

Notice of Decision Not To Adopt A Maximum Contaminant Level Regulating PFAS as a Class in Public Drinking Water Systems

INTRODUCTION AND EXECUTIVE SUMMARY

The most appropriate way to regulate per and polyfluoroalkyl substances (PFAS) is through a class-based approach. A class-based approach provides greater protection to the public, decreases the burden on regulatory agencies, and provides greater certainty to the operators of public water systems.

In evaluating whether to adopt a class based MCL to include other PFAS, several barriers were identified which are described below. Notwithstanding the clear advantages of adopting a class based maximum contaminant level (MCL) for a broad range of PFAS compounds, it is technically infeasible at this time to do so. The primary technical barrier to adopting a MCL for PFAS as a class is the lack of the comprehensive comparative or relative toxicological information necessary for all PFAS and framework to develop a class based regulatory standard. An important secondary consideration are the significant limitations that exist surrounding the ability to comprehensively quantify all PFAS in drinking water and the unreliability in a drinking water regulatory setting of using qualitative methods to require enhanced management of all PFAS.

In addition to evaluating whether PFAS could be regulated as a class, the Agency of Natural Resources (ANR) also evaluated a technology or treatment technique based standard. The most significant challenge with treatment technologies for treating PFAS (or other contaminants) is that they can present other human health risks to the community served by adoption of that treatment technology (e.g. disinfection byproducts – a known carcinogen – or increased corrosivity causing higher lead concentrations in a system), and it is costly and resource intensive to manage these risks. Also, the selection and effectiveness of a treatment technology will vary based on the type of PFAS and the relative concentrations in the system.

Again, current limitations around quantifying all PFAS prevent effective decisions on when to require treatment and effective determinations of whether that treatment has been effective. In addition, treatment techniques present operational challenges and costs for public water systems that are required to treat. Therefore, in the absence of a health based standard, ANR does not believe that a treatment technique is appropriate at this time.

Finally, the ANR evaluated regulating “subclasses” of PFAS. Act 21 does not provide a definition of what regulating PFAS as a subclass means. For purposes of this decision, we are defining regulation of PFAS that are similar in: (1) The chemical or group of chemicals is found or being investigated in Vermont; (2) The chemicals are sufficiently similar; (3) The chemicals are often found together; and (4) The chemicals elicit similar health effects.

In 2016, as a result of our discovery of significant contamination in the Town of Bennington from historic industrial operations, the Vermont Department of Health (VDH) issued a health advisory for PFOA (perfluorooctanoic acid) and PFOS (perfluorooctane sulfonic acid). That health advisory was revised in July 2018 to include five PFAS compounds: PFOA, PFOS, PFHxS (perfluorohexane sulfonic acid), PFHpA (perfluoroheptanoic acid) and PFNA (perfluorononanoic acid). This advisory establishes a subclass of PFAS compounds.

As described in greater detail within this report, there is not sufficient information from authoritative agencies, discussed in greater detail below to adopt a larger subclass of PFAS chemicals. While many national and international institutions are in the process of researching the effects that PFAS may have on the body there are challenges with expanding the class of PFAS due to lack of framework to regulate PFAS as a class. Establishing such a framework is beyond the scope that can be supported by ANR and the Department of Health. The framework for regulating chemicals as a class is developed utilizing thousands of scientific studies to support the structure of that framework. The framework could outline an additive, synergistic, weighted, or anchor approach to regulating chemicals as a class. Framework for regulating such a large scope of chemicals is rarely initiated and completed by a single state. In fact, no such examples of state frameworks other than the five or six PFAS regulated by Vermont and other states are found in literature. As illustrated by the recent publication of the toxicity assessment for PFBS by EPA then subsequent removal of that final assessment, the toxicities of certain PFAS included in EPA Method 537.1 are still being debated by authoritative bodies.

Regulation of PFAS as a subclass presents the same challenges to the public, ANR, and regulated community as regulating on a chemical-by-chemical basis. It requires the State to evaluate chemicals when toxicity information becomes available and also evaluate whether there is sufficient information to ex Notwithstanding these challenges, the ANR plans to continue its practice of regulating PFAS as a subclass.

At this time, no amendment to the water supply rule or health advisory are viewed as necessary but the Agency is committed to take the following steps to protect the public:

1. If the Agency observes elevated concentrations of a PFAS compound at a permitted facility, including a Public Water Supply, or a contaminated site the Agency will request that the Department of Health (VDH) review authoritative and peer reviewed literature

- to determine whether a revision of the health advisory and corresponding standards is possible;
2. If a significant new peer reviewed literature is published by an authoritative agency then the VDH will collaborate with ANR on whether a revision to the health advisory is warranted, and whether a revised advisory could feasibly be adopted as a standard, considering analytical methods;
 3. The Departments of Health and Environmental Conservation will conduct a general literature review for published frameworks for grouping PFAS compounds on a periodic basis and collaborate on whether revision to the health advisory and corresponding standards is warranted.
 4. The Department of Environmental Conservation in partnership with the environmental agencies from the other five New England states committed to partnering with the U.S. EPA to develop the necessary scientific and technical basis to regulate PFAS as a class.

The State of Vermont has taken numerous actions to protect the public from impacts associated with PFAS in the environment. See PFAS Roadmap. Continued leadership by the State in this area requires an investment by the legislature in staff and budget associated with PFAS and emerging contaminants.

It is important to note that this decision is focused on the narrow issue of whether it is appropriate to adopt an MCL to regulate PFAS as a class or subclass in public drinking water systems. This is not a broader discussion of how the ANR approaches regulation of PFAS in other programs. ANR continues to be concerned about the impacts that various PFAS compounds have on natural resources and humans.

STATUTORY MANDATE

Sec. 3(b) and (c) of Act 21 of the 2009 Session requires the following:

(b) On or before August 1, 2020, the Secretary of Natural Resources shall initiate a public notice and comment process by publishing an advance notice of proposed rulemaking regarding the regulation under the Water Supply Rule of per and polyfluoroalkyl (PFAS) compounds as a class or subclasses.

(c) On or before March 1, 2021, the Secretary of Natural Resources shall either:

(1) file a proposed rule with the Secretary of State regarding the regulation of PFAS compounds under the Water Supply Rule as a class or subclasses; or

(2) publish a notice of decision not to regulate PFAS compounds as a class or subclasses under the Water Supply Rule that includes, at a minimum, an identification of all legal, technical, or other

impediments to regulating PFAS compounds as a class or subclasses and a detailed response to all public comments received.

PRELIMINARY DETERMINATION AND PUBLIC INVOLVEMENT

On August 14, 2020, the Agency published an initial decision determining that it is technically infeasible to adopt a MCL to regulate PFAS as a class. A copy of that initial notice can be found at: <https://dec.vermont.gov/sites/dec/files/PFAS/20180814-PFAS-as-a-Class.pdf>

On October 16, 2020, the Agency held a public informational meeting where we received verbal comment from members of the public.

Upon issuing our initial decision, the Agency opened a public comment period on the preliminary determination. The Agency closed that public comment period on November 16, 2020 and received significant comment from the public.

All comments received have been attached to this final decision. In addition, a responsiveness summary has also been attached.

Numerous commentors provided other comments with respect to concerns surrounding impacts from landfill leachate, the land application of biosolids, or impacts from PFAS on surface waters. While all these are important topics, they are beyond the scope of this advance notice. This notice is focused on whether the Agency should amend the Vermont Public Water Supply Rule to adopt a class based MCL for PFAS. Accordingly, these comments were not responded to as a part of this advance notice.

BACKGROUND AND HISTORY OF PFAS REGULATION IN VERMONT

ANR and VDH are jointly responsible for health advisories and standards development to protect human health in Vermont. Generally, the ANR is responsible for identifying when a new standard or revision to a federal standard is needed in Vermont. This is done either by detecting a potentially harmful chemical in environmental testing performed by a permittee or the ANR or new information related to chemical risk provided by ANR's collaboration with interstate organizations.

The VDH is responsible for deriving an acceptable and protective health advisory for candidate chemicals. In general, drinking water guidance values derived by the VDH are generated by combining current toxicity values (e.g., oral reference doses, inhalation reference concentrations, oral cancer slope factors and inhalation unit risks) with a hypothetical residential exposure scenario using standard point estimate risk assessment procedures to derive an estimate of the concentration of each individual chemical or in limited instances, group of chemicals, in tap water that corresponds to a fixed level of risk i.e., a target hazard quotient (HQ) of one for noncarcinogenic (systemic) effects

or an incremental lifetime cancer risk (ILCR) of one-in-one million (1×10^{-6}). Where a chemical is known to have both noncarcinogenic and carcinogenic effects and toxicity values are available, a value is derived based on each endpoint with the most appropriate reported as the guidance.

Toxicity information and oral and inhalation toxicity values are obtained and reviewed from a number of relevant and appropriate sources including: U.S. EPA Integrated Risk Information System; U.S. EPA Office of Pesticide Programs; U.S. EPA Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center (STSC) Provisional Peer Reviewed Toxicity Values; International Agency for Research on Cancer; National Toxicology Program; California EPA Office of Environmental Health Hazard Assessment; California Department of Pesticide Regulation; and Agency for Toxic Substances and Disease Registry. (Generally referred to in this report as “Authoritative Agencies”). The VDH is familiar with the approach used by the Authoritative Agencies listed above and confident that the work done reaches a high level of rigor. The VDH also, except in situations where an emergency exists, relies on final studies that have been peer reviewed to form the basis of health advisories.

