is based on limited in vitro data using human and mouse PPARα activity and also on results from humanized PPARα animals. Although humanized PPARα activity in animals was limited, fetal liver weight was increased similarly in wild type and humanized PPARα mice after in utero exposure. Additionally expression of genes associated with PPARα in fetal liver was increased to a greater degree in humanized PPARα mice than in wild type mice.</p> <p>With respect to data from other species, the approach taken by MassDEP is consistent with that of USEPA and other regulatory groups in the US. Data from the other species noted in the comment are much more limited than that from studies on rats and mice. Information on the relative sensitivities across species is therefore limited. As for monkeys being less sensitive than rodents, the data indicate that the dose that caused lethality in monkeys (see Butenhoff et al., 2002; Goldenthal 1978) was not lethal to adult rodents (Buttenhoff 2004).</p> <p>With regard to the rabbit data cited by the commenter, a dose related increase in incidence of skeletal variation, extra ribs or 13th rib, was observed, with incidence of 16, 20, 30, and 38% in the 0, 1.5, 5, and 50 mg/kg/groups. (Gortner, 1982, cited in USEPA 2005a).</p> <p>The commenter suggested that data on non-responsive animals be considered for RfD derivation. However, the USEPA (1991) guideline on developmental risk assessment recommends the use of sensitive species.</p>

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1	Green & Crouch	MassDEP ignores reliable, relevant evidence from controlled studies of PFOA and PFOS in laboratory monkeys.	The monkey studies that the commenter is referring to have various limitations that preclude their use as the basis for RfD derivation. These include very small numbers of animals, severe toxicity at the lowest dose, loss of animals during the study due to toxicity and/or mortality, and lack of dose-response for key endpoints (e.g. increased liver weight). To MassDEP’s knowledge no US regulatory agency has relied on the cited monkey data as the basis of an RfD derivation for PFAS.
1	GZA	The USEPA had already applied sufficiently conservative and protective uncertainty factors in developing the current advisory levels and the addition of further vague uncertainty factors is not supported by available toxicity data.	MassDEP disagrees with this statement. As discussed in detail in the accompanying Technical Support Document, considerable data demonstrates that the USEPA values are not sufficiently health protective. Other states have reached the same conclusion and the MA Health Advisory Committee concurred with this conclusion as well.
1	GZA	It is unclear if immunotoxicity in humans represents a truly critical health effect or rather a transient, short-term effect.	Immunotoxicity is a significant concern as indicated by the National Toxicology Program, which has concluded that both PFOA and PFOS are presumed to be an immune hazard to humans. Research at Harvard University has also documented immune effects in children exposed to PFAS and have stated that these effects are clinically relevant.
1	LSPA	As the science of these compounds continues to evolve, we expect that MassDEP policy will reflect sound technical and scientific principles, and that the standards will continue to evolve with the science.	MassDEP is committed to follow scientific developments in this area and will consider revisions as appropriate.
1	MCWRS	MCWRS had previously recommended that MassDEP pursue a state Maximum Contaminant Level (MCL) for Per- and Polyfluoroalkyl Substances (PFAS) if it intended to regulate this contaminant, rather than regulating via health advisory and guidance documents. MCWRS stands by this earlier comment but believes it is premature at this time to set an MCL or a Massachusetts Contingency Plan (MCP) standard for PFAS. As an alternative, MCWRS suggests that MassDEP continue to use the current federal health advisory of 70 nanogram per liter (ng/L), while evaluating or performing the science needed to arrive at a reasonable and achievable protective standard.	<p>MassDEP has evaluated the science and arrived at a reasonable and achievable, protective GW-1 standard for drinking water.</p> <p>As discussed in the Technical Support Document, MassDEP has concluded that the available data demonstrate that the USEPA health advisory of 70 ppt is not health protective. Several other states that have evaluated the toxicity information relating to these PFAS have reached the same conclusion. MassDEP is pursuing the adoption of an MCL as part of a separate regulatory promulgation process.</p>
1	MWWA	The RfD for PFOA/PFOS contains 3 safety factors. These factors more than compensate for the additional safety factor of 4 proposed by MassDEP.	MassDEP disagrees. The additional uncertainty factor accounts for data not addressed by USEPA indicating that effects are likely at lower exposure levels. See the accompanying Technical Support Document. As noted, the additional UF is equal to the square root of 10, not 4.
1	MWWA	MWWA believes that MassDEP should not rely on the ATSDR toxicity profiles until they are final, but they should consider comments submitted by Drs. Green and Crouch.	MassDEP considered information in the ATSDR document, along with many others. MassDEP’s standards are not based on the ATSDR document. Comments by Green and Crouch have been considered and specific responses to their comments are included herein.
1	Sanborn Head	Current, important, scientific evidence (some not available when USEPA established its guideline of 70 ppt) demonstrates that concentrations this low pose no significant threat to public health. We urge MassDEP to carefully review and consider comments submitted by Green Toxicology that discuss this new evidence.	<p>MassDEP has reviewed the scientific evidence and has reached a different conclusion. As discussed in detail in the accompanying Technical Support Document, many other independent toxicologists have reached similar, although not identical conclusions. The MassDEP Health Effects Advisory Committee also agreed with MassDEP’s determination that the USEPA HA of 70 ppt for PFOS and PFOA does not adequately protect the health of the fetus, infants and children.</p> <p>Comments provided by Green Toxicology have been reviewed and addressed separately.</p>

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
1	Sanborn Head	<p>A principal reason to believe that the USEPA drinking water health advisory of 70 ppt is a “safe level” stems from the safety factor of 300 built into the underlying reference dose..... While this is a common standard “default” assumption for deriving reference doses, evidence related to PFAS effects mediated via the PPARα (which effects include actions on the liver and on development) indicates precisely the opposite from the default. PFOA is now known to be much more toxic to mice and rats than it is even to other rodents, such as guinea pigs and hamsters, let alone to monkeys and, importantly, humans.</p> <p>It would thus be scientifically justifiable, and based on the evidence more technically correct, to either remove this safety factor of 3 or to apply the factor in the opposite sense (and by doing so increase the LHA by a factor of about 10).</p>	<p>USEPA relied upon a well-established approach for selecting and applying UFs in the derivation of its RfDs and clearly justified each UF applied to the point of departures in its derivation of the PFOS and PFOA RfDs (USEPA 2016).</p> <p>The commenter has also indicated that mice and rats are more sensitive to PFOA toxicity than other rodents, primates and humans since endpoints like liver and developmental effects are mediated by the PPARα which is implied to be expressed in mice and rats to a greater degree than in the other stated species.</p> <p>MassDEP does not agree with the statement that humans are less sensitive than mice as there are no clear data to support the statement. In fact, available data indicate that the toxicity of PFOA is mediated by both PPARα independent pathways and PPARα dependent pathways. None of these pathways is fully understood in either humans or animals. Thus, the commenter’s recommendation to lower the UFs is unjustified, is not a human health protective approach and is inconsistent with existing practice.</p>
1	Sanborn Head	<p>The commenters suggest that various uncertainty factors that were applied by USEPA in its RfD derivation were unnecessary. They suggest that well established uncertainty factors used to account for interspecies variability, variability in sensitivities among people and uncertainty relating to exposure levels that cause effects should be either reduced or removed.</p> <p>For example, commenters specifically suggested that the Uncertainty factor of 10 to protect sensitive sub-populations is arguably unnecessary because the subpopulation thought to be most sensitive to PFAS – developing infants – is explicitly accounted for in the derivation of the LHA from the RfD – which is designed to protect the developing fetus and nursing infant, via the child’s nursing mother.</p>	<p>The proposed reductions in uncertainty factors suggested by the commenters are inconsistent with accepted methodologies. Notably USEPA, ATSDR, as well as public health and environmental agencies in other States that have closely assessed the data have determined it appropriate to apply the UFs used by USEPA in its RfD derivation and in some cases additional UF.</p> <p>The UF is designed and needed to account for differences between people, not only life stages. Infants may also vary considerably in their sensitivities to toxic compounds due a number of factors.</p>
1	Sanborn Head	<p>MassDEP has proposed to add another safety factor of 4 to the USEPA’s RfD to reduce the level from 20 ng/kg-d to 5 ng/kg-d to account for potential immunotoxicity effects. In the absence of a scientifically reliable study, the additional safety factor of 4 is entirely arbitrary. MassDEP’s stated basis of the additional factor of 4 reflects concern over potential Immunotoxicity effects, which differs from the developmental basis of the USEPA RfD. This is a non-standard and unjustified approach.</p>	<p>As described in the accompanying Technical Support Document, MassDEP is applying an additional database UF equal to the square root of 10. The resulting values, when rounded, yield the proposed RfD. This decision is consistent with longstanding USEPA UF selection practice and guidance. This decision is well supported based on a review of existing data that indicate a lower reference value would likely result if additional data on various endpoints were available. It accounts for a significant potential that the existing USEPA RfD is under-protective as a result of an incomplete characterization of the chemicals’ toxicity.</p>
1	Sanborn Head	<p>Commenter notes that the USEPA chose a developmental toxicity study in laboratory mice as the basis of its RfD even though no developmental health effects were linked to PFOA in the C8 Studies (the most comprehensive epidemiological studies conducted to date on people exposed to high levels of PFOA in their drinking water with approximately 70,000 respondents). Specifically, these studies found no associations between exposures to PFOA (whether measured in water or assessed according to concentrations in people’s blood) and rates of birth defects, miscarriages, stillbirths, and/or preterm/low birth weight.</p>	<p>USEPA identified a variety of different endpoints as candidate points of departure for RfD development for PFOA, many of which yielded values equivalent to the final RfD. Epidemiological studies on people are insensitive in their ability to detect effects due to confounding factors and exposure level variation. Nevertheless, MassDEP notes that some epidemiological studies have reported associations between PFOA serum levels and adverse developmental outcomes.</p>
1	STEEP	<p>The reference doses (RfDs) developed by EPA for PFOS and PFOA are not adequately protective.</p>	<p>MassDEP agrees and has proposed to lower the USEPA RfD.</p>

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
1	STEEP	Harvard researcher Philippe Grandjean on the Faroe Islands has shown associations between PFAS exposures in young children and suppressed antibody response to vaccines. Based on benchmark dose calculations of immunotoxic effects, Grandjean and Budtz-Jorgensen ⁴ suggested that 0.1 ng/mL serum would be an appropriate benchmark dose level for PFOS and PFOA, which corresponds to 1 ng/L when converted to drinking water concentration assuming a ratio of 1:100.	MassDEP has reviewed this study as well as other information and concurs that immune effects observed in humans and animals are a sensitive effect for PFOS. As discussed in the accompanying Technical Support Document, MassDEP has addressed this data, as well as other data indicating effects at lower levels, through the application of an additional data base uncertainty factor (UF) in the RfD derivation. MassDEP analyzed various data to determine the magnitude of the UF and decided that an additional UF of the square root of 10 was appropriate and consistent with UF selection guidance. The MA Health Effects Advisory Committee agreed with this determination.
1	STEEP	Current evidence on rodent models has shown that low-dose PFOA exposures can impair mammary gland development. While NJDEP’s recommended MCL was not based on this endpoint due to a lack of precedent for using this endpoint as the basis for risk assessment, NJDEP applied an extra uncertainty factor to account for this and other sensitive endpoints.	As discussed in the accompanying Technical Support Document, MassDEP has reviewed the studies of PFOA on the mammary gland and considers these study results as evidence supporting a lower RfD for PFOA.
1	MWWA	Guinea pig studies may be more appropriate for determining MCLs for PFAS compounds than mice.	To our knowledge, no regulatory agency has relied on these studies of guinea pigs as basis of toxicity or drinking water values in part because the data from studies on this species are very limited.
1	WRAFT	The commenter included a presentation made by Dr. Linda Birnbaum, former Director of the National Institute for Environmental Health Sciences at the second National PFAS Conference held in June at Northeastern University where Dr. Birnbaum stated that if pancreatic tumors on rats were used as the endpoint, a health protective regulatory level for PFOA would be more like 0.1 parts per trillion.	MassDEP is aware of the new NTP study data that Dr. Birnbaum discussed at the conference documenting increased pancreatic cancer rates in animals exposed to PFOA. However, the NRP has not issued a final report on this data and there are a number of issues regarding the interpretation of the data with respect to lower dose exposures. Thus, as detailed in the accompanying Technical Support Document, the proposed Method 1 Standard for groundwater is based on the revised RfD derived therein. MassDEP will follow developments regarding the interpretation and use of the data noted by Dr. Birnbaum.
1	3M	The scientific decision of lowering the PFAS reference doses appears to be based on MASSDEP’s review of published assessments done by ATSDR, NTP, and NJDQWI, but MassDEP does not clearly nor thoroughly describe how it derived the reference dose used to set the proposed Method 1 Standards.	As discussed in more detail in the accompanying Technical Support Document, MassDEP concluded that the RfDs for PFOA and PFOS derived by USEPA were insufficiently health protective. This conclusion is consistent with that reached by a number of other Agencies that have reassessed the data regarding the toxicology of these compounds. The MassDEP Health Effects Advisory Committee concurred with this conclusion.
1	3M	MassDEP reduced the 2018 ORSG to 20 ng/L by applying a database uncertainty factor, but failed to specifically describe or document the need for a data base uncertainty factor or how it derived the specific uncertainty factor value. This decision lacks a logical scientific basis and is inconsistent with EPA guidance on setting and uncertainty factor based on database uncertainty. MassDEP provided no information to ascertain what specific data was lacking; Asserting that adverse responses occur at levels below those used in the RfD calculations is not the same as saying that data is lacking.	The accompanying Technical Support Document further explains the basis of MassDEP’s approach. Regarding the Uncertainty Factor (UF) selection, highlighted information below from USEPA guidance on UF allocation, as quoted by the 3M in its comments, supports MassDEP’s application of an additional UF in this case. “The database UF is intended to account for the potential for deriving an under protective RfD/RfC as a result of an incomplete characterization of the chemical’s toxicity. In addition to identifying toxicity information that is lacking, review of existing data may also suggest that a lower reference value might result if additional data were available. Consequently, in deciding to apply this factor to account for deficiencies in the available data set and in identifying its magnitude, the assessor should consider both the data lacking and the data available for particular organ systems as well as lifestages.” Information on the specific data limitation issues that informed MassDEP’s UF selection and approach is presented in the accompanying Technical Support Document. This approach is both consistent with USEPA guidance and logical.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
1	3M	Post hoc application of an uncertainty Factor on the reference dose derived by EPA is without precedent – MassDEP must perform its own chemical specific GW-1 standard assessment for each of the six PFAS	<p>As discussed in more detail in the accompanying Technical Support Document, MassDEP concluded that the RfDs for PFOA and PFOS derived by USEPA were insufficiently health protective. This conclusion is consistent with those of a number of agencies that have reassessed the data regarding the toxicology of these compounds. The MassDEP Health Effects Advisory Committee concurred with this conclusion. MassDEP concluded it was appropriate to address this issue through the application of an additional UF. Application of an UF like this to account for existing data that clearly suggests that a lower reference value might result if additional data were available is appropriate and, in fact, consistent with established approaches regarding the application of uncertainty factors in RfD derivations.</p> <p>MassDEP acknowledges that chemical specific values, with a combined hazard index approach, would constitute a reasonable alternative approach. However, this does not invalidate the approach taken by the Department.</p>
1	3M	The studies and conclusions relied upon by ATSDR, NJDEP and NTP contain critical flaws, and cannot be used to support the proposed uncertainty factor and should be carefully and critically reviewed By MassDEP.	MassDEP has critically reviewed key elements of the studies and conclusions by the noted organizations, as well as additional information including materials provided to the Department during the public comment period. The accompanying Technical Support Document details the basis of MassDEP’s final conclusions, which differ from those reached by ATSDR and NJDEP.
1	3M	MassDEP’s reliance on the MRLs set by ATSDR is inappropriate because the MRLs are critically flawed, unsupported by the science, and should not be used by MassDEP for the reference dose derivation.	MassDEP does not agree with the commenter’s statement regarding the ATSDR draft MRLs being critically flawed. However, the Department did not rely on these values as the basis of its proposed values.
1	3M	The NTP immunotoxicity monograph (2016) on PFOA and PFOS provided insufficient support for extrapolating effects in animals to humans.	NTP states: “NTP conducted a systematic review to evaluate the evidence on exposure to PFOA or PFOS and immune-related health effects to determine whether exposure to either chemical is associated with immunotoxicity for humans. NTP concludes that both PFOA and PFOS are presumed to be an immune hazard to humans based on a high level of evidence from animal studies that PFOA and PFOS suppressed the antibody response and a moderate level of evidence from studies in humans. The evidence that these chemicals affect multiple aspects of the immune system supports the overall conclusion that both PFOA and PFOS alter immune functions in humans.”
1	3M	NJ DWQI’s use of increased liver weights in rodents with PFOA exposure is not appropriate nor scientifically justified for human risk assessments. There was a serious technical error by NJ DWQI in its BMD modelling which resulted in an artificially low PFOS MCL; and increased liver weights in rodents with PFOA exposure is not appropriate nor scientifically justified for human risk assessments.	MassDEP considered, but did not rely specifically on the NJ DWQI value or assessment as the basis of its PFOS RfD and GW-1 values. However, MassDEP does not agree with commenter’s statement regarding the relevance of increased liver weights in rodents as an endpoint of concern to humans. This is a matter of ongoing toxicological discussion and debate and different agencies and toxicologists have reached differing conclusions on this issue.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
1	3M	<p>The developmental epidemiologic association reported between lower birthweight per measured PFOA or PFOS maternal or cord blood is likely not causal but consistent with confounding and/or reverse causation via glomerular filtration rate (GFR).</p> <p>Human Epidemiological Evidence Does Not Support an Association Between PFAS Exposure and Immune Effects. There is a lack of support for decreased antibody response to vaccines. There is a lack of support for increased risk of asthma diagnosis.</p>	<p>MassDEP is aware of this issue regarding the reduced birth weight data. However, MassDEP has not relied on this data or other epidemiological data in its derivations. The human epidemiological data does however provide compelling evidence that PFAS impact human health and support policy and regulatory efforts to reduce exposures.</p> <p>It is appropriate to rely on the conclusions of the independent NTP. NTP conducted a systematic review to evaluate the evidence on exposure to PFOA or PFOS and immune-related health effects to determine whether exposure to either chemical is associated with immunotoxicity for humans. NTP concludes that both PFOA and PFOS are presumed to be an immune hazard to humans based on a high level of evidence from animal studies that PFOA and PFOS suppressed the antibody response and a moderate level of evidence from studies in humans. The evidence that these chemicals affect multiple aspects of the immune system supports the overall conclusion that both PFOA and PFOS alter immune functions in humans.</p> <p>https://ntp.niehs.nih.gov/pubhealth/hat/noms/pfoa/index.html</p>
1	3M	<p>Commenter also provided Aug 20, 2018 3M Comments on ATSDR Draft Toxicological Profile for Perfluoroalkyls.</p>	<p>MassDEP considered, but did not base its proposed standards on the draft ATSDR document. The ATSDR draft document, with lower more conservative toxicity values (MRLs) compared to the USEPA RfDs for PFOS and PFOA, was merely one of several reasons that prompted MassDEP to reassess its toxicity and drinking water guidance values for PFAS. Please see the accompanying Technical Support Document for additional details.</p>

Question 2

As proposed, the GW-1 standard applies to the sum of the six PFAS (one additional compound beyond those included in MassDEP’s June 2018 ORSG). In light of the dearth of toxicity, epidemiology and pharmacokinetic data on PFHpA and PFDA, should these compounds be included in this approach, excluded or treated separately? Should additional compounds be included and if so why?

The comparison of the sum of the PFAS concentrations to a single standard addresses the similar toxicity/mechanism of action of these compounds – similar to the 2,3,7,-TCDD (dioxin) standard. Alternatively, MassDEP could (a) promulgate chemical-specific standards for each PFAS, or (b) promulgate chemical-specific standards AND a cumulative (possibly higher) standard which would also have to be met (for example, the individual chemicals would have to be below 20ppt and the sum would have to be below 35 ppt). **MassDEP seeks comment on which PFAS should be summed, if any, and the target concentration for the summed and chemical-specific standards.**

Summary of written comments received in response to Question 2-- A range of comments were received on this topic. Briefly these included:

- All PFAS should be included, not just the six.
- Include PFHpA and PFDA and add two more longer-chain compounds.
- Do not include these compounds, or any others, due to a lack of data.
- Chemical specific values should be derived for each compound and either only PFOS and PFOA should be summed, consistent with USEPA, or none should be summed.
- The GW-1 standard should be lower – 1 ppt or as low as possible.
- The GW-1 standard should be higher.

MassDEP's general response to written comments on Question 2-- MassDEP has concluded that its approach, which treats a subgroup of six PFAS, which are highly similar in chemical structures, being +/- two in carbon chain length and having the same functional groups as PFOS and PFOA, as being equipotent and additive in toxicity is appropriate. Thus MassDEP is neither dropping PFHpA or PFDA nor adding other PFAS compounds to the subgroup being addressed. Although other PFAS may well contribute to overall toxicity, the relative potencies of other compounds are more likely to differ as chemical structures diverge.

Specific comments and responses related to Question 2 are summarized below.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
1,2	MWWA	Attached: Comments from Drs. Green & Crouch to ATSDR re: Comments on ATSDR’s Toxicological Profile for Perfluoroalkyls, August 20, 2018.	MassDEP did not rely on the draft ATSDR Toxicological Profile for Perfluoroalkyls as the basis of its revised PFAS values.
1,2	MWWA	Attached: Health-Based Drinking Water Value Recommendations for PFAS in Michigan, Michigan Science Advisory Workgroup, 2019.	MassDEP is aware of this document and has reviewed it.
2	ACC	The available science does not support applying a single value to multiple PFAS. MassDEP has proposed to apply a single groundwater standard to the sum of six PFAS that vary significantly in the availability of health effects information and metabolism. While much is known about PFOS and PFOA, less data is available for the other four substances. Even in the case of PFOS and PFOA, the mechanism by which exposure to these substances causes health effects in laboratory animals is unknown.	MassDEP agrees that there is considerable variability in the extent of health effects information for these compounds. What is clear is that they share very similar chemical structures and cause similar types of effects. USEPA concluded that the two most studied compounds in this group, PFOA and PFOS, should be considered to have additive and equipotent effects. As discussed in the accompanying Technical Support Document, MassDEP has extended this approach to an additional four compounds within +/- two carbons of PFOS and PFOA and containing the same functional groups. Treating PFAS in subgroups based on highly similar structural determinants and similarities in toxicity test outcomes is a logical and scientifically appropriate approach to addressing exposure limits for the PFAS compounds.
2	ACC	The grouping of substances under a single standard is justified only when the substances are believed to cause health effects by the same mechanism of action.	As appropriately noted by the commenter, the mechanism(s) of action of these compounds is unknown. These compounds are, however, known to interact with a variety of cellular receptors, exhibit well established structural similarities, and cause similar biological effects. Following USEPA’s approach to PFOA and PFOS, MassDEP has concluded that it is appropriately health protective to treat these compounds as being additive.
2	ACC	Similar evaluations of the potential health effects of exposure to PFHxS, PFHpA, PFNA, or PFDA are not available from EPA, and the draft evaluations for PFHxS and PFNA from the Agency for Toxic Substances and Disease Registry (ATSDR) indicate that a very limited amount of data exist for these substances – particularly data related to mechanism of action. In the case of PFDA and PFHpA, ATSDR concluded that “insufficient data are available for derivation” of minimum risk levels.	As discussed in the accompanying Technical Support Document, MassDEP agrees with these statements and has concluded that these issues support MassDEP’s approach.
2	ACC	Existing calculations of the risks associated with exposure to PFAS are highly dependent on estimates of the elimination half-lives of the substances. In the case of the PFAS identified by MassDEP, significant differences exist. While the half-life of PFHxS in humans is estimated to be on the order of 5 to 8 years, the half-life for PFHpA is estimated to be much shorter, and the limited data for PFDA and PFNA do not allow for a robust estimate of their half-life.	MassDEP notes that the half-life estimates, when available for individual people, vary considerably and overlap across compounds. The half-life data for PFHpA, while consistent with a shorter duration, are very limited. One study estimated a human half-life of about 1 year based on urinary excretion. A second study, based on a small number of adult male ski wax applicators, estimated half-lives ranging from approximately 1 -4 months. The limited extent of this data precludes firm conclusions regarding the typical range of half-lives in the general population for this compound. The limited data on PFDA indicate that it is likely to exhibit a human serum half-life comparable to PFOA and PFOS.
2	CDM Smith	MassDEP should develop compound-specific standards for each compound of concern and not combine them in an additive approach because their respective health effects and treatability may be different and contain a level of uncertainty. Examples of other states and Agencies taking this approach were provided.	MassDEP is aware that some other agencies have approached regulating PFAS one compound at a time. However, other agencies have taken an additive subclass approach and used the same toxicity value (e.g. VT; CT). The six compounds addressed in these standards are structurally very similar, where data exists, are associated with similar health effects (see accompanying Technical Support Document), and are all well-controlled using standard water treatment technologies.
2	CDM Smith	A combined sum standard for the proposed six compounds, which are commonly detected together in groundwater, may show an exceedance of the standard even though individually the compounds may be close to the minimum reporting limits.	MRLs for drinking water are sufficiently low that this not an issue.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
2	Clean Water Action	Clean Water Action applauds the steps taken by MassDEP to address this growing concern to public health; but urges you to take greater action in the form of regulating these chemicals, as a class, as strictly as technologically possible, which is far below the proposed 20 ppt sum the GW-1 Standards.	<p>MassDEP understands the scope of the PFAS issue and agrees that much additional research and policy work remains to be done regarding other PFAS compounds.</p> <p>With regard to more sensitive endpoints, MassDEP has evaluated the available studies and data, and judged that an additional uncertainty factor equal to the square root of 10 is well-supported at this time, but notes that additional data could support a different value in the future.</p> <p>With regard to other PFAS compounds to date, MassDEP scientists have not identified appropriate approaches to comprehensively address all PFAS. MassDEP has concluded, based on available data, that the longer-chain PFAS (+/- 2 carbons compared to PFOS and PFOA) are likely to present the greatest risk with respect to drinking water exposures. MassDEP is following scientific and policy development regarding other PFAS.</p>
2	CLF	Other PFAS (beyond the 6 proposed) should be considered. MassDEP should consider additive and cumulative from the many thousands of PFAS compounds currently under review.	MassDEP understands the scope of the PFAS issue and agrees that much additional research and policy work remains to be done regarding other PFAS compounds. To date, MassDEP scientists have not identified appropriate approaches to comprehensively address all PFAS. MassDEP has concluded, based on available data, that the longer-chain PFAS (+/- 2 carbons compared to PFOS and PFOA) are likely to present the greatest risk with respect to drinking water exposures. MassDEP is following scientific and policy development regarding other PFAS.
2	CLF	<p>MassDEP should establish a 1 ppt GW-1 standard as this limit is more consistent with the most recent research on health effects, or alternatively set the standard at the detection limit or the limit of treatment efficiency.</p> <p>MassDEP should establish a treatment technique standard for the PFAS class of chemicals</p>	MassDEP does not agree with this comment: 1) as discussed in responses to other comments, the current scientific data do not firmly support a GW-1 standard of 1 ppt based on toxicological considerations; 2) it is impracticable to set and enforce standards at or near analytical detection limits as quantifiably reproducible results cannot be achieved at that level; 3) to our knowledge the term “limit of treatment efficacy” has not been defined nor any such value derived. Any such value would need to consider the PFAS present, impacts on other water quality parameters and associated risks, which will vary from situation to situation.
2	DoD	DoD 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 and notification criteria for soil and groundwater, for all six PFAS.	MassDEP disagrees with this conclusion. See the accompanying Technical Support Document. Under the current law and regulations, PRPs are required to assess all chemical contamination at sites and to achieve a condition of “No Significant Risk” considering all contaminants. A decision against setting specific requirements would lead to uncertainty about the acceptability of site-specific cleanups and a great deal of variability in the levels of protection achieved at different sites. The proposed standards for the six PFAS are supported by science.
2	DoD	DoD finds the approach and justification for combining all six PFAS into one toxicity reference value is not technically defensible.	MassDEP disagrees. See accompanying Technical Support Document.
2	DoD	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.	<p>Relying on toxicity information from closely related chemical compounds to inform decisions regarding the toxicity of less-tested or untested compounds, a procedure known as “read across,” is a scientifically accepted approach.</p> <p>The MassDEP process is transparent, and the assessment and information relied upon in the assessment are publicly available.</p>