A detailed description of how drinking water guidance values are derived can be found at:

https://www.healthvermont.gov/sites/default/files/documents/pdf/ENV_ECP_GeneralScreeningValues_Water.pdf

Once derived, this value is referred to as a Health Advisory and is provided to the ANR for its consideration and ultimately adoption as a standard used in regulatory programs. ANR has two primary rules that address groundwater protection and quality. The Groundwater Protection Rule and Strategy is a rule that classifies groundwater, provides guidelines to permitting programs on how to manage groundwater, and provides guidance on how to clean up groundwater if impacted (for permitting programs). In Vermont, unless reclassified, all groundwater is classified to be suitable for use as a drinking water source.

As a result, the permitting and groundwater cleanup standards that are used in Vermont are based off the Health Advisories adopted by VDH and presume groundwater’s use as a drinking water source. These standards are referred to as Groundwater Enforcement Standards (GES) and are adopted in the Groundwater Protection Rule and Strategy. The Groundwater Protection Rule and Strategy is also used by ANR when developing cleanup plans for contaminated sites.

The Public Water Supply Rule establishes standards (referred to as Maximum Contaminant Levels or MCLs) that apply to public water systems. The Public Water Supply Rule is the state rule that implements the federal Safe Drinking Water Act and Vermont has been authorized to administer that program in the State. ANR usually follows the federal government in establishing MCLs, but has established state MCLs for five PFAS compounds, uranium, and nickel.

FINAL DETERMINATION

A) CHALLENGES DETECTING AND QUANTIFYING PFAS IN EXISTING ANALYTICAL METHODS

The current limitations associated with our ability to detect and quantify levels of PFAS in drinking water present significant challenges in all approaches to regulate a broader set of PFAS compounds.

The Drinking Water Program in the ANR requires that any analytical method used by a laboratory being reported by a regulated system be certified by the VDH. This certification requires National Environmental Laboratory Accreditation Program (NELAP) accreditation or equivalent. This review looks both at the method and the laboratory performing it to ensure that the approach is proper and done in accordance with a validated and standard method. This is important because this standardization ensures that when different laboratories analyze a drinking water sample the process by which the results are obtained are consistent. It also ensures consistent results in the same lab. Reliance on standardized methods also reduces the opportunity for the regulated community or persons responsible for releases of a harmful substance to question or dispute the data.

At this time, the Drinking Water Program requires EPA Standard Method 537.1 to analyze for PFAS in drinking water. That method has been validated and approved by EPA, NELAP, and VDH. The method will detect 18 PFAS in drinking water.

ANR examined several other analytical techniques that could more broadly detect PFAS in drinking water. Total Organic Fluorine (TOF), Total Organic Precursors (TOP), and e Department of Defense QSM 5.1 performance-based standards are not suitable to use for purposes of regulating PFAS in drinking water at this time. These methods are not suitable because: (1) all these techniques are nonstandard and do not have accompanying laboratory certifications that ensure appropriate quality assurance and quality control at the laboratories processing a sample. This nonstandard approach may lead to differing results of the same drinking water by different labs. It also creates significant issues with respect to the enforceability of violations of any of these drinking water standards; and (2) the techniques discussed above are qualitative methods or screening techniques that do not provide a quantitative result that is suitable for use regulating a drinking water system.

To set forth a sampling program relying on either total organic fluorine (TOF), total oxidizable precursor (TOP), or Department of Defense modifications to existing standard methodologies, the technique would need to establish the minimum qualifications necessary for certified by an accrediting authority to allow for use in a regulatory program. This means that an existing accrediting agency, would need to grant a certification first.

To be certified, the laboratories would need an established standard to which the analysis would be based. This is necessary to ensure that the analytical results of a sample are accurate, replicable, and consistent between laboratories. None of the approaches described above (TOF, TOP, or DOD) meet these minimal standards and therefore are not suitable for use in the drinking water program.

In addition to these analytical techniques not being standard, Total organic fluorine (TOF) measured by combustion ion chromatography (CIC) is qualitative, as it measures fluorine content, and is not specific to PFAS, nor is it quantitative. Qualitative or screening techniques are not relied upon for quantifying PFAS, nor for meeting regulatory requirements. ANR will consider this in the future as a screening tool if a multi-laboratory validated method is promulgated utilizing this technique.

Total organofluorine Analysis using Combustion Ion Chromatography (TOF) is noted as a high priority for USEPA, and ORD is working with OW-OST to develop a draft method.

As identified above, all laboratories performing analysis must be certified/accredited. The Department of Health is the accrediting body for laboratories in Vermont and can only certify analysis under the NELAP. There are only a few labs nationally who are currently certified for DoD validation standards.

Modifications of USEPA Methods present challenges with reproducibility, quality control and assurance, and data validation. The Department of Defense Quality Systems Manual Table B-15 is a robust set of quality control measures, but it is not a method. Modifications of USEPA 537.1 are not endorsed by the USEPA, and are not standardized or validated, thus are not able to be used in the drinking water program decision-making. The EPA states that if modifications are made that are not explicitly listed in the method, the method is not considered USEPA 537.1. ANR does not have the resources (time, money, capacity) to generate a new method utilizing the DoD QSM Table B-15 quality control parameters and undergo a multi-laboratory validation process.

TOP is not suitable for use in a regulatory program. Oxidation of PFAAs does not represent biotransformation under natural conditions. Additionally, PFAA precursors would be primarily abiotically oxidized to PFCAs, whether or not the precursors contained telomer or sulfonamido functionalities. For instance, a precursor that would likely form PFOS in the environment would be oxidized to PFOA under the conditions of the TOP assay. Other limitations of the TOP Assay are that telomer-based short chain precursors are biased low, larger molecular weight compounds may not be captured, and this assay does not close the mass balance on PFAS.

There is not currently a multilaboratory validated method for Total Oxidizable Precursor, as it is still considered a qualitative technique. Decisions pertaining to enforcement of standards cannot be made from qualitative (as opposed to quantitative) techniques.

B) ADOPTION OF A MCL FOR PFAS AS A CLASS UNDER THE VERMONT WATER SUPPLY RULE

Most chemicals in the United States, including those that belong to families with similar properties, are considered on a chemical-by-chemical approach for determining the health effects associated with that chemical. It is rare to develop a standard that addresses a broad class of chemicals. These broad classes of chemicals have historically been designated by EPA or other authoritative bodies, such as the National Toxicology Program, not states

Very few environmental contaminants are regulated as a class, or family. Three prominent examples are Dioxins, Polychlorinated Biphenyls (PCBs) and Polycyclic Aromatic Hydrocarbons (PAHs).

One EPA approach to grouping is to rank according to potency against the most toxic chemical member. This allows for a weighted assessment of a group chemicals. TEQs are developed by authoritative government sources. The scope of TEF/TEQ development exceeds Vermont's capacity.

The use of TEFs was first considered in the late 1970s and early 1980s when data indicated consistent relative toxicity of different congeners of chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans (CDDs/CDFs) when compared to an index chemical. In 1987, EPA adopted the use of TEFs on an interim basis. When EPA adopted the use of TEFs for Dioxins and PCBs in the mid 1990s tens of millions of dollars had been spent examining the toxicologic effects of dioxins and PCBs and significant human resources had been spent developing and validating a TEQ approach to dioxins and PCBs globally.

Some chemicals are members of the same family or group and have been shown to exhibit similar toxicological properties; however, each chemical may differ in the degree of toxicity (EPA, 2019). In some such instances, a toxicity (sometimes referred to as toxic) equivalency factor (TEF) or relative potency factor (RPF) must be applied to convert the reported concentration of each member of the group to a toxicity (sometimes referred to as toxic) equivalent concentration (TEQ) or to toxic equivalents (TE) relative to the toxicity of the index chemical for the group. The index chemical is assigned a TEF or RPF of 1. Total TEQ or TE can be compared to risk-based values derived for the index chemical or assessed using as any other single chemical in a quantitative risk assessment.

The index chemical for Dioxins, Furans and dioxin-like Polychlorinated Biphenyls (PCBs) is 2,3,7,8-Tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD). Benzo(a)pyrene (B(a)P) is the index chemical for Carcinogenic Polycyclic Aromatic Hydrocarbons (cPAH).

Vermont currently manages these chemical groups as a class based on EPA-published guidance for evaluating TEQ. Vermont relies on the EPA publications to assign TEQ to each member of the class.

Another approach taken by EPA, illustrated by the approach to evaluating noncancer risk of PCBs, is to describe various acceptable methods to analyze for this class of 209 chemicals (Aroclor, homologue, congener), then advise that the concentrations be summed and compared to a standard.

Finally, as illustrated by EPA's regulation of disinfection byproducts, EPA selected four primary trihalomethanes and five haloacetic acids to respectively monitor and sum. In this approach, EPA considers the four trihalomethanes and five haloacetic acids representative of a larger class.

C) REGULATION OF PFAS THROUGH A TREATMENT TECHNIQUE

In addition to examining the possible regulation of PFAS as a class, ANR considered whether to use a treatment technique to treat PFAS at public water systems. A treatment technique is appropriate when there is no standard for a contaminant. The challenge with managing PFAS through a treatment technique include our limitations with monitoring all PFAS compounds with any precision, the fact that recommended treatment will differ based on the PFAS present in the groundwater, and the limitations on monitoring will not provide the public water system an accurate picture of when breakthrough may occur through the treatment media.

Given the expense and complexity of treatment, including the expenses of managing treatment in a comprehensive manner to account for disinfection byproducts, setting a treatment technique at detection is not an appropriate approach to manage PFAS in Vermont. Treatment techniques are employed separate and apart from MCLs.

GAC filtration presents technical and expensive problems for public water systems, especially when accounting for the size of the systems where treatment is needed, both presently and in the future, especially if MCLs are lowered or if short-chain PFAS is added to MCLs based on future toxicological data. At the most basic level, in Vermont installing GAC treatment requires an increase operational expertise from Class 2 to Class 3 based on the system classification criteria established in the Water Supply Rule.

Small water systems, for the most part, cannot find these operators and must contract out to get them. This is expensive and the result can be a Class 3 operator who visits the water system infrequently, leaving a lower-classified or non-certified operator to do the daily work. GAC filtration requires post disinfection (usually via chlorine), so a system that has not previously disinfected will now analyze daily for chlorine and produce water with disinfection byproducts at a level usually proportional to dissolved inorganic carbon.

Disinfection byproducts will have their own deleterious health effects if not properly managed. Chlorine will also increase the corrosivity of the water, potentially increasing lead corrosion. If iron or manganese is present in the water, even in low levels, any dissolved oxygen in the water will oxidize the iron and manganese that is adsorbed onto the GAC potentially clogging the GAC filter. Iron and manganese pre-treatment may therefore be required. The resulting treatment scheme would be oxidation, iron and manganese filtration, possible dechlorination, and GAC filtration and disinfection.

Anionic exchange resins work similarly to GAC filtration. The anionic resin substitutes an anion (usually chloride) for a PFAS anion. Once all the exchange capacity is exceeded, PFAS will bleed through. The resin is then discarded and new resin is loaded.

As with GAC, other contaminants (competing ions) must be addressed as part of the treatment process to adequately remove PFAS. We have no experience with this anionic resin treatment in Vermont and no framework to understand its lifespan in a Vermont system. Research shows that it is superior to GAC with some PFAS and inferior with others. Just as with GAC filtration, performance is poorer with short-chain PFAS. The resin is reported to be more costly than GAC with fewer manufacturers. The current limitations on handling, storage, and treatment of spent media also increases the costs of this method of treatment. It is loaded with PFAS when exhausted, and unlike GAC, where regeneration decomposes the PFAS, this media is not regenerated, leaving it to be managed through the waste stream, at a considerable expense.

The final treatment technique considered was high pressure membrane filtration, specifically reverse osmosis, to remove PFAS from water. The molecules are simply too large to pass through the membrane and removal is nearly complete whether they are short-chain or long-chain. For small Vermont water systems, this method, is not a preferred treatment alternative. The process wastes water, conservative estimates report it to waste between 5-30%. This water has reject PFAS in it with concentrations three to twenty times greater than the raw water. This water must be properly disposed of.

Current EPA guidance is to provide “interim storage” until the time comes when disposal options become available. Centralized RO is nothing like an under-sink unit that treats a small amount of water. Additionally, the efficiency of the units will require more water be pumped from the sources (mostly groundwater wells) which has a deleterious effect on the aquifer. RO membranes are subject to fouling or “clogging” and must be rejuvenated with strong acids and other chemicals which must be managed and disposed of properly.

Centralized RO also requires increased operator training, which has concerns previously addressed above. The RO process would remove PFAS and other contaminant compounds but it also removes alkalinity and hardness, leaving a low pH and extremely corrosive water. Corrosion control would be needed, likely with two or more of lime, carbon dioxide, sodium hydroxide, or sodium bicarbonate. These all come with respective additional costs, storage and operation requirements, and need for time and attention from the water system operator.

ANR’s Draft PFAS Response Plan, developed under contract with Weston and Sampson Engineers identifies some of the details of the various treatment methodologies mentioned in the comments.

The document is available here:

<https://dec.vermont.gov/sites/dec/files/PFAS/Draft-Final-PFAs-Response.pdf>

D) REGULATION OF SUBCLASSES

As stated above, Vermont currently regulates PFAS as a subclass looking at five long chain PFAS compounds. The modification of that existing subclass continues to represent a one-by-one approach. The State doesn't have the personnel or resources to continuously update the subclass. While there are numerous studies ongoing by various foreign and state governments each of these studies are examining different PFAS compounds, are looking at different adverse impacts of PFAS on the human body, and many are either draft or have not been peer reviewed.

In this review process, ANR examined one cited framework – the analysis of PFAS by the Dutch National Institute for Public Health and the Environment (RIVM).

There are several issues with utilizing the Dutch National Institute for Public Health and the Environment (RIVM) literature as the basis for developing a class-based approach to regulating PFAS. The RIVM is based on an endpoint that was not considered adverse by the US EPA, namely liver hypertrophy. EPA considered and rejected liver hypertrophy as an adverse endpoint as a part of its 2017 Health Effects evaluation of PFOA and PFOS.

Based on our initial review, the RIVM approach is not peer reviewed, as the phrase “peer-review” is not found in the publication. Therefore there would be little scientific support for using this approach in Vermont. The RIVM report includes several variations of relative potency factors, and for many PFAS, includes a range rather than a discreet relative potency factor. As outlined above, ANR will continue to review published PFAS frameworks to determine if they are suitable for use as the basis of a revised health advisory.

Vermont's current advisory of 20 ppt for the sum of five PFAS is a health-protective approach. The EPA established the reference doses for PFOA and PFOS in 2016. As detailed in the health advisory support document, the reference doses for PFOA and PFOS are based on their ability to impact the developing fetus.

Reference doses are combined with exposure estimates of the most sensitive receptor to derive an advisory that is protective of the most vulnerable population. In Vermont, the reference dose was combined with the drinking water intake rate for infants 0-1 year old. Therefore the MCL is protective of this most sensitive population.

While it is true that some states have derived toxicity values for PFAS, these toxicity values are used to support individual drinking water advisories for PFAS compounds. This approach results in drinking water advisory levels for PFAS that are higher than the advisory adopted by Vermont. While there are many studies on several PFAS, reviewing the merit and quality of each study, for each PFAS, is a one-by-one approach that is not sustainable.

As mentioned in other parts of the Agency response, Vermont will consider guidance from NTP or another US government agency on how to address the thousands of existing PFAS as a class, rather than take a one-by-one approach.

Based on our work reviewing available information, the work done by other foreign governments and US states, including risk assessments, there is not enough information to set a more rigorous MCL grouping of PFAS than Vermont already adopted.

APPENDIX A: RESPONSE TO COMMENTS

I. GENERAL COMMENTS RELATED TO PFAS OR THIS NOTICE OF PROPOSED RULEMAKING.

COMMENT: Summarize briefly what this means in terms of on-the-ground procedure for persons responsible for water in buildings that serve the public, whether they be publicly owned, or private.

RESPONSE: Since the Agency is not seeking to make any changes to the current approach, the governing requirements are provided in Chapter 21 of the Environmental Protection Rules, Water Supply Rule.

COMMENT: Will systems be required to sample PFAS more frequently than they currently are?

RESPONSE: Since the Agency is not seeking to make any changes to the current approach, the governing requirements are provided in Chapter 21 of the Environmental Protection Rules, Water Supply Rule.

COMMENT: Will there be a need to take more "baseline" samples as we did last year and again this year?

RESPONSE: Since the Agency is not seeking to make any changes to the current approach, the governing requirements are provided in Chapter 21 of the Environmental Protection Rules, Water Supply Rule.

COMMENT: I am dismayed at the information that Vt ANR is not setting standards for PFAS that include the plethora of chemicals that are water solvent and deemed harmful to life on our planet. PFAS in our drinking water is not acceptable for any enlightened community or one that is concerned with the health and well being of humans. To say nothing about the fact that the outlawing of discharge of such

substances in our ground water and surface waters, should be made illegal. We should continue to support all legislation and legal means to inhibit the wanton release of pollutants into our ecosystems. Please let me know how you are working towards the betterment of our environment and protection of our species from ourselves via corporate and political interests, in light of the proposal by our ANR to deregulate the thousands of chemicals that are classified as PFAS.

RESPONSE: The Agency believes adopting a revised MCL to manage PFAS as a class in Public Drinking Water Systems is the preferred alternative if science provides enough information for such an approach under the guidelines for setting MCLs; however, regulation of PFAS as a class at this time is not technically feasible. Based on the current understanding of the toxicology for thousands of PFAS compounds, limitations for methodologies for analysis and detection, we are unable to adopt a class-based approach to adopting a MCL for PFAS. We will continue to review existing literature as information evolves to see if/when it becomes feasible. Other comments pertaining to impact to the environment are outside of the scope of this notice.

COMMENT: Please be careful about which substances you decide to stop monitoring. Chemical companies are always eager to externalize the costs of disposing of dangerous and harmful chemicals, and these chemicals are often carcinogenic or have effects on gender expression or are harmful in other ways. Please be guided by science rather than politics in such decisions.

RESPONSE: There is currently a state-wide required PFAS sampling protocol and requirements under the Vermont Water Supply Rule; monitoring will not be stopped. The Agency is considering current science from leading experts in the field to make its current determination.

COMMENT: There is some very convincing evidence that PFAS in our drinking water has serious health effects. That being said, I am also concerned about tightening the MCLs of any of the known PFAS when there is no aggressive action on decreasing or eliminating the initial production of PFAS that are the root cause of the problem. I don't see any issues with increased monitoring to get more data to be used to determine the extent of the problem. But if we start having violations that

we cannot possibly mitigate, resulting in the necessity to inform our consumers that, once again, they can't feel confident to drink the water we supply, I am not in favor of this direction.

RESPONSE: Vermont is committed to evaluating its standards as new scientific and technical information becomes available. Ongoing monitoring for 18 PFAS compounds will continue in Vermont's public water systems.