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
2	DoD	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.	<p>USEPA’s Risk Assessment Guidance for Superfund (RAGS) Part A provides guidelines for conducting site-specific risk assessment. It is not primarily a handbook for toxicological assessment. That said, the content of the cited section does not contradict MassDEP’s proposed approach.</p> <p>The half-life data for PFHpA are discussed in the accompanying Technical Support Document. Briefly, this data is very limited. One study estimated a human half-life of about 1 year based on urinary excretion. A second study, based on a small number of adult male ski wax applicators, estimated half-lives ranging from approximately 1 - 4 months. MassDEP is unaware of any data supporting a PFHpA human half-life of days.</p> <p>No data or references to support the claim that PFHxS is 10-fold less toxic were provided. As detailed in the accompanying Technical Support Document, MassDEP determined that the applied dose toxicity of PFHxS was within the range of the uncertainty and experimental variability with respect to effects on thyroid hormones. Other comparative data are insufficient to conclude that a 10-fold difference in potency exists.</p>
2	DoD	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.	As discussed in the accompanying Technical Support Document, available comparative toxicology data indicates that these longer-chain PFAS cause a similar range of responses. All the compounds addressed by MassDEP are very structurally similar to PFOA and PFOS. USEPA previously concluded that PFOS and PFOA should be addressed additively. To date, the mechanism(s) of action for PFAS toxicity has not been identified. MassDEP has concluded that it is logical and health protective to treat these compounds additively.
2	DoD	MassDEP should provide the rationale for the selection of the PFAS compounds MassDEP selected for Method 1 Standards.	The rationale for the selection of the PFAS addressed is fully explained in the accompanying Technical Support Document. Briefly, the compounds were selected based on chemical structural similarity (+/- two carbons compared to PFOS and PFOA with same functional groups). Compounds included in UCMR 3 and USEPA Method 537, for which data on drinking water concentrations is being determined were focused on.
2	DoD	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.	The accompanying Technical Support Document explains MassDEP’s reasons for applying the adjusted PFOS/PFOA RfD to the other four PFAS. Briefly, the available compound-specific information necessary to develop individual RfDs for the additional four compounds was deemed insufficient to demonstrate differences in toxicological potencies. Despite the vague comments regarding the limitations of NOAELs and LOAELs in toxicity evaluations, their use is consistent with well-established methods.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
2	DoD	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."	<p>A more complete assessment of the noted National Academies report ("A Class Approach to Hazard Assessment of Organohalogen Flame Retardants," 2019) supports the subclass approach to PFAS taken by MassDEP. The National Academies report cited by the commenter also states that “the class approach provides a mechanism for extrapolating from data-rich chemicals to data-poor chemicals and eliminates the need to collect data on all compounds.” It also cites examples of class and subclass approaches that have been taken by various agencies to assess groups of chemicals, stating that “The examples (cited) show that some classes have been defined solely by structure, others by a common metabolite, and still others by a mechanism of action.”</p> <p>Additionally, the cited report also states, regarding a class-based approach applied to phthalates (another group of chemicals), that “phthalates may not all act by the same mechanisms, and they do not have parallel dose–response curves. However, those facts do not negate the appropriateness of using general dose-addition methods in a cumulative risk assessment” (Phthalates and Cumulative Risk Assessment: The Tasks Ahead , NRC 2008). The National Academies report then goes on to state, “The concern expressed by the committee that wrote that report applies to other classes of chemicals if chemicals in those classes have similar activity in biologic systems.”</p> <p>Again, the PFAS subclass compounds addressed by MassDEP are very similar in chemical structure and have similar toxicities.</p>
2	DoD	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."	MassDEP agrees that PFOS and PFOA are not the same compound and have different structures. However, they are very similar, not identical. MassDEP acknowledges that the universe of thousands of PFAS includes a variety of chemical classes and structures and does not claim that these are all structurally closely related and similar in potencies and toxicities. MassDEP’s current proposal considers only perfluoroalkyl compounds that are +/- 2 carbons in chain length from PFOS and PFOA to be structurally very similar.
2	DoD	Consider revisions to the document that state that data not currently available for most PFAS and that, until such data are available, and as such, the assessment made assumptions of additivity and add concentrations of all PFAS as a default.	The accompanying Technical Support Document identifies data gaps and limitations. MassDEP’s approach regarding additivity does not apply to all PFAS, but is limited to six compounds that are very similar in chemical structures.
2	GHD	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.	MassDEP’s reasons for applying the adjusted PFOS/PFOA RfD to the other four PFAS are discussed in the Technical Support Document. Briefly, the available compound-specific information was deemed insufficient to demonstrate convincing differences in toxicological potencies.
2	GHD	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.	The PFAS subclass compounds addressed by MassDEP are very similar in chemical structure and have similar toxicities. MassDEP is specifically not regulating all PFAS as suggested by the commenter.
2	GHD	An alternate approach could be modeled after the relative potency factors developed by the USEPA for carcinogenic polycyclic aromatic hydrocarbons (cPAHs). Something similar could be developed for PFAS to provide a scientific basis for potency estimation (such as has been done by the Dutch National Institute for Public Health and the Environment.	MassDEP considered the data and analysis by the noted group and concluded that assessment, in consideration with other relative potency data, did not support different relative potency factors across the subgroup being addressed by MassDEP. This is discussed in the accompanying Technical Support Document.
2	GHD	GHD recommends that MassDEP develop a science-based approach that considers a larger group of compounds than just four.	The subclass of six PFAS addressed under these regulations was selected using a science based approach.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
2	GreenCAPE	At least 14 PFAS chemicals -so far-have been detected in Hyannis water due to the use of AFFF so it’s concerning that only 6 PFAS have been addressed in this document.	MassDEP understands the scope of the PFAS issue and agrees that additional research and policy work may be done regarding other PFAS compounds. To date, MassDEP scientists have not identified appropriate approaches to comprehensively address all PFAS. MassDEP has concluded, based on available data, that the longer-chain PFAS (+/- 2 carbons compared to PFOS and PFOA) are likely to present the greatest risk with respect to drinking water exposures. MassDEP will continue to follow scientific and policy developments regarding other PFAS.
2	GreenCAPE	We continue to encourage a class-based standard for PFAS.	MassDEP agrees that regulating these compounds one at time is inefficient and likely an impossible task. We also agree that PFAS as a group exhibit certain similar physiochemical characteristics. Our approach focuses on a prevalent subclass that exhibits great structural similarity, and where data exist, similar toxicity. MassDEP will follow scientific developments on the larger class going forward and consider alternatives for addressing additional subgroups.
2	GreenCAPE	The identity of 50% of PFAS precursors is still a mystery and they matter because they eventually become PFOS/PFOA. In addition, PFAS fluorotelomers transform into PFOA and PFOS in the body, so these compounds should also be studied for possible inclusion into a subclass of PFAS variants.	MassDEP is aware of this concern and will monitor future developments in the science of these compounds.
2	GreenCAPE	There is a need for a reliable, affordable analytical method to quantify the aggregate of all forms of PFAS.	MassDEP will continue to follow developments in analytical methods for PFAS.
2	LSPA	<p>There are insufficient data currently available that support the assumption of simple equipotency among all PFAS, particularly for compounds where ample toxicity data exist (as for PFOA) or little to no data exist (PFDA).</p> <p>Data suggest varying toxicity/potency among the PFAS compounds, which supports the use of separate RfDs.</p> <p>In lieu of applying one RfD to all 6 PFAS, we recommend that individual RfDs be derived based on compound-specific information. This approach would also be consistent with that used in other states (NJ, NH, MN etc.) and agencies (e.g., ATSDR).</p>	<p>This issue is discussed in the accompanying Technical Support Document. The proposed approach relies on the data from the compounds that have ample toxicity data (e.g. PFOA and PFOS) to inform decisions about very closely related compounds with more limited data (e.g., PFDA and PFHpA).</p> <p>Data available for some PFAS compounds are limited, and do not provide convincing evidence of significant differences in toxicological potencies across this particular subclass of compounds.</p> <p>MassDEP notes that the toxicity values adopted by several of the cited agencies do not differ significantly as they are within the range of uncertainty associated with such values.</p> <p>Additionally, VT and CT are treating 5 of the 6 compounds addressed by MassDEP in these regulations equivalently.</p>
2	LSPA	MassDEP recognizes that there is a dearth of toxicity, epidemiological, and pharmacokinetic data on two of these six compounds (PFHpA and PFDA) and asks if they should be included or excluded from the proposed standard. Since there is uncertainty concerning these two compounds, the LSPA proposes to exclude them until there is sufficient scientific data to develop a separate standard.	Existing data and evidence, including the similarity of certain PFAS compounds, justify the proposed standards.
2	LSPA	The RfD of 5E-06 in 310 CMR 40.0993 (6)(f) can also be applied to each individual PFAS when calculating hazard index – not just the sum, since Method 3 is calculating cumulative hazard.	All other factors being equal, the hazard index approach would yield the same value as the concentration addition approach.
2	Sanborn Head	The GW-1 groundwater standard would be protective of human health and the environment if set at 70 parts per trillion (ppt) consistent with the USEPA’s Lifetime Health Advisory (LHA) level. The LHA already contains a considerable degree of health protectiveness. The MassDEP’s proposed lower level of 20 ppt as a GW-1 groundwater standard is not based on scientific data but is the result of an additional safety factor that is not robustly evidence-based.	As discussed in the accompanying Technical Support Document, MassDEP does not agree with this conclusion.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
2	MWWA	If MassDEP moves forward with MMCL/GW-1 standard, they should not use a cumulative approach, but rather develop compound specific standards.	MassDEP has concluded that a cumulative approach is warranted by evidence that these compounds cause or are likely to cause similar health effects. See the accompanying Technical Support Document.
2	MWWA	New Hampshire and several other states are regulating individual MCLs.	MassDEP is aware of this but notes that these states are addressing these compounds individually at lower levels. MassDEP also notes, as discussed in the accompanying Technical Support Document and in other comment responses, that other states (Vermont; Connecticut; Minnesota) are also regulating some PFAS additively.
2	MWWA	MassDEP asked if PFHpA and PFDA should be included, excluded or treated separately, and MWWA would like to point out that New Hampshire is not regulating PFHpA and PFDA at this time. Because, as it admits, there is a dearth of toxicity, epidemiology and pharmacokinetic data on PFHpA and PFDA, MWWA believes it would be premature for MassDEP to regulate these compounds at this time.	As discussed in the accompanying Technical Support Document, MassDEP has concluded that the structural similarity of these compounds support their inclusion until more data become available. Excluding these compounds when there are compelling reasons to conclude that they are likely to cause effects similar to those of the more well studied and very structurally similar compounds would not be health protective as they would essentially be treated as having no toxicity.
2	NAIOP	There are insufficient data currently available to support an assumption of simple equipotency among all PFAS, particularly for compounds where ample toxicity data exist (as for PFOA) or little to no data exist (PFDA). Data suggest varying toxicity/potency among the PFAS compounds, supporting the use of separate RfDs.	MassDEP agrees that there is variability in the extent of health effects information for these compounds. What is clear is that they share very similar chemical structures and cause similar types of effects. USEPA concluded that the two most studied compounds in this group, PFOA and PFOS, should be considered to have additive and equipotent effects. As discussed in the accompanying Technical Support Document, MassDEP has extended this approach to an additional four compounds within +/- two carbons of PFOS and PFOA and containing the same functional groups. Treating PFAS in subgroups based on highly similar structural determinants and similarities in toxicity test outcomes is a logical and scientifically appropriate approach to addressing exposure limits for PFAS compounds. The available compound-specific information necessary to develop individual RfDs for the additional four compounds addressed by MassDEP was deemed insufficient to demonstrate convincing differences in toxicological potencies.
2	NAIOP	If MassDEP is going to stay with a summing approach and single RfD, we recommend deleting PFHpA and PFDA from the regulated group, as there is insufficient toxicity information available for these two compounds.	As discussed in the accompanying Technical Support Document, MassDEP has concluded that the structural similarity of these compounds supports their inclusion. Excluding these compounds when there are compelling reasons to conclude that they are likely to cause effects similar to structurally very similar compounds would not be health protective.
2	Sierra Club, Cape Cod	The MCP proposal to develop an MCL for 6 PFAS chemicals at 20 ppt is a big improvement over EPA’s draft Recommendations for Addressing Groundwater Contaminated by PFOS and PFOA.	MassDEP appreciates this support.
2	Sierra Club, Cape Cod	The waste site cleanup standards need to address alternative technologies to granular activated carbon (GAC) to remove PFAS chemicals as a class from contaminated drinking water.	This comment is beyond the scope of the proposed regulations. The MCP does not specify remedial technologies.
2	Sierra Club, Cape Cod	The Sierra Club assumes that all 5000 PFAS chemicals are potentially toxic and hazardous chemicals and should be treated as such until evidence shows this not to be true.	MassDEP’s approach focuses on a prevalent subclass of PFAS that exhibits great structural similarity, and where data exist, similar toxicity. MassDEP will follow scientific developments on the larger class going forward.
2	STEEP	There is ample evidence that MRLs ought to be considered for PFUnDA (C11) and PFDoDA (C12), along with PFDA that has already been added to the original five PFAS compounds in the proposed GW-1 standard.	MassDEP intends to monitor the developing science on these compounds. However, expanding the subgroup addressed to include these compounds would extend the carbon chain length beyond +/- 2 carbons from PFOA and PFOS, decreasing the overall structural similarity of the subgroup addressed. MassDEP believes that it is increasingly likely that differences in pharmacokinetics and toxicity will exist as chain lengths and functional groups vary further from the subgroup delineated by MassDEP in these regulations. Thus, at this time, MassDEP is not including these compounds in this subgroup approach. MassDEP will continue to evaluate the data to determine occurrence and whether additional standards are warranted.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
2	STEEP	Emerging research demonstrates that select shorter-chain alternatives may bioaccumulate to the same extent or to a greater degree than legacy compounds such as PFOA or PFOS. Pharmacokinetic models suggest that shorter-chain alternatives may be equally toxic compared to legacy compounds after adjusting for differences in toxicokinetics.	The data that MassDEP has reviewed indicate that some of these shorter-chain compounds exhibit lower applied dose toxicity and shorter serum half-lives compared to the compounds being addressed in these standards. While this does not imply these compounds present no risk, it does suggest that the risks attributable to applied doses (as opposed to serum levels) will be lower. MassDEP has decided to focus our current efforts on the higher risk compounds, but will continue to assess exposure, analytical methods and toxicity information on the shorter-chain compounds going forward.
2	STEEP	To the extent possible, PFAS should be considered as a class, or relevant subclasses, rather than attempting to regulate them one at a time. The scientific community has repeatedly acknowledged similar physicochemical characteristics linking >4,000 PFAS and has suggested PFAS be considered and regulated as a group or as subgroups.	MassDEP agrees that regulating these compounds one at time is inefficient and likely an impossible task. We also agree that PFAS as a group exhibit certain similar physiochemical characteristics. Our approach focuses on a prevalent subclass that exhibits great structural similarity, and where data exist, similar toxicity. MassDEP will follow scientific development on the larger class going forward.
2	STEEP	The current regulatory paradigm essentially assigns zero toxicity to PFAS not included in GW/MCL standards. While setting a total PFAS standard will be difficult to establish, it would be advisable to include a measure of total PFAS on a regular basis to be able to assess how abundant non-targeted PFASs are. This approach would allow MassDEP to be alerted to the presence of other PFASs that might become threats to public health.	MassDEP will consider such an approach in the future.
2	3M	<p>The additivity grouping approach proposed by MassDEP is not scientifically justified or adequately explained by MassDEP</p> <p>In deciding to group the PFAS compounds, MassDEP states that they have similar adverse effects, chemical structure, structural activity and serum half-life, but MassDEP provides no detailed analysis and assessment to prove its point; there is no reference to a published study or research; the grouping fails to recognize that in fact there are distinct differences in potencies and modes of action; there is a myriad of data available that provide compelling evidence illustrating the difference.</p>	As discussed in the accompanying Technical Support Document, MassDEP does not agree that the available data provide compelling evidence that clearly demonstrates differences in potencies and modes of action. In light of similarities in the chemical structures of the group of longer-chain PFAS addressed by MassDEP (+/- 2 carbons from the more well characterized PFOA and PFOS) and in their toxic endpoints and responses, MassDEP has concluded it is appropriate to treat these compounds as having additive toxicity. This is consistent with USEPA’s decision to treat PFOS and PFOA drinking water exposures in this manner. As drinking water exposures often involve multiple compounds in this group, MassDEP believes it is inappropriate to ignore likely additivity in assessing risks from exposure to these compounds.
2	3M	Other than Vermont, no other state or federal agencies are using the additivity grouping approach.	This statement is incorrect. As noted above, this is an extension of the approach taken by USEPA with respect to the derivation of the drinking water Health Advisory values for PFOS and PFOA. In addition to Vermont, Connecticut is also using the same approach, summing across five of the longer-chain PFAS. Minnesota is also using an additivity approach as they are relying on a combined hazard index to evaluate exposures to PFOS, PFOA and PFHxS.

Question 3

How should the GW-1 standard consider Relative Source Contribution? The target Hazard Index used to develop the Method 1 Standards is 0.2 to account for multiple chemical- and multiple pathway-exposures at and from 21E sites. PFAS has been described as “ubiquitous” in the environment, including exposures from common household products and foods. Is the assumption that 20% of a person’s exposure comes from drinking water sufficiently protective?

Summary of written comments received in response to Question 3 -- A number of comments were received relating to this issue. The RSC apportions the “acceptable dose” between drinking water and other sources of exposure such as the diet, allowing 20% of the total to come from drinking water. Some commenters supported MassDEP’s selection of a relative source contribution term of 20%. Others suggested a lower value should be used, which would result in a lower GW-1 standard. Some objected to this choice and argued that either no relative source contribution term was necessary or that the value selected should be 50% or higher, due to data indicating that exposures to several of these compounds are decreasing in the general population, based on levels in blood. This would result in a higher GW-1 standard.

Additional related comments were also submitted pertaining to other exposure parameters used in deriving the GW-1 standards. Some commenters suggested that MassDEP should use bodyweight and water intake rates for an infant rather than a nursing mother. This would result in a lower GW-1 standard. Other commenters suggested that MassDEP should use modeled estimates of exposures to nursing infants, which would also lead to a lower GW-1 standard. Others supported using values for an adult, which would lead to a higher GW-1 standard.

MassDEP's general response to written comments on Question 3-- In summary, MassDEP has concluded that its choice of a relative source contribution of 20%, together with the selected exposure parameters for a nursing woman, are appropriately health protective and supported by the available science. These parameters are the same as those used by USEPA in its derivation of the drinking water Health Advisories for PFOA and PFOS. A 20% RSC is the lowest value consistent with standard practice and USEPA guidance. Higher values are not warranted as they would not adequately account for exposures from other sources such as diet, including documented infant exposures from breast milk, and consumer products, to the subgroup of compounds being addressed and related compounds for which exposure data is either very limited or not available.

Specific comments and responses related to Question 3 are summarized below.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
3	ACC	Applying EPA’s Drinking Water advisory level to groundwater is inappropriate and unnecessary. The EPA LHAs for PFOS and PFOA were developed as health-based guidelines for assessing potential exposure in drinking water. They are based on a number of conservative assumptions regarding levels of water consumption, exposures among sensitive populations, and exposure to sources other than drinking water. Consequently, they indicate a level of conservatism that is inappropriate and unnecessary for groundwater standards. Cleaning up groundwater to the levels proposed by MassDEP, moreover, is not a practical approach to protecting public health.	The GW-1 standard is applicable only to groundwater currently used or potentially used in the future as drinking water. Thus, the drinking water exposure parameters are appropriate.
3	CLF	The proposed standard is based on assumptions that do not protect the most vulnerable populations. MassDEP used a water ingestion rate of 0.054 L/kg/day based on a lactating woman. This value is much less protective than the ingestion rate used by Vermont of 0.143 L/kg/day based on an infant. The standards should protect fetuses, infants and developing children.	<p>The MassDEP GW-1 standard is based on a revised RfD for PFOA and PFOS adjusted downward by a factor of the square root of ten to account for data indicating lower dose effects. MassDEP relied on the drinking water exposure parameters used to calculate the USEPA drinking water Health Advisory, which included the drinking water intake rate and body weight for a lactating woman and a relative source contribution factor of 20%.</p> <p>Other federal and state agencies have applied different values for various parameters in the RfD and drinking water limit derivations for PFAS. These reflect differing interpretations of the available scientific data and differing policy and risk management decisions. No agency has adopted the most conservative option for all parameters. The options selected by MassDEP for the various parameters are summarized in the Technical Support Document. These are all within the range of scientifically appropriate values selected by one or more regulatory agencies. MassDEP has concluded that the exposure parameters it has selected, together with use of a RSC of 20%, results in a drinking water value appropriate for all groups.</p>
3	GHD	MassDEP makes a passing reference to the “likely conservativeness of the RSC” without detailed justification, background or discussion.	MassDEP believes the 20% RSC it has applied is protective and appropriate. This value is the same as that used by USEPA in deriving their drinking water health advisories for PFOA and PFOS, a decision made to account for other sources of exposure. The 20% value is also justified as it accounts for exposures to infants in utero and from breastfeeding.
3	GreenCAPE	Commenter questions whether the 20% RSC is sufficiently protective if an infant has been developing in vivo while exposed to a variety of PFAS since conception.	MassDEP applied the approach used by USEPA in its derivation of the combined drinking water health advisories for PFOS and PFOA. MassDEP has concluded that this 20% RSC is appropriate as it addresses uncertain and variable exposures attributable to a variety of exposures. MassDEP also notes that the RfD is based on developmental effects.
3	LSPA	Regarding the Relative Source Contribution (RSC) factor: We suggest increasing the RSC from 20% to 50%. The levels of PFOA/S in consumer products and in population blood levels have demonstrated decreasing concentrations since phase-out of PFOS and PFOA, and it is anticipated that these levels will further reduce with time. Note that other states have adopted or propose to adopt higher RSCs. Minnesota uses an RSC of 50% (https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfoa.pdf ; August 2018), and NHDES uses a 40-50% RSC (https://www.des.nh.gov/organization/commissioner/pip/publications/documents/r-wd-19-01.pdf).	MassDEP applied the approach used by USEPA in its derivation of the combined drinking water health advisories for PFOS and PFOA. MassDEP has concluded that this 20% RSC is appropriate as it addresses uncertain and variable exposures attributable to the diet (including infant exposures to breast milk) and consumer products.
3	NAIOP	We suggest increasing the Relative Source Contribution (RSC) from 20% to 50%. The levels of PFOA/S in consumer products and in population blood levels have demonstrated decreasing concentrations since the phase-out of PFOS and PFOA, and it is anticipated that these levels will further decrease with time. Note that other states have adopted or propose to adopt higher RSCs. Minnesota uses an RSC of 50%.	MassDEP applied the approach used by USEPA in its derivation of the combined drinking water health advisories for PFOS and PFOA. MassDEP has concluded that this 20% RSC is appropriate as it addresses uncertain and variable exposures attributable to the diet (including infant exposures to breast milk) and consumer products.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
3	Wood	<p>For food, the best estimate of the PFAS contents of any foodstuffs is available in the ATSDR PFAS Toxicological Profile on page 588, which provides concentrations of PFOA in 31 food items, primarily protein and dairy with some starches, produce items, and oils/butter. If one uses the average of these PFOA concentrations (and ½ the DL for non-detects), the average PFOA concentration is 0.165 ng/g. Further, the weighted average per capita for total food consumption for ages 6 months to 70 years is 1,107.5 g/day (USEPA Exposure Factors Handbook, Table 14-3). If this is multiplied by 0.165 ng/g, the total PFAS (as PFOA) consumption per day from food is approximately 183 ng/day.</p> <p>An assumption that 20 percent of PFAS exposure occurs from drinking water appears reasonable based on the information that is currently available. Therefore, no adjustment for relative source contribution would be warranted for the PFAS GW-1 standard.</p>	<p>The ingestion rate of 183 ng/day estimated by the commenter supports MassDEP application of a relative source contribution factor of 20% in the derivation of the GW-1 standard. This estimate accounts for PFOA from food and indicates that this source of exposure accounts for about half of the allowable exposure at the MassDEP RfD. In light of the fact that exposures to the other PFAS addressed in the regulation were not provided nor were exposures to the nursing infant estimated, MassDEP’s application of a relative source contribution factor of 20%, which is the same as that applied by USEPA in its derivation of the drinking water health advisories for PFOA and PFOS, is appropriate.</p>
3	3M	<p>MassDEP’s implicit adoption of exposure assumptions embedded in EPA’s Drinking Water Health Advisory is contrary to Its own guidance for determining GW-1 and ignores recent changes in EPA exposure guidance directly affecting EPA PFOA and PFOS DWHA.</p> <p>The consumption rate used by EPA has been recently reduced based on additional data sets.</p>	<p>The exposure parameters used to calculate the Method 1 standards are based on published scientific data and technical information, but also reflect MassDEP policy decisions regarding which parameters are used in consideration of sensitive populations potentially at risk and other factors. For calculating the PFAS GW-1 Standard, MassDEP has applied the exposure parameters used by USEPA to develop the PFOA and PFOS Drinking Water Health Advisories. USEPA used exposure factors based on a lactating woman to derive the Health Advisories because infants were identified as a sensitive subgroup for PFAS. For other chemicals, MassDEP has used water intake rates of one and two liters for children and adults, respectively. There is, however, no rule requiring the use of the same exposure factors for all MassDEP GW-1 standards, and MassDEP has judged USEPA’s exposure values to be appropriate for PFAS.</p> <p>USEPA used the 90th percentile water ingestion rate for lactating women published in the 2011 Exposure Factors Handbook (Table 3-81). The value published in the February 2019 update is identical.</p>
3	3M	<p>MassDEP should reconsider its use of relative source contribution. At a minimum, MassDEP should use a 50 percent value instead of the 20 percent currently proposed. The available data from PFOA drinking water affected communities has provided substantial and compelling evidence that elevated PFOA levels in the drinking water are likely to be the primary route of PFOA exposure. At a minimum, MassDEP should use a 50% value instead of the 20% currently proposed.</p>	<p>MassDEP applied the approach used by USEPA in its derivation of the combined drinking water health advisories for PFOS and PFOA. MassDEP has concluded that this 20% RSC is appropriate as it addresses uncertain and variable exposures attributable to the diet (including infant exposures to breast milk) and consumer products.</p>
3	3M	<p>3M believes that MassDEP confuses and conflates its Hazard Index concept with Relative source contribution.</p>	<p>MassDEP is aware of the differences between these concepts. For the drinking water exposure pathway addressed by the GW-1 standards, especially for contaminants like PFAS that are very long-lived in the human body and have many additional sources of exposure, an RSC adjustment is appropriate and necessary in the derivation of the standards.</p>
3	Sanborn Head	<p>As correctly noted by MassDEP, there is yet another factor of safety built into the procedural basis of deriving GW-1 standards. The target hazard quotient of 0.2 that serves as the basis of GW-1 standards allows for background exposure (from pathways other than drinking water) to contribute up to 80% of the safe exposure level. But recent blood serum data collected by the Center for Disease Control indicate that current background exposure to PFAS is much smaller than16 ng/kg-d (80% of the RfD). Our calculations, which are based on serum levels of several PFAS in human subpopulations over time and are described in Appendix A, indicate that current background exposure to four of the PFAS compounds of interest to MassDEP is only about 1 ng/kg-d, meaning that almost all the 80% assumed exposure via background is unnecessary (and hence highly protective) for a typical person.</p>	<p>MassDEP has concluded that the 20% RSC it has applied is appropriate. This value is the same as that used by USEPA in deriving their drinking water health advisories for PFOA and PFOS, a decision made due to considerable uncertainties about other sources of exposure. The 20% value is also justified as it accounts for exposures to infants in utero and from breastfeeding. These higher exposures are not otherwise accounted for in the detailed calculations provided by the commenter or other determinations supporting a higher RSC.</p>

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
3: Water intake rate	Sanborn Head	The assumed drinking water ingestion rate of 0.054 liters per kilogram body weight per day (L/kg-d) for a nursing mother is almost twice as large as the 0.029 L/kg-d ingestion rate typically used to derive Maximum Contaminant Levels (MCLs) and health advisories.	The exposure parameters used to calculate the Method 1 standards are based on published scientific data and technical information, but also reflect MassDEP policy decision regarding which parameters are used in consideration of sensitive populations potentially at risk and other factors. For calculating the PFAS GW-1 Standard, MassDEP has applied the exposure parameters used by USEPA to develop the PFOA and PFOS Drinking Water Health Advisories. USEPA used exposure factors based on a lactating woman to derive the Health Advisories because infants were identified as a sensitive subgroup for PFAS. For other chemicals, MassDEP has used water intake rates of one and two liters for children and adults, respectively. There is, however, no rule requiring the use of the same exposure factors for all MassDEP GW-1 standards, and MassDEP has judged USEPA’s exposure values to be appropriate for PFAS.

Question 4

Comments regarding analytical issues relating to quantification thresholds and data reproducibility at the proposed low parts-per-trillion levels are also requested.

Summary of written comments received in response to Question 4-- MassDEP received a number of comments related to this issue. Comments were received related to the lack of USEPA approved methods for determining PFAS in media other than drinking water and the ability of available methods to reliably quantify PFAS at the level of the proposed standards.

A number of comments were also received regarding background levels of PFAS. Commenters noted that the proposed soil standards are likely to be below PFAS concentrations in typical surficial soils, specifically citing data from a study of Vermont soils, which was issued after the proposed regulations were released for public review, to support this claim.

Comments were also received stating that MassDEP’s assessment of potential leaching of PFAS from soils to groundwater was likely to overestimate impact to groundwater.

MassDEP's general response to written comments on Question 4--In summary, MassDEP concurs that the available data indicate that the proposed soil standards are likely to be below background levels attributable to historic and widespread use of these compounds in a variety of consumer products and other applications, as well as their persistence in the environment once released. Background concentrations are considered in establishing appropriate soil standards under the MCP. Specifically, MassDEP typically establishes MCP soil standards at an upper end concentration of the distribution of concentrations as determined from samples collected in areas not impacted by specific point sources or releases of the contaminant in question. MassDEP has therefore revised the proposed soil standards to reflect available information on background concentrations. The revised values were established at the 90th percentile of the distribution of concentrations reported in the Vermont study. Further, the Vermont study is consistent with available Massachusetts–specific background data.

Because the new higher soil standards are based on background data rather than leaching to groundwater, the comments received regarding the latter issue are not further addressed. MassDEP does, however, note that the values used to estimate leaching to groundwater from soil in the original proposed standard derivations were intentionally conservative. Additionally, the new soil values are well within the analytical capabilities of existing laboratory methods.