COMMENT: In Newport, the total PFAS, at 355 ppt is 17 times the 20ppt for drinking water set by the state! The total for 5 regulated is 65ppt, more than 3x the state standard. This finding registers my concern that not regulating PFAS as a class will allow an inexcusable amount of the entire class of PFAS chemicals to be dumped untreated into Lake Memphremagog, assuming the temporary moratorium on disposing of leachate in Newport's WWTF is lifted. All of these ppts of PFAS are being dumped into the Montpelier facility. What better argument could be made for regulating the family of PFAS as a class? The other 4,000 plus chemicals beyond the 5 regulated for now are deemed to be as or potentially more harmful, especially at the volume we are looking at in this report.

[Reference: Treatment of Contaminants of Emerging Concern in Landfill Leachate, A report submitted pursuant to Act 21 of 2019, February 5, 2020]

RESPONSE: The purpose of this advance notice is to evaluate the scientific and technical feasibility of managing PFAS as a class for Public Water Supplies. The results provided are not from a public drinking water system. Comments not related to whether to regulate PFAS as a class in public drinking water supplies are beyond the scope of this advance notice.

COMMENT: Water system operators have a legal obligation to provide safe drinking water to consumers. In fulfilling these obligations to provide safe drinking water and protect public health, the State, public water systems, and other impacted entities have funding assistance options they can pursue, including the Drinking Water State Revolving Loan Fund or Environmental Contingency Fund. Ultimately, the chemical manufacturers that created this crisis should be held accountable for the costs associating with cleaning up PFAS contamination. The Attorney General has filed a

lawsuit against 3M, Du Pont, and other entities to hold chemical manufacturers and polluters that have contributed and are contributing to the PFAS pollution crisis accountable for the harm they have caused. This lawsuit should generate substantial resource support to compensate the State and public entities for incurring costs to clean up PFAS contamination.

RESPONSE: The State of Vermont has filed claims against manufacturers for the impacts of their products on Vermont natural resources, including groundwater and drinking water. ANR also agree that the incremental cost benefit analysis that is used under federal standard adoption for the Safe Drinking Water Act is not required when adopting standards under state law. The State is required to examine the general economic impacts of any proposed rule consistent with the requirements of 3 V.S.A. § 838(b). We are also required to provide a robust technical basis for any proposed rule consistent with the requirements of 3 V.S.A. § 838(a)(8). As we stated in our final decision, ANR and VDH do not believe there is a basis at this time to adopt a class based MCL for PFAS. We also do not believe that changes to our existing subclass are warranted at this time.

COMMENTS: 1) PFAS is a particular class of chemicals where if we only regulate a subset of chemicals, we will fail to capture the full range of hazardous chemicals in our environment and in our water.

2) Object to the Vermont Agency of Natural Resources (ANR) proposal to regulate only a small subset of PFAS chemicals in drinking water. PFAS pollution is a worldwide problem, and unfortunately, many Vermont citizens have suffered from the effects of PFAS chemicals in their water supplies. PFAS contamination in water supplies have occurred in Bennington, Pownal, Rutland, Clarendon, and Grafton. This is a lot of contamination for a state that prides itself on clean water. There is no evidence that any of the PFAS chemicals are safe. Therefore, VT ANR should regulate all PFAS chemicals, not a select few.

3) hope that any regulation of PFAs be expanded to the fullest extent that all of the many versions of this forever toxin are included. I urge the State of Vermont to go full on to try to mitigate current PFA problems, and prevent future ones. Vermont needs to put forth a comprehensive law.

4) High level of concern about the threat of PFAS chemicals in drinking water to Vermonters as events in Bennington have highlighted recently; Disappointment and concern about ANR's unwillingness to address the entire class of PFAS chemicals, which will leave Vermonters' health at risk from drinking PFAS-contaminated drinking water; My request that your agency do strategic high sensitivity testing for PFAS chemicals in drinking water sources throughout Vermont communities to proactively identify new sources of these hazardous chemicals.

5) Concern that ANR has, so far, not been willing to regulate the entire class of PFAS, even though they are showing up in our waters and in tissue samples for most Vermonters. We know these chemicals can negatively impact our health, particularly the young and it's time to require manufacturers to certify their safety before they are put in use. This should be the case for all chemicals.

6) Please keep the entire class of PFAS chemicals out of our drinking water.

7) Address the entire class of PFAS chemicals in our water.

8) My sense is that bigger than we thought or not, ANR has to go after the whole class of PFAS compounds.

9) disappointed and upset to hear that the Agency of Natural Resources is not planning to address all of the PFAS chemicals that may be in drinking water in Vermont. I don't want me or my family to drink water that may be hazardous to our health. Please pledge that the ANR will address the entire class of PFAS chemicals.

10) Why regulate only a small subset of PFAS chemicals in our drinking water, rather than the thousands of chemicals that fall within the PFAS class of chemicals?

11) I am concerned about the threat of PFAS chemicals in drinking water, and I am disappointed and concerned about ANR's unwillingness to address the entire class of PFAS chemicals, which will leave Vermonters' health at risk from drinking PFAS-contaminated drinking water. We must move toward manufacturers having to prove there are no adverse health effects. Dropping State health regulation of any PFAS will not move us in that direction.

12) Toxicity data, combined with concerns over their similar environmental mobility and persistence and widespread human and environmental exposure, have led scientists and other health professionals to express concern about the continued and increasing production and release of PFAS. As a result scientists from around the world have called for PFAS to be managed as a class.

RESPONSE (Comments 1-12 above): The Agency believes adopting a revised MCL to manage PFAS as a class in Public Drinking Water Systems is the preferred alternative if science provides enough information for such an approach under the guidelines for setting MCLs; however, regulation of PFAS as a class at this time is not technically feasible. Based on the current understanding of the toxicology for thousands of PFAS compounds, limitations for methodologies for analysis and detection, we are unable to adopt a class-based approach to adopting a MCL for PFAS. We will continue to review existing literature as information evolves to see if/when it becomes feasible. Other comments pertaining to impact to the environment are outside of the scope of this notice.

COMMENTS: 1) In the Advanced Notice, the Review Team stated:

“There are no existing templates from peer-reviewed and authoritative sources on how to regulate PFAS as a subclass.”

- Though it was not available at the time that the Review Team met and prepared the advanced notice, a recent paper from Cousins et al., (2020) does exactly this. This paper summarizes nine different approaches for grouping PFAS based either on their intrinsic properties or those that estimate cumulative exposure and/or health effects (see Figure).⁸ The extent that these approaches are already in use in regulatory contexts

throughout the world is discussed.

2) We do not agree with the finding that there is no way to move forward on a class-based approach to addressing PFAS and recommend that ANR begin by addressing PFAS as a class in ground and drinking water. Multiple resources are available to guide ANR in developing class-based approaches for regulating PFAS. In the following section we outline a hierarchy of class-based approaches for regulating PFAS in ground and drinking water, from most health protective to least, that should be further considered by ANR in order to fulfill their legislative mandate to protect Vermont residents from undue PFAS exposure. We note a very important resource (Cousins et al., 2020), which summarizes nine different approaches for grouping PFAS based either on their intrinsic properties or those that estimate cumulative exposure and/or health effects (See Figure).⁸ The extent that these approaches are already in use in regulatory contexts throughout the world is discussed by the report authors. [See comment for details]

RESPONSE: Vermont currently regulates a subclass of PFAS compounds and the State’s current approach to PFAS is represented in the Cousins approach, which is listed as the “simple additive toxicity approach.” The “peer-reviewed authoritative sources” that are needed for adopting an MCL with an additional grouping of PFAS by class. would come from authoritative bodies, such as EPA. An approach outlined in a peer-reviewed paper does not constitute an authoritative source upon which Vermont could base the adoption of a broader MCL for PFAS. As the Cousins paper outlines in the section on “the way forward” The US National Toxicology Program is spearheading the work to group PFAS beyond the groupings listed in Table 3, which include Vermont’s strategy.

COMMENTS 1) “No peer-reviewed authoritative bodies have published TEQs to evaluate PFAS as a class.”

- RIVM has derived relative potency factors (RPFs) for 19 PFAAs, including PFOA and PFOS, and selected PFOA as the index chemical to extrapolate to other PFAAs.

2) In 2019, several European countries committed to phasing out all non-essential uses of PFAS by 2030.¹⁷ Following this, in October 2020 the EU Chemical Strategy for Sustainability proposed a comprehensive set of actions to address PFAS to ensure, in particular, that “the use of PFAS is phased out in the EU, unless it is proven essential for society.

The Commission will:

1. ban all PFAS as a group in fire-fighting foams as well as in other uses, allowing their use only where they are essential for society;
2. address PFAS with a group approach, under relevant legislation on water, sustainable products, food, industrial emissions, and waste;
3. address PFAS concerns on a global scale through the relevant international fora and in bilateral policy dialogues with third countries;
4. establish an EU-wide approach and provide financial support under research and innovation programmes to identify and develop innovative methodologies for remediating PFAS contamination in the environment and in products;
5. provide research and innovation funding for safe innovations to substitute PFAS under Horizon Europe.”¹⁸

RESPONSE: There are several issues with utilizing the Dutch National Institute for Public Health and the Environment (RIVM) literature as the basis for developing a class based approach to regulating PFAS. The RIVM is based on an endpoint that was not considered adverse by the US EPA, namely liver hypertrophy. The RIVM approach is not peer reviewed, as the phrase “peer-review” is not found in the publication. Therefore, there would be little scientific support for using this approach in Vermont. The RIVM report includes several variations of relative potency factors, and for many PFAS, includes a range rather than a discreet relative potency factor. The trade-off for including 20 PFAS in the EU grouping approach is that the corresponding limit must be increased to account for reporting levels for a larger group of compounds.

(See below for analysis of VT data and comparisons with other states’ standards).

COMMENT: “Some regulatory programs may be using TEQ for the first time, and there would be a learning curve involved with this approach. Potential for conflicting goals based on impacted sensitive receptor (fish tissue vs. human child).”