Specific comments and responses related to Question 4 are summarized below.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
4: Analytical methods	MWRA	MWRA notes that, currently, there are no methods approved by the Environmental Protection Agency (EPA) for PFAS in matrices other than finished drinking water. The Test Methods for Evaluating the Solid Wastes: Physical/Chemical Methods, a compendium of methods that EPA has developed in support of the Resource Conservation and Recovery Act, commonly known as SW-846 methods, are normally the default standard for MCP, related determinations. EPA recently released a draft of SW-846 Method 8327 for public comment. However, it does not appear to be sufficiently sensitive to support the 20 ng/L standard that MassDEP has proposed. The suggested Lower Limit of Qualification (LLOQ) in Method 8327 is only 40 ng/L for PFHxS and PFHpA before even considering the other four compounds that MassDEP has proposed summing together with these two. This method as written is not sufficient to support the cleanup standard that MassDEP has proposed and it is therefore unclear how determinations would be made absent an applicable method.	<p>The MCP does not specify specific analytical methods such as SW 846 methods. The MCP instead relies on performance based criteria to assess data quality and acceptability, which allows for a wider range of methods including the most current methods, to be used, provided appropriate quality control elements are documented. Some laboratories are able to achieve reporting limits (RLs) of 10 ppt using the noted method and as low as 2 ppt using modified isotopic dilution methods (e.g., see https://www.testamericainc.com/services-we-offer/services-we-offer-by-method-group/pfas-including-pfoa-and-pfos/epa-method-8327-for-24-pfas-compounds-draft-method-update/). Isotopic dilution methods are being used by a number of laboratories for PFAS analysis and are capable of achieving lower RLs than those noted by the commenter.</p> <p>With respect to the GW-1 standard, this value is applicable to groundwater used or potentially used as drinking water. Samples from such GW are typically amenable to EPA Method 537.1 analysis, which can achieve RLs of less than 2 ppt.</p>
4: Analytical methods	MWRA	The sum of the Lowest Concentration Minimum Reporting Limits (LCMRLs) published in Method 537 for the six PFAS compounds that MassDEP is proposing to sum is 32.7 ng/L. This is also problematic for demonstrating compliance with a cleanup standard of 20 mg/L due to the large analytical uncertainty that could be present at this level. The published LCMRLs in EPA 537.1 are much improved, however, they still sum to only 10.7 ng/L. Since some laboratories may occasionally see recoveries up to 150% of this value, it is impractical for MassDEP to implement a cleanup standard of 20 ng/L for the sum of six PFAS compounds. MWRA recommends that MassDEP set the cleanup standard at a level that has been demonstrated to be reasonably free of analytical uncertainty and sampling artifacts.	USEPA Method 537.1 is well established and, as noted in the comment, is capable of achieving reporting limits sufficient to assess the concentrations of the covered PFAS in aggregate at the GW-1 standard.
4: Analytical methods	MWWA	Summing the 6 PFAS compounds has the effect of regulating any PFAS detection as a GW-1 exceedance since typical laboratory reporting limit for the 6 PFAS is ~ 5 ppt, and adding in NDs at half detection limits will push 6 PFAS sum to near or above 20 ppt. Since the compounds being regulated are the most commonly detected compounds, it is likely that more than one PFAS will be detected in many samples. Based on the decision to sum the six compounds to be regulated at 20 ppt, the proposed GW-1 is actually 5 ppt or effectively the practical quantitation limit (PQL) for each compound.	This comment appears to reference an approach for handling results less than the MRL that is being proposed in the public hearing draft that would establish a PFAS MCL in the Massachusetts Drinking Water Regulations, 310 CMR 22.00. This comment has been provided to the Drinking Water Program for consideration.
4: Analytical methods	MWWA	MWWA is concerned about analytical capabilities to reliably quantify the compounds when looking at very low ppt. MassDEP is further suggesting that anything between ½ the MRL and the MRL be considered as ½ the MRL. MWWA believes that anything detected below MRL should not be governed by an arbitrary rule assuming a certain level exists; such an interpretation is not scientific. Values < MRL should not be reportable nor counted towards anything at these low ppt levels. We note that in other areas of the Drinking Water Program, it is explicit that all values below the MDL be recorded as zero. Why would PFAS be treated differently?	This comment appears to reference an approach for handling results less than the MRL that is being proposed in the public hearing draft that would establish a PFAS MCL in the Massachusetts Drinking Water Regulations, 310 CMR 22.00. This comment has been provided to the Drinking Water Program for consideration.
4: Analytical methods	MWWA	EPA does not have an approved method for soil evaluation. How will MassDEP reliably and accurately evaluate PFAS concentrations in soil?	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. There are methods (including proposed EPA Methods) available for quantifying PFAS in soil. The LSP may have to work with the laboratory to ensure that the data quality objectives are met.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
4: Analytical methods	ACC	Standard measurement methods for PFAS in soil are still being developed. USEPA has not yet developed validated methods for measuring PFAS levels in soils.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. There are methods (including proposed EPA Methods) available for quantifying PFAS in soil. The LSP may have to work with the laboratory to ensure that the data quality objectives are met.
4: Analytical methods	Agresource	EPA has not yet established test methods for soils.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. There are methods (including proposed EPA Methods) available for quantifying PFAS in soil. The LSP may have to work with the laboratory to ensure that the data quality objectives are met.
4: Analytical methods	CDM Smith	There is currently only one approved EPA analytical method for certain PFAS compounds, and that is for drinking water, Method 537.1. Laboratories have modified that method for non-drinking water uses, but the analytical results vary from lab to lab and constituent to constituent. EPA has announced that it will seek comment on a third method this fall that many experts are more encouraged by, but that method may not be finalized for another year or more.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. The LSP may have to work with the laboratory to ensure that the data quality objectives are met.
4: Analytical methods	CDM Smith	The PFAS standard needs to take into consideration the uncertainty associated with low level detections at or close to the reporting limits, high risk of cross-contamination, and potential PFAS fluctuation in background levels that are not fully understood. Integration of these considerations allow realistic operation and maintenance of the PFAS treatment facilities and avoid inefficient use of resources, such as requiring an excessive number of PFAS samples to ensure accurate results and expedited turnaround time on those samples.	Analytical reporting limits for the compounds addressed are sufficiently low to assess compliance. Cross contamination is not an issue if sample collection protocols are followed, and can be identified through the use of appropriate controls. The basis of concerns regarding potential PFAS fluctuations in background levels is not clear, but MassDEP does not consider this to be a significant issue.
4: Analytical methods	City/Town water officials	There are concerns about analytical controls and capabilities to reliably and accurately quantify the compounds when looking at very low parts per trillion.	Analytical methods exist that are able to reliably and accurately quantify the compounds addressed in this regulation in drinking water (EPA method 537.1). The revised soils standards can also be quantified. The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. There are methods (including proposed EPA methods) available for quantifying PFAS in soil. The LSP may have to work with the laboratory to ensure that the data quality objectives are met.
4: Analytical methods	CLF	MassDEP appears to rely on a survey of laboratory reporting standards to establish the soil standards. However, that survey does not appear in the materials on the MassDEP website related to the rulemaking.	MassDEP's survey of its contract laboratories resulted in a snap-shot in time estimate of achievable reporting limits. Rather than rely upon that survey specifically, MassDEP framed a specific question as part of the public comment process to elicit a wide range of comments on what is/could be achievable.
4: Analytical methods	DoD	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 assessment of PFAS contamination.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. The LSP may have to work with the laboratory to ensure that the data quality objectives are met.
4: Analytical methods	GZA	The proposed PFAS soil standard for GW-1 areas (200 ppt) is well below the practical quantitation limit for normal soil samples.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90 th percentile value of specific PFAS compounds in soil based on the Vermont background study, and are consistent with other available data. The soil levels are no longer leaching-based.
4: Analytical methods	GZA	We recommend establishing the soil cleanup standard and Reportable Concentration at a level which can be consistently achieved by most laboratories and which is above expected background levels– likely an order of magnitude higher than the proposed value.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90 th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
4: Analytical methods	Haley & Aldrich	There is currently no EPA-approved analytical method for PFAS in soil. Under these circumstances, the accuracy and reproducibility of analytical results may be questionable.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. The LSP may have to work with the laboratory to ensure that the data quality objectives are met.
4: Analytical methods	LSPA	There currently is no EPA-approved standard method to analyze PFAS in soil. While laboratories may be able to achieve the proposed soil standards, we are concerned with the reproducibility, consistency and accuracy of such results when trying to achieve part per trillion levels in soil, in light of the lack of a published method.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. The LSP may have to work with the laboratory to ensure that the data quality objectives are met. The revised soil standards are well within the analytical capability of available methods.
4: Analytical methods	Sanborn Head	Given the lack of a published and recognized method for analyzing PFAS in soil, an analytical method should also be specified for PFAS in soil, and a study made of the ability of commercial laboratories to generate reliable data from the method.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. The LSP may have to work with the laboratory to ensure that the data quality objectives are met. The revised soil standards are well within the analytical capability of available methods.
4: Analytical methods	Sanborn Head	The proposed standard, set at the MassDEP’s proposed reporting limits for the six PFAS, is less than common commercial laboratory reporting limits for those six PFAS. Technical documentation supporting the anticipated reporting limit has not been provided for review and comment.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. The LSP may have to work with the laboratory to ensure that the data quality objectives are met. The revised soil standards are well within the analytical capability of available methods.
4: Analytical methods	Weston & Sampson	Commenter is unaware of a standard and reliable lab method for testing PFAS in soil.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. The LSP may have to work with the laboratory to ensure that the data quality objectives are met. The revised soil standards are well within the analytical capability of available methods.
4: Analytical methods	NAIOP	There currently is no EPA-approved standard method to analyze PFAS in soil. While laboratories may be able to achieve the proposed soil standards, we are concerned with the reproducibility, consistency, and accuracy of such results when trying to achieve part per trillion levels in soil, in light of the lack of a published method.	The MCP establishes performance standards for data useability and does not rely upon "approved methods" or laboratory certification. The LSP may have to work with the laboratory to ensure that the data quality objectives are met. The revised soil standards are well within the analytical capability of available methods.
4: Background	Agresource	We believe that establishment of this limit at this value is not appropriate. At present there is a paucity of data on background soil levels and it is likely that the proposed limit may be at or below background levels.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Background	CDM Smith	We would request that MassDEP consider the ubiquitous nature of these compounds and consider “background” concentrations, including the data by the University of Vermont and Sanborn, Head and Associates, in the development of these standards. It is suggested that higher RCS-1 criteria be used to ensure that true “releases” of PFAS are being regulated.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Background	CDM Smith	Similar to the soil criteria, potential for background supply and potable water and groundwater concentrations above established standards is likely and may require many more municipalities to install treatment than one may expect.	Available data does not support widespread background levels of these PFAS in groundwater above the proposed GW-1 standard. MassDEP is looking at the occurrence and potential sources of PFAS through a variety of means, including testing that has been conducted nationally (UCMR3, Dept. of Defense), regionally (including Vermont and New Hampshire sampling efforts) and locally (contaminated site work, voluntary public and private water supply testing and research studies). This work will continue through the MCL-setting process, including the implementation of a state-wide sampling effort funded through a supplemental budget appropriation. The proposed notification criteria and cleanup standards are supported by available data and will provide necessary direction for parties needing to address PFAS on/from their properties under the MCP.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
4: Background	City/Town water officials	There needs to be a better understanding of expected background levels and sources.	MassDEP is looking at the occurrence and potential sources of PFAS through a variety of means, including testing that has been conducted nationally (UCMR3, Dept. of Defense), regionally (including Vermont and New Hampshire sampling efforts) and locally (contaminated site work, voluntary public and private water supply testing and research studies). This work will continue through the MCL-setting process, including the implementation of a state-wide sampling effort funded through a supplemental budget appropriation. The proposed notification criteria and cleanup standards are supported by available data and will provide necessary direction for parties needing to address PFAS on/from their properties under the MCP.
4: Background	GZA	This value is well below the lower end of the range of background concentrations for total PFAS in shallow soils based on several recent studies. (See for example, “PFAS Background in Vermont Shallow Soils” by Zhu et al, February 2019)	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Background	Haley & Aldrich	We note that the proposed GW-1-based soil standard of 0.0002 mg/kg for total PFAS is likely within the range of typical background values. A recent study by the University of Vermont found concentrations of PFOA and PFOS in non-source area soil within the range of the proposed soil standard.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Background	LSPA	The proposed value is likely within typical "background" values for PFAS due to the widespread use of these compounds in a variety of products/applications and airborne dispersal/transport mechanisms. Recently, the University of Vermont produced a whitepaper discussing the results of a background study of PFAS in soil in non-source areas of Vermont and found PFOA concentrations ranging from 52-4,400 ng/kg (median of 390 ng/kg) and PFOS concentrations ranging from 110-4,400 ng/kg (median of 680 ng/kg). The proposed GW-1 based soil standard for total PFAS is within these ranges of observed background values.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Background	NAIOP	The proposed soil level is within "background" levels for PFAS in soil; we are not aware of empirical data suggesting that these low background levels in soil are resulting in drinking water level exceedances in groundwater. A recent University of Vermont “white paper” described background PFOA concentrations ranging from 52-4,400 ng/kg (median of 390 ng/kg) and PFOS concentrations ranging from 110-4,400 ng/kg (median of 680 ng/kg). The GW-1-based soil standard for total PFAS proposed in the draft regulations is within these ranges of observed background values.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based, but are based on background.
4: Background	Nantucket AP	Given that general background levels of PFAS range from 3-10 ppb, triggering the MCP at a 20 ppb threshold is fairly certain conclusion. The concern of Nantucket Memorial Airport is that airports may assume responsibility for many other release categories and uses that have been discovered on Airport property.	Available data do not support widespread groundwater contamination above 20 ppt. As with any 21E investigation, the potential for elevated "background" levels—or more likely, contributing sources—should be considered and noted where appropriate.
4: Background	Sanborn Head	The proposed S-1/GW-1 soil standard of 0.2 parts per billion (ppb) for the sum of six PFAS compounds is likely lower than background conditions in soil. MassDEP should either use available data to assign background levels to PFAS in oils or engage in a state-specific study of background levels in Massachusetts. MassDEP could consider using the VT Background Soil Study results to develop the interim SI-GW-1 Standards. Based on a recent study of background PFAS in shallow soils in Vermont, the S-1/GW-1 soil standard could be set at 4.2 ppb, which is the 90th percentile value of the summed concentrations of six PFAS compounds measured in the Vermont study.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
4: Background	Sanborn Head	The proposed standard is less than likely background levels in shallow soils. Studies indicating a global background distribution of PFAS in soils, with mean and median concentrations of summed PFAS in North America likely exceeding the proposed S-1/GW-1 standard were cited.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Background	Sanborn Head	MassDEP should either use available data to assign background levels to PFAS in soils or engage in a state-specific study of background levels in Massachusetts. Consistent with MassDEP policies under the MCP, background levels should be set at upper percentile levels (e.g., 90th percentile) and should also consider potential differences in urban and rural areas.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Background	Sanborn Head	MassDEP could consider using the VT Background Soil Study results to develop interim S-1/GW-1 standards. The table above suggests that a S-1/GW-1 standard of 4.2 ppb for the sum of six PFAS could be used as an interim standard until a background study can be completed in Massachusetts.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Background	VT DEC	VT DEC directs MassDEP to the recent University of Vermont study/report on background PFAS levels in shallow Vermont soils: https://anrweb.vt.gov/PubDocs/DEC/PFOA/Soil-Background/PFAS-Background-Vermont-Shallow-Soils-03-24-19.pdf . The study found background for PFAS (sum of 17 analytes) ranged from 0.5 to 35 ppb. Nearly all of the samples from shallow soils showed PFOS > 0.2ppb.	MassDEP appreciates the excellent work done by VT DEC on PFAS. The cited study has been reviewed and the results are reflected in revised soil standards detailed elsewhere in this response to comments document.
4: Background, fingerprinting	LSPA	<p>Further study needs to be performed to establish some type of background concentration for each of these compounds and to develop a method (not unlike petroleum fingerprinting) to be able to better identify the source of the particular suite of PFAS compounds (for example, being able to differentiate the dissolved PFAS compounds in groundwater of AFFF fire-fighting foam vs. Gore-Tex vs. Teflon vs. fire-fighting turnout gear, etc.)</p> <p>A better understanding of background conditions for PFAS would also inform a reasonable lower limit for development of Method 1 standards.</p>	<p>Although the soil concentrations initially proposed for GW-1 areas were leaching-based values, more recent information on background concentrations led to an upward revision of the proposed soil concentrations.</p> <p>“Finger printing” approaches are being developed and offer a potentially promising method to differentiate PFAS sources. Development of such methods is outside of the scope of these regulations.</p>
4: Background	Sanborn Head	Proposed standards should be compared with actual soil and groundwater data, including background studies, to support the feasibility and appropriateness.	Available data do not indicate that background groundwater concentrations are high enough to present an issue. As noted elsewhere, MassDEP has adjusted the proposed soil standards to reflect what is currently known about background.
4: Background, prevalence	City/Town water officials	There needs to be a better understanding of the extent of PFAS and prevalence in the Commonwealth.	MassDEP is looking at the occurrence and potential sources of PFAS through a variety of means, including testing that has been conducted nationally (UCMR3, Dept. of Defense), regionally (including Vermont and New Hampshire sampling efforts) and locally (contaminated site work, voluntary public and private water supply testing and research studies). MassDEP will continue to evaluate new occurrence information. The proposed notification criteria and cleanup standards are supported by available data and will provide necessary direction for parties needing to address PFAS on/from their properties under the MCP.
4: Background, prevalence	MWWA	MassDEP needs to give more thought to the issue of background levels of PFAS in this regulation package. Clarification is necessary in this section of the regulations to prevent drinking water sources from being classified as waste sites if they find PFAS upon initial sampling.	MassDEP is looking at the occurrence and potential sources of PFAS through a variety of means, including testing that has been conducted nationally (UCMR3, Dept. of Defense), regionally (including Vermont and New Hampshire sampling efforts) and locally (contaminated site work, voluntary public and private water supply testing and research studies). This work will continue through the MCL-setting process, including the implementation of a state-wide sampling effort funded through a supplemental budget appropriation. The proposed notification criteria and cleanup standards are supported by available data and will provide necessary direction for parties needing to address PFAS on/from their properties under the MCP. There are existing notification exemptions for public water supplies affected by contamination (not just PFAS) that would be applicable.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
4: Background, prevalence	NEBRA	The extent of PFAS contamination in the Commonwealth has not been fully evaluated	MassDEP is looking at the occurrence and potential sources of PFAS through a variety of means, including testing that has been conducted nationally (UCMR3, Dept. of Defense), regionally (including Vermont and New Hampshire sampling efforts) and locally (contaminated site work, voluntary public and private water supply testing and research studies). This work will continue through the MCL-setting process, including the implementation of a state-wide sampling effort funded through a supplemental budget appropriation.
4: Background, prevalence	NEBRA	Given the ubiquitous finding of PFAS in many places (for example, see Vermont Department of Environmental Conservation’s report on background soil levels on that state), can MassDEP know, at this point, that the proposed low soil cleanup standards will be attainable around any of the above (recycling, reuse and waste management) activities? Or will the proposed soil cleanup standards become de facto bans on some of these activities, activities that have proven benefits?	There are specific notification exemptions applicable to the re-use/recycling of material consistent with applicable regulations. The proposed S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards have been raised to take into account the Vermont background study.
4: Prevalence	MCWRS	The needed scientific investigation should also include a better understanding of occurrence and sources of PFAS in Massachusetts.	MassDEP is looking at the occurrence and potential sources of PFAS through a variety of means, including testing that has been conducted nationally (UCMR 3, Dept. of Defense), regionally (including Vermont and New Hampshire sampling efforts) and locally (contaminated site work, voluntary public and private water supply testing and research studies). MassDEP will continue to evaluate new occurrence information. The proposed notification criteria and cleanup standards are supported by available data and will provide necessary direction for parties needing to address PFAS on/from their properties under the MCP.
4: prevalence	MCWRS	Before regulating PFAS, the occurrence, potential environmental sources and implications of regulation of PFAS need to be better understood.	MassDEP is looking at the occurrence and potential sources of PFAS through a variety of means, including testing that has been conducted nationally (UCMR3, Dept. of Defense), regionally (including Vermont and New Hampshire sampling efforts) and locally (contaminated site work, voluntary public and private water supply testing and research studies). MassDEP will continue to evaluate new occurrence information. The proposed notification criteria and cleanup standards are supported by available data and will provide necessary direction for parties needing to address PFAS on/from their properties under the MCP.
4: Leaching	Agresource	There is a lack of good data on the distribution of PFAS compounds in soils in the Commonwealth and the movement of these compounds through soils is not fully understood.	MassDEP is looking at the occurrence and potential sources of PFAS through a variety of means, including testing that has been conducted nationally (UCMR3, Dept. of Defense), regionally (including Vermont and New Hampshire sampling efforts) and locally (contaminated site work, voluntary public and private water supply testing and research studies). This work will continue through the MCL-setting process, including the implementation of a state-wide sampling effort funded through a supplemental budget appropriation. The proposed notification criteria and cleanup standards are supported by available data and will provide necessary direction for parties needing to address PFAS on/from their properties under the MCP.
4: Leaching	DoD	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.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Leaching	LSPA	The LSPA is very concerned with the proposed GW-1-based soil standards. The proposed value (0.0002 mg/kg) is a leaching-based value. In the derivation of leaching-based standards (provided on MassDEP’s Excel spreadsheet 'MCP Leach') a default DAF of one for PFAS is used, citing EPA Regional Screening Levels for PFOA/S as the source. However, there are no RSLs for either of those compounds at this time. – The LSPA requests that MassDEP provide documentation to support the use of this default value. When reviewing a simple comparison of leaching-based values for other very soluble constituents (such as MBTE, 1,4-dioxane etc.), the ratio of the leaching-based soil standard to the GW-1 level is significantly higher for PFAS than for other compounds.	Although the soil concentrations initially proposed for GW-1 areas were leaching-based values, more recent information on background concentrations led to an upward revision of the proposed soil concentrations. The revised values are not based on leaching.