- The fact that agency staff will have to learn new approaches is simply not a sufficient justification for failing to put in place necessary health protections. The benefits of removing additional PFAS from drinking water will far outweigh the impact to the agency associated with training agency staff.

RESPONSE: The Agency agrees that additional staff training is not a sufficient justification from applying an approach. The rationale for the Agency not developing a TEQ is that data do not exist to establish a TEQ, the Agency does not have the capacity (either the appropriate personnel or fiscal resources) to do the research necessary to develop a TEQ.

COMMENT: “For chemicals that do not have established toxicity values from authoritative sources but are part of a group of chemicals in which one or more chemicals do have toxicity values, a single Health Advisory may be developed that is applicable to the sum of multiple contaminants, including chemicals that do not have toxicity values. This process is followed when the following four conditions are met:

1. The chemical or group of chemicals is found or being investigated in Vermont,
2. The chemicals are sufficiently similar,
3. The chemicals are often found together, and
4. The chemicals elicit similar health effects.”³⁹

Firstly, we note here that states have already conducted risk assessments for PFAS that are not currently part of Vermont’s combined standard including: PFBA, PFPeA, PFHxA, PFDA, PFUnA, PFDoA, PFTA, PFTrDA, PFBS, PFDS, PFOSA, and HFPODA (GenX) (Table 1). Thus, established toxicity values do exist for additional PFAS beyond the five currently regulated in Vermont, many of which also meet the 4 conditions listed by Vermont Department of Health

RESPONSE: Vermont’s grouping process applies to chemicals without established toxicity values. Authoritative sources have established draft toxicity values for several PFAS. When finalized, those PFAS toxicity values will be evaluated.

COMMENT: Massachusetts recently adopted a combined drinking water standard for six PFAS (PFOA, PFOS, PFNA, PFHxS, PFHpA, and PFDA) at 20 ppt. This currently represents the most PFAS regulated as a combined standard in the US and incorporates the 5 regulated in Vermont plus PFDA. It should be noted however, that Texas has published the greatest number of reference doses (RfD) for individual PFAS. Texas has derived RfD for 16 individual PFAS, and though these do not currently represent regulatory limits, these efforts and those outlined above show that it is feasible to regulate more than the 5 PFAS currently regulated by Vermont. More recently, Wisconsin just announced it is developing recommendations for 16 PFAS.²¹

RESPONSE: The RfDs referenced from Texas represent a one-by-one approach. Each RfD would translate into a drinking water level for an individual PFAS; this does not represent a grouping strategy for PFAS.

COMMENT: I heartily agree with the statement that Vermont should be seeking the same end as the Netherlands National Institute for Public Health and the Environment. Developing and supporting the research necessary for efficient and affordable treatment of contaminated water is of paramount importance.

RESPONSE: See response to the RIVM study above.

COMMENT: A further push against the use and spread of these contaminants is a better place to spend the State's effort and resources than in greatly increasing the regulatory burden on Public Water Systems.

RESPONSE: Such an effort is outside the scope of this notice.

II. COMMENTS RELATED TO COST TO SYSTEM / BURDEN

COMMENTS: 1) The current PFAS regulations are already a financial burden and we are concerned about additional costs of testing if PFAS was regulated as a class or sub-class. We support the Agency's recommendation that PFAS not be more broadly regulated as a class.

2) Reservations against the Vermont approach to the regulation of PFAS before a funding program is in place for aid to Public Water Systems.

3) Based on the findings of the review, our associations support DEC's conclusion that it is not currently feasible to regulate PFAS as a class. The current regulations of PFAS, established by Act 21, have already caused financial and technical burdens for public water systems in Vermont. Collecting the water sample requires training or hiring a contractor, and sample analysis is expensive. Those systems that have been found to have PFAS levels exceeding the MCL have had to spend large amounts on engineering services and remediation in addition to the social consequences of issuing a Do Not Drink order to their customers. Additional regulations will likely cause water rates to rise, which will harm our most vulnerable populations.

4) If the Vermont Legislature does decide to increase regulations of PFAS compounds now or in the future, we urge them to provide funding to water systems to cover the cost of sampling and treatment, and to perform a cost/benefit analysis of regulations.

5) The chemical manufacturers that created PFAS compounds should be responsible for their remediation in the environment, including our drinking water. We are proud that Vermont is a national leader in protecting public health by regulating contaminants in drinking water. However, the financial integrity of water utilities is also a threat to public health. This is especially the case for our small, rural system members.

RESPONSE: The State of Vermont has filed claims against manufacturers for the impacts of their products on Vermont natural resources, including groundwater and drinking water. ANR also agree that the incremental cost benefit analysis that is used under federal standard adoption for the Safe Drinking Water Act is not required when adopting standards under state law. The State is required to examine the general economic impacts of any proposed rule consistent with the requirements of 3 V.S.A. § 838(b). We are also required to provide a robust technical basis for any proposed rule consistent with the requirements of 3 V.S.A. § 838(a)(8). As we stated in our final decision, ANR and VDH do not believe there is a basis at this time to adopt a class based MCL for PFAS. We also do not believe that changes to our existing subclass are warranted at this time.

While we share the view that PFAS manufacturers are responsible for damage that their products caused to groundwater and other drinking water sources and the State seeks to recover as part of its lawsuit costs related to treating PFAS in public water systems, a drinking water system is responsible for ensuring compliance with the Water Supply Rule and other laws. The State has created the Drinking Water State Revolving Fund and Contaminants of Emerging Concern Fund to provide grants and loans to public water supplies impacted by PFAS.

COMMENTS 1) In addition, the economic impacts to public water supply operators is not an appropriate justification for failing to move forward with new drinking water rules for PFAS, and the Agency is not required to conduct a cost-benefit analysis when setting drinking water standards.²⁴² Here, the Review Team has not articulated what the anticipated increased costs to regulated entities will be.²⁴³ Nor has it identified the significant avoided costs and benefits associated with removing additional PFAS from drinking water.²⁴⁴ At a bare minimum, if the Agency intends to rely on costs to public water supply operators as a rationale, the Agency must also include a comprehensive accounting of the avoided costs and benefits associated with removal of additional PFAS from drinking water. For all these reasons, the Agency cannot support a determination that promulgating new rules based on the additive approach is not possible. In conclusion, the Agency should move forward with

new rules to protect Vermonters from all PFAS chemicals consistent with the recommendations set forth in this section.

2) The State and public water systems have options to address the financial costs associated with the clean-up of PFAS contamination in drinking water. DuPont, 3M, and other chemical manufacturers recklessly produced these dangerous chemicals for decades despite being aware of the significant health risks associated with PFAS and must ultimately be held accountable for cleaning up toxic drinking water. In the short term, there will be monitoring costs, and may be costs associated with the treatment to remove PFAS from drinking water, to water system operators. There are also substantial avoided costs and benefits from stopping or preventing exposure to these dangerous chemicals in Vermont communities.²⁴⁵

RESPONSE: The Agency's expectation is that owners of public drinking water systems to operate water systems in compliance with the applicable regulations. The purpose of the Vermont Water Supply Rule is to regulate water systems in the state so that they provide clean and safe drinking water to Vermont's citizens. The Water Supply Rule establishes standards designed to mitigate impacts to public health through drinking water. There is currently an MCL established in the rule for 5 PFAS compounds as discussed elsewhere in these responses. There is insufficient evidence to adopt a regulatory standard at this time as discussed elsewhere in this document.

III. COMMENTS RELATED TO PUBLIC HEALTH AND PFAS TOXICITY

COMMENT: State drinking water standards that prevent exposure to unsafe levels of the PFAS class of chemicals are necessary to protect Vermont communities. PFAS chemicals are a public health perfect storm because they (1) are extremely persistent; (2) tend to be highly mobile in the environment; (3) can bioaccumulate; (4) can be toxic in small concentrations; (5) are used in hundreds of different industrial and commercial processes and found in a

wide variety of consumer products; and (6) there are over 9,000 different kinds of these dangerous chemicals. PFAS include presumed carcinogens and have been linked to a variety of severe health problems, including learning disorders in infants and children, fertility and pregnancy issues, and impaired liver, thyroid, pancreatic, and immune function.⁴ Alarmingly, epidemiological studies identify the immune system as a target of PFAS toxicity.⁵ Some studies have found decreased antibody response to vaccines, and associations between blood serum PFAS levels and immune system hypersensitivity (asthma) and autoimmune disorders (ulcerative colitis).⁶ On top of these serious health threats, a former Director of the National Institute of Environmental Health Sciences recently warned that exposure to even small amounts of PFAS may make people more vulnerable to COVID-19.⁷

RESPONSE: The agencies agree that the immune system is a target of PFAS, as outlined in the Health Department’s advisory for PFAS. Research on the effect of PFAS in our bodies on our ability to fight off COVID is ongoing.

COMMENTS: 1) As detailed in the Technical Comments, the Agency did not consider health and toxicological data for nearly 30 PFAS, including risk assessments and hundreds of human epidemiological, experimental animal, and mechanistic and/or in vitro studies.⁴² For example, the Advance Notice fails to even acknowledge—much less include a discussion of—the fact that states have conducted risk assessments for PFAS that are not currently part of Vermont’s combined standard or that other jurisdictions have derived relative potency factors for many PFAS using PFOA as the index chemical.⁴³ The information is completely absent from the Advance Notice.⁴⁴ Among other things, health and toxicological data for PFAS beyond the five PFAS currently regulated is critical information that the Agency must fully consider as part of the review.