Question # /Topic	Commenter	Summary of Comment	MassDEP’s Response
4: Leaching	LSPA	We are not aware of empirical data suggesting that these low background levels in soil are resulting in drinking water level exceedances in groundwater.	Although the soil concentrations initially proposed for GW-1 areas were leaching-based values, more recent information on background concentrations led to an upward revision of the proposed soil concentrations. The revised values are not based on leaching.
4: leaching	NAIOP	The proposed soil value (0.0002 mg/kg) is a leaching-based value. In the derivation of leaching-based standards (provided on the Excel spreadsheet 'MCP Leach'), a default DAF of 1 for PFAS is used, citing EPA Regional Screening Levels for PFOA/S as the source. However, there are no RSLs for either of those compounds at this time, and MassDEP has not provided documentation to support the use of this default value. When reviewing a simple comparison of leaching-based values for other very soluble constituents (such as MBTE, 1,4-dioxane etc.), the ratio of the leaching-based soil standard to the GW-1 level is significantly higher for PFAS than for other compounds.	The S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards, as well as the RCS-1 criteria have been adjusted upward to reflect the 90th percentile value of specific PFAS compounds in soil based on the Vermont background study. The soil levels are no longer leaching-based.
4: Leaching	Sanborn Head	<p>The leaching-based value is based on the proposed GW-1 standard and a DAF. The ΣPFAS leaching-based value was calculated from an assumed/default DAF of 1 and the target GW-1 standard of 20 ppt, resulting in a value of 0.02 ppb based strictly on leaching from soil.</p> <p>Documentation of the DAF is unclear. The MassDEP apparently did not model the DAF for ΣPFAS or the DAFs for individual PFAS using its standard MCP approach.</p> <p>MassDEP’s assumed DAF of 1 is inconsistent with reasonable models for PFAS in the environment. In addition to neglecting sorption of the PFAS to soil, the DAF of 1 does not include dilution that can be anticipated from groundwater dilution and flow within a typical aquifer system. The result is an unrealistic leaching scenario that is not based on any chemical-specific information or hydrogeologic model.</p>	The revised soils standards are no longer based on leaching to groundwater, but are instead based on background levels.

Additional Comments/Issues

Topic	Commenter	Summary of Comment	MassDEP’s Response
AIR	MassDOT	Is MassDEP planning to develop standards for PFAS in air emissions?	This comment is beyond the scope of the proposed regulations. Other MassDEP programs are considering the potential significance and need for regulations to address this issue.
AFF Incineration	GreenCAPE	Commenter opposes MassDEP’s practice of incinerating unused firefighting foams. The potential exists for the conversion of some of the PFAS into airborne contamination that unintentionally impacts other populations. Until newer technologies are discovered, it would be preferable to store the fluorine foam in a secure facility.	This comment is beyond the scope of the proposed regulations. However, MassDEP and other state and federal agencies are considering potential impacts of air emissions and deposition of these compounds. As the need to dispose of AFFF arises, MassDEP has and will continue to evaluate options for the appropriate management of these materials.
AFF Incineration	Sierra Club, Cape Cod	We oppose MassDEP’s practice of incinerating unused fire -fighting foams. This simply converts some of the foam PFAS into airborne chemical contamination in other regions.	This comment is beyond the scope of the proposed regulations. However, MassDEP and other state and federal agencies are considering potential impacts of air emissions and deposition of these compounds. As the need to dispose of AFFF arises, MassDEP has and will continue to evaluate options for the appropriate management of these materials.
Benefits v. Costs	GHD	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.	The MCP allows for benefit/cost considerations to be factored into whether a Permanent or Temporary Solution is achievable for a specific site. The regulations also allow for the application of land use restrictions to limit potential exposures and do not require unrestricted use cleanups in all cases.
Benefits v. Costs	NEBRA	Various uncertainties mean that MassDEP cannot and has not quantified the benefits of the proposed regulatory changes. There will likely be, however, significant costs to public and private organizations, including many municipalities and utilities. MassDEP has not evaluated all of the potential impacts to a wide variety of activities important to Massachusetts residents.	The proposed MCP standards help establish what constitutes a condition of "No Significant Risk" at a site, but there is significant flexibility in how to achieve that goal, including the use of site-specific risk assessment and the achievement of a Temporary where a Permanent Solution is not currently feasible. Cost is an explicit consideration when considering the feasibility of a Permanent Solution in both the statute and regulations on a site-by-site basis. Where a party is on the receiving end of contamination (e.g., a downgradient water supplier), there is also the potential for cost recovery against the upstream responsible party. This comment has also been passed on the Drinking Water Program for consideration in the development of a draft MCL.
Biosolids	Agresource	Establishment of these limits will likely have the unintended consequences of discouraging the beneficial use of recycled materials including biosolids	The proposed standards do not directly apply to biosolids. MassDEP will continue to study and work with stakeholders on this issue.
Biosolids	NEBRA	We fear that the beneficial use of biosolids and residuals and other long-standing activities will be disrupted significantly by the proposed MCP revisions.	The proposed standards do not directly apply to biosolids. MassDEP will continue to study and work with stakeholders on this issue.
Biosolids	WRAFT	Residents of PFAS contaminated communities - those with longtime exposures and high body burdens - very much need biosolids/ compost/ sludge regulation. Eliminating biosolids as a source of PFAS contamination of the food supply is crucial to reduction of PFAS in humans.	The proposed standards do not directly apply to biosolids. MassDEP will continue to study and work with stakeholders on this issue.
Biosolids & WWTPs	GreenCAPE	Additional materials such as biosolids/sludge and effluent from wastewater treatment plants-noting the disastrous results on farms in AZ and ME- require investigation.	The proposed standards do not directly apply to biosolids or wastewater treatment plant effluent. MassDEP will continue to study and work with stakeholders on this issue.
Cleanup Feasibility	ACC	MassDEP’s proposal to require cleanup of groundwater to the proposed GW-1 standard would require expensive systems to bring the groundwater to the surface for treatment or to install extensive treatment networks underground.	MassDEP notes that PFAS that has come to be located in public water supplies will be regulated primarily by the MassDEP Drinking Water Program. This comment has been passed on to that program to be considered in the development of a draft MCL. Contamination in GW-1 areas is addressed in a number of ways under the MCP, but always taking into account the feasibility of achieving a Permanent Solution. Cost is explicitly one factor as a matter of regulation.

Topic	Commenter	Summary of Comment	MassDEP’s Response
Cleanup Feasibility	CDM Smith	Because the Method 1 S-1 Soil Standards are so low, cleanup of these sites may not be technically and/or financially feasible, resulting in numerous sites with either Temporary Solutions or Activity and Use Limitations.	In response to new data and public comment, MassDEP has revised its soil standards (S-1/GW-1, S-2/GW-1 and S-3/GW-1) for these PFAS. Note that the cleanup requirement may depend on the actual leaching to groundwater and the levels reported in the GW-1 area - the MCP's Method 2 may be used to identify site-specific soil concentrations protective of both direct contact and groundwater. These levels may vary from the Method 1 standards.
Closed Sites	Weston & Sampson	How will revised standards be interpreted for closed sites? Will there be retroactive reopening of closed sites?	MassDEP would consider the need to investigate PFAS contamination at any location (including closed sites) based on current known or suspected contamination and public health risk.
Costs - MCLs	City/Town water officials	It is unfair to expect water system ratepayers alone to bear the burden of the costs associated with treatment.	This comment is beyond the scope of the proposed regulations. However, MassDEP notes that MGL c. 21E and the MCP provide mechanisms that allow for impacted water systems to hold responsible parties accountable. This comment has been passed along to the Drinking Water Program for consideration in the development of a draft MCL.
Costs - MCLs	LSPA	The MCP will establish a de facto maximum contaminant level (MCL) by promulgation of a GW-1 standard, without incorporating the technical feasibility and/or cost considerations of the MCL process.	Method 1 Standards do not incorporate cost or feasibility consideration for public water suppliers. The MMCL will be subject to public comment and may ultimately differ from the proposed GW-1 standard. If any MMCL is adopted that differs from the proposed MCP GW-1 standard, the MCP would be subsequently amended to adopt in MMCL value as a GW-1 standard. This comment has been passed along to the Drinking Water Program for consideration in the development of a draft MCL.
Costs - MCLs	MCWRS	The desire to set standards that are all-protective and risk free from a health perspective has to be tempered by the reality of waste site cleanup and drinking water treatment costs and technical feasibility. The Safe Drinking Water Act includes many examples of contaminant MCLs that are generally protective of public health by reducing health risks to acceptable levels but not eliminating all risks (e.g., THMs, HAAs, Lead, and Arsenic).	MCP Method 1 standards do not take such costs into account. By statute and regulation, feasibility (including cost) is taken into account explicitly at several points in the assessment/cleanup process, including the determination as to whether a Permanent Solution is feasible. This comment has been passed along to the Drinking Water Program for consideration in the development of a draft MCL.
Costs - MCLs	MWWA	Revised MCL may require many more municipalities to install treatment significantly increasing the cost of response actions but providing no additional benefit.	This comment has been passed along to the Drinking Water Program for consideration in the development of a draft MCL.
Costs - MCLs	MCWRS	Maximum Contaminant Level Goals are often set to a concentration of zero, but the MCLs are typically higher to recognize the feasibility of achieving desired levels and the diminishing health benefits derived as standards reach ever lower limits.	This comment is correct, but is outside of the scope of the proposed regulations. This comment has been passed along to the Drinking Water Program for consideration in the development of a draft MCL.
Costs - MCLs	MCWRS	MCWRS believes that the current federal health advisory of 70 ng/L is very protective and appropriate until gaps in scientific understanding are closed. Selecting the lowest possible levels may satisfy those with health-based concerns but the implications are enormous for ratepayers.	MassDEP disagrees with this statement. As discussed elsewhere in these responses to comments as well as in the accompanying Technical Support Document, MassDEP has concluded, based on the weight of the evidence, that its PFAS standards are appropriate and health protective. MassDEP has not selected the lowest possible level.
Cost recovery from military, manufacturers	Sierra Club, Cape Cod	Both Joint Base Cape Cod and the AFFF foam production companies should share in cleanup costs. Sierra Club believes every effort should be made to recover these costs from the AFFF manufacturers.	MassDEP recognizes the importance of seeking contribution from all Potentially Responsible Parties through a variety of mechanisms.
Cost of Site Cleanup	Nantucket AP	Will municipal airport sponsors bear the costs of a general community cleanup, and what funds are available to assist in that mitigation?	Potentially Responsible Parties, which may include municipal airports, must address contamination at or from the disposal site. MassDEP takes the referenced term "general community cleanup" to mean "background" levels or perhaps "non-point" sources not specific to the airport. A comprehensive site assessment would provide information as to what contamination is site-related and what is not. A PRP is not required to conduct a general community cleanup if the PRP is not otherwise liable for that contamination.

Topic	Commenter	Summary of Comment	MassDEP’s Response
Documentation	Clean Water Action	There is room for improvement in terms of how MassDEP communicates with the public and even official stakeholders around what research is dictating the decision-making process how said research was selected.	MassDEP has followed an open and transparent process with multiple opportunities for public engagement. The accompanying Technical Support Document also provides extensive explanation of the data and approach MassDEP used to derive the proposed standards, reflect comment received in response to MassDEP “Notes to Reviewers,” and provides detailed information responsive to many of the comments received.
Documentation	MWRA	MWRA recommends that MassDEP consider providing additional clarity and context for the toxicology and epidemiology support for the proposed standards. As currently presented, reviews cannot determine the specific uncertainty (safety factors) used by MassDEP’s Office of Research and Standards in moving from each toxicology “point of departure” based on an effect to a particular laboratory animal to the standard to be applied to people. A more explicit account of this process for each contaminant would provide helpful context to reviewers.	MassDEP appreciates this comment and directs MWRA to the accompanying Technical Support Document for a more detailed explanation.
Ecological Risk	DoD	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.	In non-GW-1 areas, the soil standards account for human health risk from direct contact with soil and ecological risk from leaching to groundwater that discharges to surface water. The groundwater target concentration is not the same for all chemicals, and so individual standards were developed. However, the commenter is correct in noting that soil exposures could also be additive.
Ecological Risk	OARS	<p>PFAS standards and monitoring should be strengthened specifically to protect aquatic life. In particular, the proposed revisions at 310 CMR 40.0993(3) related to Applicable and Suitably Analogous Standards under Method 3 Environmental Risk Characterization should also be applied, as relevant, to 310 CMR 40.0995(3) [Stage I Environmental Screening] for Environmental Risk Characterization.</p> <p>PFAS should be included in the Massachusetts Surface Water Quality Standards.</p>	<p>MassDEP agrees that ecological resources should be protected against harm from waste site contaminants, and the Bureau of Waste Site Cleanup has established regulations and risk assessment guidance and practices to achieve that end. Where surface water has been impacted by contaminants from a waste site, a Method 3 site-specific ecological risk assessment must be conducted.</p> <p>For surface water, the risk assessment involves two components: (1) a site-specific evaluation of harm to aquatic and semi-aquatic organisms; and (2) comparison of surface water concentrations to Applicable Standards (Massachusetts Surface Water Standards), if available for the contaminants of concern. Only standards that have been promulgated through a formal standard setting process are “Applicable Standards” under the MCP. To date, however, no PFAS surface water standards for the protection of aquatic organisms have been developed.</p>
Ecological Risk	OARS	As known or suspected carcinogens, mutagens and endocrine disruptors in humans, there is reason to believe that chemicals in the PFAS family may have similar effects on aquatic wildlife.	MassDEP is unaware of toxicity information that would indicate greater sensitivity to PFAS than is reflected in the Minnesota aquatic life values, which were incorporated in the GW-3 standard.
Ecological Risk	OARS	Commenter notes that the Method1 GW-3 standard should reflect that GW constitutes base flow for streams and other waterbodies. Monitoring requirements should ensure that locations reflect inputs to waterbodies especially during sensitive seasons.	The GW-3 standards incorporate a factor of 10 to account for dilution where groundwater discharges to surface water. This is a minimal dilution factor, and is intended to be protective under most conditions.
Education	AIM	In addition to making sure any testing follows valid MassDEP protocols, MassDEP should also develop educational resources on the specific health threats posed by the presence of PFAS.	MassDEP has developed educational materials for the public on PFAS which are available on its website. MassDEP anticipates additional materials will be developed in the future.
Evolving science	City/Town water officials	It seems premature for MassDEP to be moving forward with regulating PFAS right now because the science around toxicity and health impacts of PFAS compounds is evolving.	MassDEP disagrees that it is premature to move ahead with these regulations. Although the science is evolving, this is always the case with respect to emerging contaminants, and will likely continue far into the future. However, the available science is more than sufficient to conclude that regulatory actions to protect public health and the environment are warranted.
Evolving science	Clean Water Action	We especially hope that MassDEP will continue to monitor for new information as well as continue internal assessment as to whether or not the current methodology selected for the MCP is actually the one that makes the most sense from the standpoint of public health.	MassDEP will continue to follow developments in these areas.
Evolving science	Weston & Sampson	How will the MCP keep up with the rapidly changing science and knowledge of PFAS, specifically related to its toxicology, leachability, and standards promulgated in other states.	MassDEP will continue to follow developments in these areas.