2) There is a strong scientific basis and available technology for the management of PFAS as a class, subclasses, and groups, and it is unacceptable for the State to waste limited resources and time to chase these dangerous chemicals down one by one while communities are exposed to unsafe drinking water that has permanent health consequences. The current Maximum Contaminant Level (MCL), which sets a combined 20 ppt standard for perfluorooctanoic acid (PFOA), perfluorooctane

sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluoroheptanoic acid (PFHpA), and perfluorononanoic acid (PFNA), does not protect public health because (1) it does not account for impacts to sensitive endpoints or protect vulnerable populations and (2) only regulates five out of more than 9,000 compounds.

3) Any standard set by ANR must be set at the most health protective level currently achievable given current technical limitations

4) Studies suggest a more protective reference dose is appropriate to account for more sensitive endpoints such as increased cancer risk, impacts to mammary gland development, and immune system dysfunction.¹⁵³ For example, in August of 2019, California's Office of Environmental Health Hazard Assessment (OEHHA) developed reference levels for PFOA and PFOS in drinking water for both cancer and non-cancer effects.¹⁵⁴ The cancer effect reference level is based on the concentration of the chemical in drinking water that would not pose more than a one in one million cancer risk over a lifetime.¹⁵⁵ For PFOA, OEHHA derived a reference level of *0.1 ppt* based on pancreatic and liver tumors found in male rats in a new NTP study.¹⁵⁶ For PFOS, OEHHA derived a reference level of *0.4 ppt* based on liver tumors in male rats and the structural and biological similarity of PFOS to PFOA.¹⁵⁷

5) The Review Team, however, summarily dismissed this potential approach to regulating PFAS beyond the five currently regulated.²³⁸ Specifically, the Review Team noted that there is "limited data" to support "the inclusion of additional PFAS."²³⁹ This is just not accurate. As the Technical Comments note, "states have already conducted risk assessments for PFAS that are not currently part of Vermont's combined standard including: PFBA, PFPeA, PFHxA, PFDA, PFUnA, PFDoA, PFTA, PFTrDA, PFBS, PFDS, PFOSA, and HFPODA (Gen X). Thus, established toxicity values do exist for additional PFAS beyond the five currently regulated in Vermont."²⁴⁰

6) The Review Team also noted as a "con" that this approach could lead to the need for regular review and revision of the regulatory standard to keep pace with science and outreach to public water supply operators due to an increase in compliance costs.²⁴¹ As discussed previously, the need for

regular review of public health standards is expected and required, and absolutely cannot be used as an excuse to delay putting in place drinking water rules that are necessary to protect Vermonters from PFAS.

RESPONSE: The work done by other states, including risk assessments, do not lend support for a more rigorous grouping of PFAS than Vermont already adopted. While it is true that some states have derived toxicity values for PFAS, these toxicity values are used to support individual drinking water advisories for PFAS compounds. This approach results in drinking water advisory levels for PFAS that are higher than the advisory adopted by Vermont. While the commenters rightly point out that there are many studies on several PFAS, reviewing the merit and quality of each study, for each PFAS, is a one-by-one approach that is not sustainable because there are thousands of PFAS chemicals. As mentioned in other parts of the Agency response, Vermont will consider guidance from NTP or another US government agency on how to address the thousands of existing PFAS as a class, rather than take a one-by-one approach.

COMMENT: In addition, the Advance Notice does not include any discussion of other factors relevant to regulations to better protect Vermonters from exposure to the PFAS class in drinking water, including:

- data that demonstrates that PFAS are present in more than 100 public water supplies;
- data that shows PFAS beyond the five currently regulated are present in public water supplies and other media in Vermont;
- available treatment technologies to remove PFAS from drinking water;
- public health and economic benefits of regulating PFAS as a class or subclasses or PFAS beyond the five currently regulated; and
- the public health and economic benefits associated with the removal of other unregulated contaminants that would occur with installation of treatment to remove PFAS.

RESPONSE: See elsewhere in the Agency's comments on discussions of data analysis, treatment technology available, costs of treatment, and public health protection.

COMMENTS: 1) Protective state standards for the PFAS class are necessary to prevent exposure to unsafe levels of PFAS in drinking water.

In light of EPA's failure to act over decades, states must establish drinking water standards for the PFAS class or subclasses. The Agency has broad authority to protect drinking water, and the legislature specifically directed the Agency to promulgate new rules to better protect Vermonters from the PFAS class of chemicals. PFAS can be highly toxic to humans in small concentrations and testing in the State has revealed these chemicals are in drinking water, groundwater, and surface water, as well as landfill leachate, and wastewater treatment plant discharges and sludge.

The current PFAS MCL is an important first step to prevent exposure to dangerous toxic "forever chemicals." However, the PFAS MCL does not fully protect public health because it does not protect for the most sensitive endpoints or our most vulnerable populations, including fetuses, infants, and children; other states have adopted more protective individual MCLs and the Massachusetts combined standard includes one additional PFAS; and the standard does not address all PFAS compounds. Class regulation is necessary to protect Vermont communities.

2) Developing fetuses and newborn babies are particularly sensitive to PFAS chemicals.⁷⁹

The impacts of PFAS exposure on fetal development and the young have been studied in both humans and animals. These studies find similar and profound adverse health effects.

Since infants and children consume more water per body weight than adults, their exposures may be higher than adults in communities with PFAS in drinking water. In addition, the young may also be more sensitive to the

effects of PFAS due to their immature developing immune system, and rapid body growth during development. Exposure to PFAS before birth or in early childhood may result in decreased birth weight, decreased immune responses, and hormonal effects later in life.⁸⁰

As described in a recent study, PFAS exposure occurs *in utero* as a result of placental transfer of PFAS, and there is also a significant, additive PFAS exposure that occurs in infants through breast-feeding.⁸¹

3) Alarming, epidemiological studies identify the immune system as a target of PFAS toxicity. Some studies have found decreased antibody response to vaccines, and associations between blood serum PFAS levels and both immune system hypersensitivity and autoimmune disorders like asthma and ulcerative colitis.⁸² On top of these serious health threats, a former Director of the National Institute of Environmental Health Sciences recently warned that exposure to even small amounts of PFAS may make people more vulnerable to COVID-19.⁸³

While a great deal of public attention has recently been paid to PFOA, PFOS, and other long-chain PFAS, EPA and other scientists have raised concerns that other chemicals in the PFAS class of compounds are similar in chemical structure and are likely to pose similar health risks.⁸⁴ For example, all PFAS share a strong carbon-fluorine bond and “degrade very slowly, if at all, under environmental conditions.”⁸⁵ Although we have less information about these newer compounds, the information we do have suggests that they are not safe and some may even be more harmful.⁸⁶ While some newer fluorinated alternatives seem to be less bioaccumulative, they are still as environmentally persistent as long-chain substances or have persistent degradation products.⁸⁷ For example, “[a] recent hazard assessment based on the internal dose of Gen X[, a short-chain PFAS,] suggests that it has a higher toxicity than PFOA after accounting for toxicokinetic differences.”⁸⁸ Because some of the newer PFAS are less effective, larger quantities may be needed to provide the same performance.⁸⁹ In addition, these newer PFAS compounds are more mobile in the environment. In conclusion, scientific experts agree that these

chemicals should be managed as a class due to extreme environmental persistence, toxicity of the PFAS that have been studied, and the potential toxicity and health risks posed by the entire class due to similarities in chemical structure.⁹⁰

4) The PFAS MCL does not protect public health. The current PFAS MCL is not sufficient to protect Vermont communities. As a preliminary matter, the Agency has already set a MCLG of zero for PFOA, PFOS, PFHxS, PFHpA, and PFNA.¹³⁷ An MCLG is “the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety.”¹³⁸ Thus, the Agency has already determined that there is no safe level of these five PFAS and has not provided a technical justification for setting the MCL at 20 ppt for PFOA, PFOS, PFHxS, PFHpA, and PFNA combined.¹³⁹ As discussed below, these compounds can be reliably reported at levels as low as 2 ppt using standard laboratory methods¹⁴⁰ and treatment technologies are available to remove these PFAS to below detection limits.¹⁴¹

5) The current combined MCL is not reflective of the recently adopted MCLG of zero, and the MCL is based on an outdated risk assessment that does not account for the most sensitive endpoints, including cancer, development and immune harm, or health impacts to vulnerable populations such as fetuses, infants, and children. In addition, other states have adopted more protective individual MCLs and the Massachusetts combined standard includes more PFAS. Finally, the current PFAS MCL addresses just five out of more than 9,000 PFAS.