Topic	Commenter	Summary of Comment	MassDEP’s Response
Financial responsibility	AIM	It is unfair to force companies that once used PFAS containing materials to shoulder the burden of paying for cleanup, even though their contribution to the overall contamination level was small. This is particularly true where ground contamination or groundwater contamination will not result in health impacts.	MassDEP works within state law, such as MGL c. 21E, to identify parties with obligation to assess and cleanup contamination, including PFAS. The proposed standards consider potential health impacts and the risk posed by these contaminants.
Financial responsibility	Clean Water Action	MassDEP and the state need to ensure that water utilities and their ratepayers or other community and local government entities are not bearing the costs of controlling PFAS contamination. Those responsible for manufacture, use, and discharge need to bear the burden of cleaning up the mess they have made	MassDEP recognizes the importance of seeking contribution from all potentially responsible parties through a variety of mechanisms. However the absence of a PRP willing and able to fund treatment of contaminated water supplies does not alter the need to take action to provide consumers with safe drinking water. The Commonwealth is making resources available, such as increased funding through the SRF, to address these issues.
Fish & game	David Dow	It is likely that the fish targeted by recreational anglers are contaminated, so that fish consumption standards need to be developed for sensitive populations (women of child bearing age and children).	In MA, fish consumption advisories are developed and implemented by the Massachusetts Department of Public Health. MassDEP will share this suggestion with that Department.
Fish & game	OARS	Commenter notes that certain PFAS accumulate in fish and that some states have established fish consumption advisories for PFAS	In MA, fish consumption advisories are developed and implemented by the Massachusetts Department of Public Health. MassDEP will share this suggestion with that Department.
Fish & game	GreenCAPE	Fish and shellfish monitoring should not be delayed, and wild game and birds should be monitored since there are a significant number of subsistence and sport fishermen and hunters on Cape Cod and western MA.	This comment is beyond the scope of these regulations. In MA, fish consumption advisories are developed and implemented by the Department of Public Health. MassDEP will share this suggestion with that Department.
Focus on drinking water	AIM	We believe MassDEP should concentrate their resources on options which ensure that residents have drinking water free from PFAS contamination. MassDEP cannot effectively clean up or monitor thousands of potential sites that may contain PFAS and classifying these sites as contaminated may stigmatize them or cause problems related to the transfer or redevelopment of commercial and industrial property. Concentrating on drinking water allows the MassDEP to generate the biggest health benefit outcome for the smallest amount of money.	MassDEP is focusing current efforts on drinking water, through the establishment of a GW-1 standard for certain PFAS in groundwater that is used, or may be used as in the future, drinking water. MassDEP is pursuing adoption of a state drinking water standard or Maximum Contaminant Level (MCL) for certain PFAS as part of a separate regulatory promulgation process.
Follow EPA process	ACC	MassDEP should review EPA cleanup levels before proceeding. Creating separate state levels for these two substances would create confusion about applicable cleanup targets among affected parties and levels of protection among the public.	MassDEP has reviewed available EPA documents. It is unclear what EPA's timeline for developing and finalizing standards for PFAS compounds will be. MassDEP has determined it is in the interest of the public to use its authority to establish standards at this time.
Follow EPA process	ACC	Given the challenges of reducing groundwater levels of the five PFAS included in the MassDEP proposal, ACC urges the Department to abandon the current proposal and base its efforts on the cleanup levels for PFOA and PFOA to be finalized by EPA.	MassDEP has reviewed available EPA documents. It is unclear what EPA's timeline for developing and finalizing standards for PFAS compounds will be. MassDEP has determined it is in the interest of the public to use its authority to establish standards at this time.
Follow EPA process	City/Town water officials	Commenters join with MWWA in asking you to let EPA take the lead on addressing regulation of PFAS, as this an issue being seen across the country and it is not particular to Massachusetts	MassDEP has reviewed available EPA documents. It is unclear what EPA's timeline for developing and finalizing standards for PFAS compounds will be. MassDEP has determined it is in the interest of the public to use its authority to establish standards at this time.
Follow EPA process	MWWA	Jumping out ahead of the EPA puts Massachusetts water suppliers in the untenable position of complying with standards of uncertain value and places a burden on the water suppliers and their customers before the public health benefits have been completely evaluated.	MassDEP has reviewed available EPA documents. It is unclear what EPA's timeline for developing and finalizing standards for PFAS compounds will be. MassDEP has determined it is in the interest of the public to use its authority to establish standards at this time.

Topic	Commenter	Summary of Comment	MassDEP’s Response
Follow EPA process	MWWA	MWWA suggests that MassDEP closely follow the EPA process on PFAS and implement standards only after the scientific and public health merits of doing so have been methodically and carefully considered.	MassDEP has reviewed available EPA documents. It is unclear what EPA's timeline for developing and finalizing standards for PFAS compounds will be. MassDEP has determined it is in the interest of the public to use its authority to establish standards at this time.
General Standard	CLF	The standards currently proposed by MassDEP are a step in the right direction, but current studies suggest the need for a far more stringent standard. The proposed cleanup standards do not adequately protect public health.	MassDEP disagrees with this statement. As discussed in the accompanying Technical Support Document, MassDEP has concluded that the GW-1 cleanup standard is adequately protective of public health based on the available scientific information and the inherent uncertainties in this data. MassDEP is committed to following scientific developments in the area of PFAS toxicity and exposure and to updating the standards in the future as warranted.
General Standard	David Dow	Commenter recently submitted comments to EPA on their proposal to develop an MCL of 70 ppt for PFOS and PFOA. Commenter told EPA that its proposed MCL was inadequate and that he supported the MCP proposal of 20 ppt for 6 PFAS chemicals and the associated waste site cleanup standards.	MassDEP acknowledges this support but notes that the proposed MCP standards are not MCL values, which are subject public review and comment under a separate regulation promulgation process.
General Standard	DoD	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.	<p>The accompanying Technical Support Document and response to comments below address many of DoDs expressed concerns.</p> <p>MassDEP believes the available information on toxicity, persistence in the environment, persistence in the human body and contamination of public water supplies is more than sufficient to support the proposed actions.</p> <p>MassDEP has appropriately applied toxicological principles. MassDEP is charged with protecting public health and the environment and is using the available scientific and technical information in a way that achieves that goal.</p>
General Standard	DoD	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 OS WER Directives 9285.7 .53 and 9285.7-86 and the 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.	<p>MassDEP disagrees. MassDEP’s RfD is based in part on the USEPA’s toxicological assessments for PFOA and PFOS, as well as other information, with an additional adjustment to account for scientific evidence indicating the potential for adverse health effects at lower levels. This adjustment and the decision to apply the same RfD to four additional PFAS are based on a weight of the evidence review of studies and data that are transparent, and that utilized scientifically accepted procedures.</p> <p>To ensure protection of public health, MassDEP’s standards address mixtures of PFAS that are prevalent in the Massachusetts environment and are structurally very similar to PFOS and PFOA. The standards have undergone a transparent public review, comment and response to comment process. The response to comments and the accompanying Technical Support Document provide extensive documentation of the approach and information used to derive the standards and is publicly available.</p>

Topic	Commenter	Summary of Comment	MassDEP’s Response
General Standard	Green & Crouch	MassDEP’s proposed PFAS standards are not based on any reliable evidence of adverse effects in humans; it remains the case that epidemiologic and/or clinical evidence has so far failed to establish that any PFAS harms human health at or near environmental exposure-levels (ATSDR, 2018). MassDEP should make this clear, but currently it does not.	<p>The comment seems to suggest that “epidemiologic and/or clinical evidence” is the gold standard as a basis for setting exposure limits. In light of the well-known limitations and insensitivity of epidemiological studies, relying exclusively on such studies is incompatible with setting limits that will prevent adverse effects and protect public health. The limitations of epidemiological studies are attributable to complex and co-occurring exposures to multiple chemicals, confounding factors, diagnostic misclassification, and other factors, which can lead to differing interpretations regarding the significance of epidemiological study results. These limitations also moderate the significance of negative epidemiological studies in situations where other lines of evidence indicate an effect is of concern.</p> <p>In meeting their obligation to protect public health, regulatory agencies must rely on available evidence. This is especially critical for compounds like the longer-chain PFAS that are extremely persistent in the environment and in the human body.</p> <p>Several regulatory agencies have reviewed the current literature on epidemiological and animal studies on PFAS and have concluded that the data support causality for some epidemiological endpoints and concordance of these effects with toxicological findings in animal model systems.</p> <p>Similar to most other regulatory agencies, MassDEP has concluded that, although there is epidemiological evidence to indicate that human exposure to low levels of PFOA and PFOS is associated with adverse effects, the data from well controlled laboratory experiments on mammalian model systems provide a stronger basis to derive protective toxicity values.</p>
General Standard	GreenCAPE	We are supportive of the addition of Reportable Concentrations (RC) and Method 1 standards for six perfluoroalkyl substances.	MassDEP appreciates this support.
General Standard	MCWRS	The science of PFAS health effects is not clear or consistent. This is best demonstrated by the vast discrepancies in PFAS health limits (including drinking water standards) across the United States and internationally. New York is looking at a standard of 10 ng/L, Germany’s limit is 100 ng/L, Canada has a 200 ng/L limit for PFOA, Australia has a limit of 560 ng/L and North Carolina is at 2,000 ng/L. Massachusetts appears to be moving to a standard of 20 ng/L, at the low end of the spectrum.	In assessing the toxicity of chemicals, MassDEP employs a conventional approach to account for data gaps and identify exposure levels that protect against adverse health effects. In the case of PFAS, an uncertainty factor equal to the square root of 10 was applied in consideration of data suggesting adverse health effects at lower exposure levels that the USEPA RfD. MassDEP has not reviewed the PFAS assessments done in Germany or Canada, and cannot comment on the reason for the differences.
General Standard	MWWA	We are very concerned that any standard that would be established based upon the “abundance of caution” principle will not only be overly protective, but given the very real and practicable impacts that we can anticipate within the drinking water industry, would be untenable and irresponsible.	In proposing a revised toxicity value for use in the MCP Standards, MassDEP’s statutory obligation is to ensure that people exposed to PFAS are not subjected to a significant risk of adverse health effects. This obligation informs the toxicity assessment and the approach to accounting for scientific uncertainty. However, MassDEP did not propose the lowest value that could be justified; lower values have been proposed by some other States. The practical impacts on the drinking water industry are taken into account in the process of setting drinking water standards.
General Standard	MWWA	The proposed 20 ppt MMCL is significantly lower than EPA’s lifetime health advisory level (70 ppt) issued in 2016. Any level below 70 ppt is unnecessarily below the “safe level”.	Based on extensive consideration of the available toxicology data, MassDEP has concluded that 70 ppt LHA does not adequately protect public health. See Technical Support Document that accompanies this response. MassDEP also notes that the revised RfD used in the deriving the 20 ppt GW-1 standard actually falls within the range of the stated uncertainty in the USEPA RfD values for PFOA and PFOS. USEPA defines the RfD as “An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. MassDEP’s revised RfD is within this range.
General Standard	OARS	Commenter supports the proposed Method 1 GW-1 Standard for groundwater used or potentially used as drinking water.	MassDEP notes this support for the proposed GW-1.

Topic	Commenter	Summary of Comment	MassDEP’s Response
General Standard	AIM	AIM’s comments are not intended in any way to discount the dangers of PFAS or to in any way impugn the work of MassDEP’s engineers and scientists in setting the levels proposed. Our concern revolves around the impacts of these new standards on businesses, both public and private, and cities and towns. In fact, AIM supports setting standards that are protective of public health, based on solid science.	MassDEP appreciates this statement of support.
General Standard	Precision Coating	We support the establishment of cleanup standards and drinking water standards that are protective of public health generally, and specifically of sensitive populations.	MassDEP notes this support and believes that the GW-1 standard accomplishes this goal with respect to cleanup standards.
General Standard	WRAFT	The commenter supports the proposed revisions of adding Per- and polyfluoroalkyl substances to the MCP, and the PFAS addition.	MassDEP appreciates this statement of support.
GW-3 Standard	MWWA	Request that MassDEP tighten the standards that are being proposed for the GW-3 standard for PFAS.	The basis of this request is unclear. For PFAS, there is a dearth of toxicological information on aquatic organisms. MassDEP is unaware of toxicity information that would indicate greater sensitivity to PFAS than is reflected in the Minnesota aquatic life values, which were incorporated in the GW-3 standard. To the extent that the comment is made out of concern for adjacent GW-1 areas, MassDEP is confident the current groundwater categorization works well and that the higher GW-3 standards pose no significant threat to drinking water.
Human Data	Green & Crouch	MassDEP fail to account for recent, relevant, clinical and epidemiological studies of PFOA.	The commenter appears to be primarily referring to a study of PFOA conducted in a limited number of cancer patients that failed to respond to other anticancer therapies (Convertino et al., 2018). The fact that this study was conducted on seriously ill people renders the results inappropriate for a basis to derive an RfD for PFOA.
Human Data	Green & Crouch	Importantly, the epidemiology on PFOA does not indicate that this chemical harms human development.	In light of the limitations of human epidemiological studies, even if this statement is correct it does not negate concerns based on animal bioassay studies which have demonstrated developmental effects.
Impact on Utilities	MCWRS	Given that approximately 55% of biosolids generated in the US are being land applied it is critical to first understand the fate and transport of these compounds before significantly disrupting how wastewater and biosolids are managed.	The proposed standards do not directly apply to biosolids or wastewater treatment plant effluent. MassDEP will continue to study and work with stakeholders on this issue.
Impact on water suppliers and industry	GZA	Impacts of such a low standard on Massachusetts water suppliers and industries should be considered.	MassDEP notes that PFAS that has come to be located in public water supplies will be regulated primarily by the MassDEP Drinking Water Program. This comment has been passed on to that program to be considered in the development of a draft MCL. Contamination in GW-1 areas is addressed in a number of ways under the MCP, but always taking into account the feasibility of achieving a Permanent Solution. Cost is explicitly one factor as a matter of regulation.
Including toxicity values, 40.0993	Haley & Aldrich	We recommend deleting 310 CMR 40.0993(6) in its entirety (remove (6)(a) through (f)). Specific toxicity values should not be written into regulation. Values could change prior to next regulatory update. The text should reference use of MassDEP-developed values.	MassDEP has weighed the issues/benefits of including specific toxicity values in regulation and has concluded that the clarity and consistency of a regulatory value outweighs the potential delays associated with a regulation change.
Including toxicity values, 40.0993	NAIOP	Given the current state of the science with respect to PFAS, these values should be provided in guidance rather than regulation, as updating them in a timely manner will be difficult. NAIOP recommends deleting this section.	MassDEP has weighed the issues/benefits of including specific toxicity values in regulation and has concluded that the clarity and consistency of a regulatory value outweighs the potential delays associated with a regulation change.

Topic	Commenter	Summary of Comment	MassDEP’s Response
Including toxicity values, 40.0993	Wood	It is understandable that MassDEP would like to instruct practitioners to preferentially use toxicity values that have been identified and developed by MassDEP. However, inserting the specific values themselves into the regulation could have unintended consequences that make this change inadvisable. The most significant risk is that new information is developed for one or more of these chemicals that leads to a re-evaluation of the toxicity and a corresponding change. In this case, updating any of the toxicity values listed in this section (or adding or deleting chemicals from this list) would require regulatory revision, which is a high barrier for a relatively minor change. In particular, the science of PFAS is still highly uncertain and likely to evolve such that the RfD listed in the proposed regulatory change and the chemicals to which it applies may even be out of date in the not too distant future. The suggested revision to this section would be to revise (7) to be (6), and state that, “When identifying toxicity values for use in Method 3 Risk Characterization, the values should be selected in accordance with the hierarchy of sources listed below” etc. Then, MassDEP could publish the toxicity values that are listed in the proposed section (6) as a separate document, perhaps a risk assessment technical update that could be updated or edited at any time. These would then qualify as “toxicity values adopted and otherwise published by MassDEP” and would be prioritized over toxicity values from other sources.	MassDEP has weighed the issues/benefits of including specific toxicity values in regulation and has concluded that the clarity and consistency of a regulatory value outweighs the potential delays associated with a regulation change.
Interim values	NEBRA	Interim, higher regulatory values are more appropriate at this time; future regulation based on more complete knowledge can make adjustments as needed.	MassDEP has proposed MCP notification criteria and cleanup standards based on the information about PFAS available at this time.
International values	GHD	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, and 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.	MassDEP has not reviewed regulatory or guidance values derived by the noted countries. MassDEP focused on derivations by US federal and State organizations. Nevertheless, MassDEP has noted that some other countries have derived higher values in the accompanying Technical Support Document.
Interstate action plan	AIM	Since other states are also addressing PFAS, MassDEP would be wise to undertake an action plan with them in order to transfer knowledge and resources.	MassDEP has been following developments in other States closely and is also sharing information with them through a number of avenues. However, no regional or multistate plan to address PFAS has yet been developed. MassDEP has had experience with such plans in the past (e.g. the New England Governors’ –Eastern Canadian Provinces Mercury Action Plan) and believes there may be merit in additional coordination between states.
Level of standard	Clean Water Action	Approaching the GW-1 standard by setting a 20 ppt cap for the sum of PFDA, PFHpA, PFHxS, PFOA, PFOS, and PFNA will certainly result in the opportunity for earlier regulatory action. However, we agree with CLF’s analysis that 20 ppt, even as a sum, will not protect the most vulnerable members of our community.	As discussed in the accompanying Technical Support Document and in the responses to comments, MassDEP has concluded that the proposed GW-1 cleanup standard is protective of public health based on the available scientific information and the inherent uncertainties in this data. Please refer to MassDEP’s responses to CLF’s comments for more details. MassDEP is committed to following scientific developments in the area of PFAS toxicity and exposure.
Level of standard	MCWRS	The extremely low levels of PFAS proposed for reportable concentrations under the MCP and ultimately for a drinking water MCL strike us as being overly conservative.	As discussed in the accompanying Technical Support Document, the standard is well supported. It is not overly conservative considering the range of potential health effects, data that indicates the likelihood of adverse effects at exposure levels below the USEPA RfD, the fact that infants and the developing fetus are at risk and the fact that the compounds addressed are extremely persistent in the environment and in the human body. MassDEP’s statutory obligation is to ensure that people exposed to PFAS are not subjected to a significant risk of adverse health effects. This obligation informs the toxicity assessment and the approach to accounting for scientific uncertainty. However, MassDEP did not propose the lowest value that could be justified; lower values have been proposed by some other states.

Topic	Commenter	Summary of Comment	MassDEP’s Response
MCL	CLF	MassDEP should establish an MCLG of zero.	The proposed values are MCP standards, not Maximum Contaminant Levels (MCL). MCP standards do not include goals analogous to Maximum Contaminant Level Goals (MCLGs) for drinking water. MassDEP will consider this comment as it moves forward with establishing drinking water standards for these compounds.
MCL	MCWRS	The greater concern for MCWRS and its members is the establishment of an MCL for PFAS and identification of wastewater, land applied or landfilled wastewater residuals or stormwater as potential PFAS sources.	This comment is beyond the scope of the proposed regulations, which do not establish an MCL. The comment has been passed on to the Drinking Water Program for consideration during the MCL development process.
MCL	MWWA	Some water systems have limited sources and those sources may be constrained by other regulatory programs. MassDEP should consider this in deriving MCLs.	This comment is beyond the scope of the proposed regulations, which do not establish an MCL. The comment has been passed on to the Drinking Water Program for consideration during the MCL development process.
MCL	MWWA	Public Water Systems may face procurement challenges if new drinking water standards are put in place. MassDEP needs to give some consideration as to whether statutory changes are needed to enable water systems to more quickly procure treatment technologies or if procurement thresholds need to be raised to avoid prolonged bidding processes.	This comment is beyond the scope of the proposed regulations, which do not establish an MCL. The comment has been passed on to the Drinking Water Program for consideration during the MCL development process.
MCL communication strategy	MWWA	Time and effort needs to be spent by the Commonwealth on a communication strategy so that water suppliers are not left on their own to individually figure out how to handle the risk communication. MassDEP needs to be better prepared to answer questions and address mounting fears of residents.	Although MassDEP generally aggress with this comment, it is none the less outside of the scope of the proposed regulations. The commenter may wish to resubmit this comment during the public comment period for MA’s proposed MCL.
MCP response action time lines	City/Town water officials	MassDEP also needs to consider establishing a strict timeframe for investigation into where contamination is coming from and then a much quicker response for the responsible party(ies) to implement remediation at a site. If water systems detect PFAS above the ORSG, they are required to immediately take action to provide finished water below the ORSG. The same urgency does not seem to exist for responsible parties to remediate the source of contamination and this must change.	The MCP establishes timelines for site assessment and remediation, including action to address contamination in public and private water supplies. Municipalities have legal options as well to pursue responsible parties for contribution for treatment costs.
MCP response action time lines	MWWA	MassDEP needs to consider establishing a strict timeframe for investigation into where contamination is coming from and then a much quicker response for the responsible party(ies) to implement remediation at a site, as well as contaminated drinking water sources.	The MCP establishes timelines for site assessment and remediation, including action to address contamination in public and private water supplies.
Monitoring frequency	GreenCAPE	Communities dependent on aquifers for drinking water should be afforded a more protection by more frequent monitoring and groundwater and drinking water should be subject to identical safety standards.	The MCP notification criteria and cleanup standards apply across the state, based on consistently determined soil and groundwater use categories. Drinking water monitoring will be a part of any proposed MCL - the comment has been passed on to the Drinking Water Program for consideration during the MCL development process.
Need for action	Sierra Club, Cape Cod	While we appreciate the fact that Cape Cod has taken some action to address PFAS contaminated drinking water (unlike some other parts of the Commonwealth), more needs to be done.	MassDEP is taking a variety of steps to expand its efforts to address PFAS throughout the Commonwealth.
New Hampshire standards	WRAFT	The commenter included the NHDES regulatory numbers for PFAS ranging from 11 to 18 parts per trillion and the background technical document. The commenter further stated that although NHDES numbers are lower than the MassDEP proposed regulatory numbers for PFAS, when Massachusetts industry representatives give MassDEP a pushback, MassDEP should make the industry representative aware that MassDEP’s numbers are not that conservative.	The Department has evaluated the NHDES and other federal and state documents on PFAS and has considered the methodological and data differences that resulted in variable regulatory numbers. The MassDEP differed from the NHDES in that NHDES has set standards for 4 individual PFAS while MassDEP has set its standard for 6 PFAS added together.
Occurrence	CDM Smith	MassDEP has not conducted a required state-wide sampling program from all public water suppliers or a background PFAS study in groundwater.	Neither of the sampling programs described is required as part of the MCP standard promulgation process. In any case, significant PFAS sampling has occurred throughout MA.

Topic	Commenter	Summary of Comment	MassDEP’s Response
Occurrence	MWWA	Before regulating these compounds through the MCP or an MMCL, MassDEP needs to have a much more comprehensive database of occurrence, in addition to data on health effects and at what levels those health effects occur.	Under the MCP, responsible parties are obligated to assess and address contaminants present at waste sites, including PFAS, wherever it occurs.
Occurrence	MWWA	MassDEP should begin sampling the groundwater wells in the climate response network used by the MA Department of Conservation and Recreation. Many of these wells have been termed “unimpacted” and would be a good place for MassDEP to begin their data collection.	MassDEP will consider this suggestion.
Prior exposure to communities	WRAFT	Prior exposures of communities to PFAS are not considered in the PFAS standards.	Prior exposures are not directly addressed in the MCP disposal site risk assessment methods or in the MCP standards. However, the GW-1 standard accounts for other sources of exposure through the use of a relative source contribution factor of 20%, which may in part reflect past exposures.
Private wells	MassDOT	How will MassDEP make sure that the private water wells are not impacted and/or not impacting the nearby public water treatment systems?	If this comment relates to treatment system wastes then MassDEP notes that, for either public or private water supplies where treatments are installed under the MCP, significant impacts to surrounding receptors would need to be addressed and controlled.
Property development implications	NAIOP	NAIOP is concerned that the over-regulation of this already-ubiquitous family of chemicals will create unnecessary chaos in the development community, as well as in the Commonwealth at large.	Numerous studies and testing of groundwater have shown that most locations have low-or-no reported levels of PFAS. Other contaminants are actually "ubiquitous" - such as lead in soil - and are well regulated. MassDEP believes regulation of PFAS can also be appropriately managed.
Proposed PFAS Task Force	Sierra Club, Cape Cod	We hope the MCP PFAS proposal will not be delayed by the proposed PFAS Task Force legislation (SD.2429) or other considerations.	MassDEP is moving forward with deliberative efforts to assess and address PFAS in MA.
Regulatory/ Public Process	Clean Water Action	We hope that the commitment to public process, with more emphasis placed on data transparency, will continue in the coming months and indefinitely as new science emerges regarding the breadth of PFAS chemicals, their threat to public health at extremely low levels, and how persistent newer and unstudied chemicals prove to be both in the environment and human body.	MassDEP remains committed to an open and transparent process.
Regulatory/ Public Process	AIM	We want to thank the Department for continuing this discussion in an open and transparent manner.	MassDEP is committed to open and transparent discussion regarding PFAS.
Regulatory/ Public Process	MWRA	It is unclear if decisions made during this MCP regulatory process will be finalized in such a way that the information exchange related to drinking water will be precluded.	The promulgation of drinking water standards for PFAS also involves a public comment period. Further, there is ongoing communication on PFAS issues among different programs within the MassDEP. If the drinking water standards that are ultimately promulgated differ from the MCP GW-1 standards, the drinking water standards will then be adopted as the MCP standards for consistency among programs.
S-2 Standard	DoD	Please note that Method 1 S-2 Standards may be required in the future for the volatile fluorotelomer alcohols.	These compounds were not addressed in this set of MCP revisions. We appreciate the reminder that this is an issue that MassDEP may need to consider in future MCP revisions and possibly in other regulatory programs as well.
S-3 Standard	DoD	Please explain why a Method 1 S-3 Soil standard cannot be derived for the protection of groundwater.	This is incorrect. The Method 1 soil standards do consider protection of groundwater.
Source identification	Nantucket AP	At a 20 ppb threshold, how will source partitioning of the discovered PFAS – that attributable to AFFF, and other sources – be determined?	Potentially Responsible Parties responsible for known or suspected releases of PFAS will need to assess this issue on a case by case basis.
State strategy	AIM	Since the cost of cleanup will likely cross state agencies and sectors of the economy MassDEP must coordinate with other agencies and others on efforts to solve this problem.	MassDEP has been sharing information on PFAS with other state agencies and will continue to do so in the future.
State strategy	AIM	One goal should be to not make the problem worse. As part of their consumer awareness campaign, MassDEP must educate the public on what daily products contain PFAS compounds and support the reduction or elimination of the use of PFAS-containing products.	Although this comment is beyond the scope of the proposed regulations, MassDEP agrees that this is an important issue and will be exploring additional pollution prevention and exposure mitigation mechanisms.

Topic	Commenter	Summary of Comment	MassDEP’s Response
State strategy	Precision Coating	Protection of public health generally and sensitive populations specifically is best achieved by a concerted effort to install filtration systems, given the ubiquitous presence of PFAS in the environment. It is important to note that current filtration and treatment technologies have been proven effective to remove PFAS from water and that PFAS can be completely eliminated from recirculation.	MassDEP has not found PFAS to be ubiquitous in groundwater. Under the MCP, releases to the environment are evaluated with respect to their impacts on surface water and soils as well as groundwater, and the regulations do not specify specific remedial approaches.
State strategy	Precision Coating	Precision Coating believes that the state should create a comprehensive PFAS plan to assist cities, towns and private residents with identified PFAS contamination to address the immediate drinking water concern, including funding support to ensure that all Massachusetts residents have safe drinking water.	The comment is beyond the scope of the proposed regulations. However the Commonwealth is looking to provide additional support to municipalities, such as by expanding use of SRF funding to support treatment systems.
State support to municipalities	MCWRS	The costs to treat drinking water for PFAS removal have already been shown to be significant. The cost to remediate contaminated soil or groundwater or to modify wastewater treatment and biosolids management practices is much less quantified. While waste site cleanup typically falls on responsible parties, that designation may be difficult to assign when such low levels will trigger action. Costs for drinking water treatment and wastewater treatment will be borne by local ratepayers until some future time if a responsible party is identified and legal proceedings conclude; that could be decades away. If the Commonwealth believes that PFAS at 20 ng/L represents a reasonable threat to public health, then it must be ready to help pay the costs to protect its residents. That burden cannot fall solely upon local water and sewer ratepayers.	This comment is beyond the scope of the proposed regulations. However, MassDEP acknowledges that responding to PFAS contamination may have significant fiscal impacts on the noted groups. MassDEP is working to facilitate and expand support, including assistance in sampling and analysis of public water supplies, design and installation of treatment systems and other support, or municipalities and other groups dealing with PFAS.
State support to municipalities	MWWA	MWWA encourages MassDEP to maintain communications with Administration and Finance, the Clean Water Trust, and the Legislature to provide more funding to communities facing PFAS contamination.	This comment is beyond the scope of the proposed regulations. However, MassDEP acknowledges that responding to PFAS contamination may have significant fiscal impacts on communities. MassDEP is working to facilitate and expand support, including assistance in sampling and analysis of public water supplies, design and installation of treatment systems and other support, or municipalities and other groups dealing with PFAS.
State support to municipalities	AIM	Because PFAS was contained in materials used by cities and towns and even the state, there is widespread contamination in areas owned by these entities that are not likely to have the money to treat the problem or clean up legacy issues. Homeowners could also be impacted if they are on private wells. Likely, cities, towns, private entities and residences will struggle to fund the filtration projects that are required to remove PFAS from drinking water to protect their health and the health of their residents. As such, MassDEP must create a state-wide comprehensive approach with a focus on funding clean water filtration systems for businesses, homeowners and municipalities with state assistance. A regional/state comprehensive approach will require funding/support at the state level. AIM is happy to support these efforts.	This comment is beyond the scope of the proposed regulations. However, MassDEP acknowledges that responding to PFAS contamination may have significant fiscal impacts on the noted groups. MassDEP is focusing efforts on addressing drinking water exposures, but under the MCP other potentially contaminated media and impacts cannot be ignored. MassDEP is working to facilitate and expand support, including assistance in sampling and analysis of public water supplies, design and installation of treatment systems and other support for municipalities and other groups dealing with PFAS.
Surface water	OARS	It is important that PFAS are included in the Massachusetts Surface Water Quality Standards.	Surface water standards are not set by BWSC or in the MCP revision process.
Technology-based standard	Clean Water Action	While we appreciate the costs that may be involved in tackling PFAS contamination, the already documented health impacts of PFAS chemicals make it clear that MassDEP should be regulating these MA chemicals as strictly as technologically possible, with the commitment to reassess these numbers as new technology both in terms of assessment and treatment presents itself.	MassDEP does routinely review and revise MCP cleanup standards.
Treatment	GreenCAPE	Most of the shorter chain PFAS pass through GAC filtration.	At this time MassDEP has not proposed a standard for shorter chain PFAS. The six compounds identified appear to be amenable to GAC treatment.
Treatment	MassDOT	Did MassDEP consider the impact (cost, technology, infrastructure) to the treatment technologies/water treatment systems if they are required to meet the new MCL?	This comment is beyond the scope of the proposed regulations as no MCL is proposed therein. The comment has been passed on to the Drinking Water Program for consideration during the MCL development process.

Topic	Commenter	Summary of Comment	MassDEP’s Response
Treatment	MWRA	Identifying the expected treatment processes necessary, the means for how residuals from the treatment processes would be expected to be handled, and the likely energy and greenhouse gas implications, would be helpful.	Standards established under the MCP do not consider these factors.
Treatment	MWWA	A cumulative-regulatory approach also ignores the complexities of selecting, implementing and operating the appropriate and affordable PFAS treatment solutions.	The six PFAS selected for regulation share physical, chemical and toxicological characteristics that MassDEP believes supports addressing them as a group and, in fact, provides a certain amount of flexibility compared to chemical-by-chemical regulation.
Treatment	MWRA	It would be helpful to Identify the expected treatment processes necessary, the means for how residuals from the treatment processes would be expected to be handled, and the likely energy and greenhouse gas implications.	Standards established under the MCP do not consider these factors.
Vegetable consumption	GreenCAPE	Vegetables and fruits, especially where grown with water in PFAS impacted communities -all contribute to the dietary intake of individuals who may already have ingested PFAS via their drinking water.	The relative source contribution factor included in the RfD accounts for food and other non-drinking water exposures.