6) At a minimum, the Agency should establish a combined MCL at the lowest, most health protective level that is technically achievable for the maximum number of quantifiable PFAS pursuant to the additive approach currently utilized. At a minimum, there is sufficient scientific and technical information for the Agency to utilize the additive approach to establish a combined MCL below 20 ppt at the lowest, most health protective level technically achievable for the maximum number of quantifiable PFAS consistent with our recommendations in Section III.A.2.²³⁰

- RESPONSE:** Unfortunately, the Commentors do not recognize the basis of the MCL, nor acknowledge the process by which a health advisory is derived to protect sensitive populations. The health advisory considers exposure of the highest exposed and most vulnerable population to PFAS. Vermont is among the few states that have taken an early and protective approach to regulating PFAS in drinking water. Establishing individual MCLs for individual PFAS would represent a step backwards in terms of protecting Vermonters from exposure to PFAS. Summing the five PFAS under a single advisory, based on the amount of water consumed by sensitive populations is health-protective approach.
- COMMENT:** The Reference Dose selected by the Department of Health does not protect for sensitive endpoints and vulnerable populations. The PFAS MCL is based on assumptions that do not protect public health. Specifically, several studies indicate that the Chronic Oral Reference Dose (Reference Dose) selected by the Department of Health for PFOA, PFOS, PFHxS, PFHpA, and PFNA is not protective for the most sensitive endpoints and our most vulnerable populations—fetuses, infants, and children.
- RESPONSE:** The reference dose that the MCL is based on comes from a developmental study, to look at the effects of PFOA on the developing fetus. Reference doses are combined with exposure estimates of the most sensitive receptor to derive an advisory that is protective of the most vulnerable population. In Vermont, the reference dose was combined with the drinking water intake rate for infants 0–1-year-old. Therefore, the MCL is protective of this most sensitive population.
- COMMENT:** Decisions made when developing a health benchmark, such as evaluation of data gaps, the selection of uncertainty factors, and choice of exposure parameters to use, should address the most sensitive endpoints and be protective of the most vulnerable populations, particularly developing fetuses, infants, and children. Fetuses and infants have greater exposure to PFAS than adults, and are also more sensitive to the effects of these contaminants.¹⁴² Almost all fetuses and infants will have some degree of exposure, including exposure as fetuses during pregnancy through placental transfer.¹⁴³ For

infants, exposure may be further elevated due to ingestion of contaminated breastmilk (a result of the mothers' ingestion of contaminated water and other sources) or infant formula prepared with contaminated drinking water.¹⁴⁴

RESPONSE: The EPA established the reference doses for PFOA and PFOS in 2016. As detailed in the health advisory support document, the reference doses for PFOA and PFOS are based on their ability to impact the developing fetus. The authors of this comment may not recognize that the reference doses for PFOA and PFOS are based on the sensitive endpoint of fetal development. As explained earlier in comments, the health advisory considers exposure to the sensitive population of infants 0-1 years old in the development of the health advisory for PFAS.

COMMENT: Levels of PFOA and other PFAS in breastmilk are much higher than what is typically found in drinking water, as PFOA and other PFAS bioaccumulate in the body and are then transferred into the breastmilk.¹⁴⁵ Moreover, since infants consume approximately five times more water per body weight than adults,¹⁴⁶ their exposure is likely higher than adults regardless of whether they are breastfed or are fed infant formula prepared with PFAS-contaminated drinking water. Infant blood serum levels of PFAS are often the highest of any age group in studies that compare people in multiple stages of life.¹⁴⁷

RESPONSE: While Minnesota developed a pharmacokinetic model to account for exposure to breastfed infants the resulting health-based guidance values for drinking water are higher than Vermont's level. Minnesota's drinking water levels are 47 ppt for PFHxS, 35 ppt for PFOA and 15 ppt for PFOS. Therefore, Vermont's additive approach for the sum of five PFAS (not to exceed 20 ppt) is more protective than the approach developed to specifically address exposure via breastfeeding.

COMMENT: Compounding the issue of increased exposure, fetuses, infants, and children are also more vulnerable to exposure-related health effects than adults. The young may be more sensitive to the effects of PFAS due to their immature, developing biological systems (such as the immune system), and rapid body growth during development.¹⁴⁸ For example, exposure to PFAS before birth and/or in early childhood may result in decreased birthweight, decreased

immune responses, and hormonal effects later in life.¹⁴⁹ In fact, the National Academy of Sciences (NAS) has recommended the use of an additional uncertainty factor of 10 to ensure protection of fetuses, infants and children who often are not sufficiently protected from toxic chemicals such as pesticides by the traditional intraspecies (human variability) uncertainty factor.¹⁵⁰ Considering the many health effects linked to PFAS that affect this vulnerable population and the substantial data gaps on exposure and toxicity of these compounds in complex mixtures, the Department of Health should rely on the most sensitive endpoints, adopt the most conservative assumptions, and use the additional uncertainty factor recommended by the NAS when deriving health-protective benchmarks for PFAS.

RESPONSE: As detailed clearly in the reference provided by the commenter, the National Academies recommendation of an extra factor of 10 apply to pesticides, not to the broader landscape of humanmade chemicals. The EPA's Office of Pesticides has incorporated the National Academies' recommendation by including the factor of 10 into their risk assessment equations. PFAS are not pesticides. The EPA's Office of Water has not included a factor of 10 in the derivation of the reference dose for PFAS or any other chemicals to account for children's sensitivities to chemicals.

COMMENTS: 1) The Department of Health selected 2×10^{-5} mg/kg BW-day for these five PFAS, which is "based on a non-cancer endpoint and derived using the oral reference dose . . . provided in US EPA's 2016 Health Effects Support Documents for PFOA and PFOS."¹⁵¹ However, the EPA's reference dose for PFOA and PFOS is not protective of the most sensitive endpoints currently linked to PFAS exposure and does not include the additional uncertainty factor recommended by the NAS.¹⁵²

2) The Agency should establish a combined MCL at the lowest, most health protective level technically achievable for the maximum number of quantifiable PFAS. The Agency should establish a combined MCL below 20 ppt at the lowest, most health protective level technically achievable for the maximum number of quantifiable PFAS.¹⁹⁸ As discussed previously, the 20 ppt standard does not protect for the most sensitive endpoints or the most vulnerable populations.¹⁹⁹ The Agency has already set an MCLG of zero for five PFAS and scientific studies suggest that adverse health impacts from

exposure to some PFAS can occur at 1 ppt or below.²⁰⁰ Commercial labs can reliably report quantifiable PFAS at levels between 2 – 5 ppt.²⁰¹

RESPONSE: In standard drinking water calculations, toxicity values are combined with drinking water intake rates (exposure estimates) to create advisories for sensitive populations. This is exactly the approach that Vermont used. In fact, no other state uses such a protective drinking water estimate for their health advisories.

COMMENT: New Jersey has calculated a reference dose based on mammary gland development, which if used to calculate a health advisory or MCL for PFOA, would be *less than 1 ppt*.¹⁵⁸ In addition, one research team documented a strong dose-response between a child's exposure to PFAS and reduced antibody concentrations against tetanus and diphtheria toxoids in serum two years later.¹⁵⁹ Based on the results of the study, the researchers concluded that even exposure to PFOA and PFOS concentrations as low as *approximately 1 ppt* may have adverse health effects for children.¹⁶⁰ If these studies were taken into account and an additional uncertainty factor applied to protect the most vulnerable populations, the Reference Dose for these five PFAS would be much more protective than the Reference Dose selected by the Department of Health. In recognition of the significant toxicity of PFAS and the vulnerability of sensitive populations like fetuses, infants, and children to PFAS exposure, the Department of Health should rely upon only the most conservative assumptions and incorporate an additional uncertainty factor to protect children in the derivation of a health advisory for PFAS.

RESPONSE: As documented in the support document for New Jersey's MCL for PFOA, the MCL is based not on mammary gland development as the authors imply, but on increased liver weight. The mammary gland endpoint was not chosen by New Jersey as the basis of their MCL:

<https://www.state.nj.us/dep/watersupply/pdf/pfoa-recommend.pdf>. As documented in the guidance document for the development of health advisories, Vermont has relied on authoritative bodies to establish peer-reviewed toxicity values, rather than candidate toxicity values from other states.

COMMENT: 1) First, there is sufficient evidence to classify PFOA as a known or probable carcinogen. Both the International Agency for Research on Cancer and EPA's findings on PFOA's carcinogenic potential are based heavily on the C8 study, whose Science Panel determined that PFOA is a probable carcinogen.¹⁸⁸ There is also significant additional animal and human evidence for an association between PFOA exposure and cancer, particularly kidney and testicular cancer, and more recently for pancreatic cancer.¹⁸⁹ OEHHA recently derived a reference level of 0.1 ppt for PFOA based on pancreatic and liver tumors found in male rats exposed to very low levels of PFOA in a NTP study.¹⁹⁰ Although the evidence of carcinogenic potential for other PFAS is not as well established as PFOA, given the similarities in structure and toxicity to PFOA, their potential for carcinogenicity cannot be ruled out.¹⁹¹

2) In addition to being a carcinogen, PFOA causes adverse non-cancer health effects at exceedingly low doses. A MCLG based on altered mammary gland development would be well below 1 ppt for PFOA, for example.¹⁹² Other shared health effects amongst PFAS occur at extremely low levels, such as immunotoxicity, developmental harm, and liver damage.¹⁹³ For example, evidence indicates that PFOS causes adverse cancer and non-cancer health effects at exceedingly low doses.¹⁹⁴ A MCLG based on immunotoxicity or cancer would be well below 1 ppt for PFOS.¹⁹⁵ A MCLG for PFNA based on developmental toxicity is below 1 ppt, approximately 2 ppt for PFHxS based on thyroid toxicity, and below 1 ppt for GenX based on liver toxicity.¹⁹⁶

RESPONSE: Per guidance, the drinking water advisory for PFOA was calculated using both cancer and noncancer toxicity values provided in the EPA 2016 Health Effects Support Document for PFOA and PFOS. The lower of those two values is selected for use as the health advisory; the lower of the two values was based on noncancer toxicity values. No animal studies on carcinogenicity of other PFAS are included the ATSDR draft, illustrating that carcinogenicity of certain other PFAS is not well document in animal studies.

COMMENTS: 1) "All PFAS share a common structural feature, the carbon-fluorine bond, which is the strongest single bond in organic chemistry and confers environmental persistence to all PFAS. In addition, PFAS can also share several other problematic properties,

including bioaccumulation, environmental mobility, and toxicity. Experts agree that persistence alone is cause for concern and sufficient for regulation” as a class in order to protect public health,¹⁹⁷ and Vermont has already adopted an MCLG of zero for five PFAS. For all these reasons, the MCLG should be zero for the entire PFAS class of chemicals.

2) VDH guidance sets forth a process for regulating multiple chemicals together to protect public health.²³¹ “For chemicals that do not have established toxicity values from authoritative sources but are part of a group of chemicals in which one or more chemicals do have toxicity values, a single Health Advisory may be developed that is applicable to the sum of multiple contaminants, including chemicals that do not have toxicity values.”²³² VDH has already acknowledged that combined regulation of PFOA, PFOS, PFHxS, PFHpA, and PFNA—even where toxicity values for some compounds are not available—is appropriate because these five compounds satisfy four criteria: (1) they are “currently being investigated in Vermont and have been found in drinking water,” (2) they are all “members of the PFAS family . . . and are considered sufficiently similar,” (3) they “are often found together,” and (4) they “elicit similar health effects ”²³³

3) The same four criteria are met with respect to the class of PFAS compounds. First, in addition to five PFAS currently regulated, other PFAS that have been found or are being investigated in Vermont, including, PFBA, PFPeA, PFHxA, PFDA, PFUnA, PFDoA, PFTA, PFTrDA, PFBS, PFPeS, PFHpS, PFNS, PFDS, PFDoS, PFOSA, HFPO-DA or GenX, NEtFOSAA, NMeFOSSA; 4:2 FTS, 6:2 FTS, and 8:2 FTS.²³⁴ There are likely many other PFAS in Vermont that the State is simply not aware of yet given the speed and secrecy with which chemical manufacturers have introduced these dangerous chemicals into commerce.

4) Second, as the Technical Comments noted, PFAS are similar with respect to chemical structure and other attributes like persistence, toxicity, potential for bioaccumulation, and mobility in water.²³⁵ Third, these PFAS chemicals are often found together and some break down into each other.²³⁶ Fourth, these PFAS are likely to have similar health effects.²³⁷ As noted previously, commercial labs can reliably quantify up to 40 PFAS to 2 ppt – 5 ppt and

treatment technologies are available to remove both long-chain and newer PFAS.

RESPONSE: There is variability among certain PFAS. The commenters perspective that all additional PFAS meet the grouping criteria established by the Health Department is a simplified viewpoint. For example, as explained by ITRC, the family of PFAS include classes, subclasses, groups, and subgroups based on structural similarities.

Naming conventions of PFAS are evolving, but the two classes of the PFAS family are Polymer and Nonpolymer. The focus is on nonpolymer PFAS, as these compounds are most commonly detected in humans, biota, and environmental media. Within the class of Nonpolymer PFAS, there are two subclasses, Perfluoroalkyl Substances and Polyfluoroalkyl Substances. These subclasses are divided based on if the carbon chain is fully (per) or partially (poly) fluorinated. An example of a group within the subclasses of Perfluoroalkyl Substances are Perfluoroalkyl acids (PFAAs), with subsequent subgroups broken into Perfluoroalkyl carboxylates (PFCAs) and Perfluoroalkyl sulfonates (PFSAs). An example of a group within the subclass Polyfluoroalkyl Substances is fluorotelomer-based substances. The image below shows the two classes of the PFAS family and is taken from the ITRC

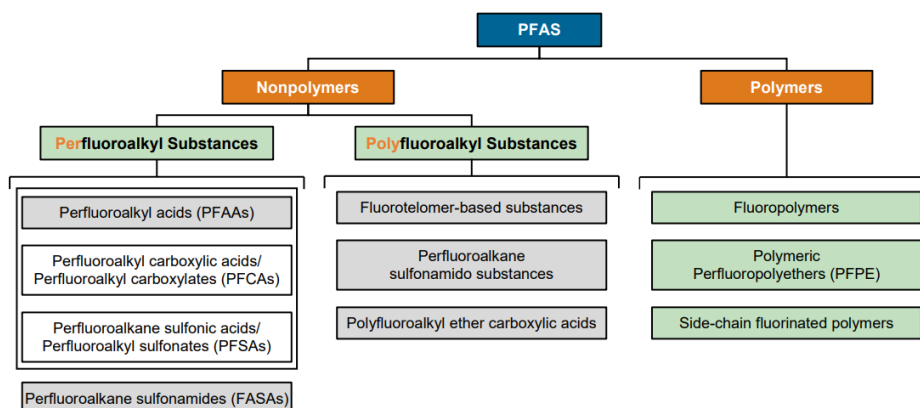


Figure 1. Summary of the PFAS family.

IV. COMMENTS RELATED TO VERMONT DATA AND COMPARISON WITH OTHER STATE STANDARDS

COMMENTS: 1) PFAS are already detected in public drinking water systems and in other environmental media in Vermont (Table 1). Fifteen percent (n=107) of public water systems tested in Vermont had detectable levels of one or more PFAS. Total levels reported for the 18 PFAS included in the US EPA Method 537.1 ranged from 2.00 to 335.04 parts per trillion (ppt), with an average of 19.71 ppt and a median of 6.80 ppt. Vermont currently has an enforceable drinking water standard (maximum contaminant level, or MCL) for 5 PFAS (PFHpA, PFHxS, PFNA, PFOA, PFOS) at a combined value of 20 ppt. Under the existing combined MCL, 19 of the 107 (17%) public water systems with detectable levels of PFAS exceed the 20 ppt standard. The existing combined MCL therefore leaves communities served by the remaining 88 public water systems with detectable PFAS at risk of PFAS-associated health harms. It is unknown how many of the public water systems contain additional PFAS that are not measured by EPA Method 537.1. Importantly, absence of data does not mean absence of harm. Given the history of PFAS manufacturing and use of PFAS by various industries in Vermont, there are likely other PFAS beyond those measured by US EPA Method 537.1 in the environment and drinking water systems in Vermont. For example, the total oxidizable precursor (TOP) assay has been used to detect a significant amount of PFAA precursors present in environmental samples. And in 2017, 40 new subclasses of PFAS were identified in aqueous film forming foam (AFFF) and AFFF-impacted groundwater.

2) Public water systems (PWS) in Vermont were recently tested using US EPA Method 537.1 and 107 of 700 tested PWS had detectable levels of one or more PFAS. We compared the levels of detection in Vermont PWS to Vermont's existing combined standard for 5 PFAS and to the approach that we propose here to, at a minimum, expand the currently utilized additive approach at a more health protective, stricter level:

- Under Vermont's existing combined standard of 20 ppt for 5 PFAS (PFHpA, PFOA, PFNA, PFHxS, PFOS), residents from only 19 of the 107 PWS with detectable PFAS are protected
- If a combined standard for the 18 PFAS on US EPA Method 537.1 of 20 ppt were applied to Vermont's PWS, residents from 27 of the 107 PWS

would be protected. This finding is largely driven by the detection of PFHxA, PFBS, HFPODA, NETFOSAA, and NMEFOSAA.

- If a lower combined standard for the 18 PFAS on US EPA Method 537.1 of 10 ppt were applied to Vermont's PWS, which reflects more recent science and risk assessment work from states such as New Hampshire, New Jersey and Michigan, residents from 41 of the 107 PWS would be protected.
- If a lower combined standard for the 18 PFAS on US EPA Method 537.1 of 2 ppt were applied to Vermont's PWS, which reflects Vermont's MCLG of zero for the PFAS it is regulating now, along with more recent science and risk assessment work from California's Office of Environmental Health Hazard Assessment, the European Food Safety Agency, and the work of prominent PFAS scientists, residents from all 107 of the PWS would be protected.

3) PFAS have been found at unsafe levels in the environment throughout Vermont, including in more than 100 public water supplies, private drinking water wells, groundwater, and surface waters. Drinking water contaminated with PFAS is a significant source of exposure.⁸ In addition to PFOA, PFOS, PFHxS, PFHpA, PFNA, at least the following PFAS are present in Vermont: PFBA, PFPeA, PFHxA, PFDA, PFUnA, PFDaA, PFTA, PFTrDA, PFBS, PFPeS, PFHpS, PFNS, PFDS, PFDoS, PFOSA, HFPO-DA or GenX, NETFOSAA, NMeFOSSA; 4:2 FTS, 6:2 FTS, and 8:2 FTS.⁹ This most likely does not reflect all PFAS present in the State due to limited testing. Without a drinking water standard for additional PFAS beyond the five PFAS currently regulated, public water systems in Vermont are not required to regularly monitor for all PFAS compounds or to treat water with unsafe levels of PFAS.

4) Drinking Water: The results of recent public water supply testing required by Act 21 is alarming. PFAS were detected in more than 100 water supplies in 2019-2020.⁹¹ Concentrations of the 18 PFAS tested sampling data was downloaded on September 1, 2020 ranged from 2 ppt to 335 ppt.⁹² In addition to the 5 PFAS currently regulated by an MCL, the following PFAS were detected: PFBS, PFHxA, HFPO-DA or GenX, NETFOSAA, and NMeFOSA.⁹³

These results likely underestimate PFAS concentrations in Vermont's water supplies because the scope of testing was just 18 compounds out of more

than 9,000 PFAS.⁹⁴ Other PFAS have been detected in Vermont including PFBA, PFPeA, PFDA, PFUnA, PFDoA, PFTA, PFTTrDA, PFPeS, PFHpS, PFDS, PFDoS, PFOSA, 4:2 FTS, 6:2 FTS, and 8:2 FTS.⁹⁵ Further, the testing that has been conducted with respect to media besides drinking water also captures a very limited number of compounds—approximately 24—compared to the number of compounds in the class.⁹⁶ Notably, at least one study has demonstrated that while concentrations of older, short-chain PFAS like PFOA and PFOS may be decreasing in some water supplies because these compounds are no longer manufactured in the U.S., concentrations of newer PFAS are increasing significantly.⁹⁷

5) Several states have adopted more protective MCLs for individual compounds. Several states have adopted MCLs for some PFAS that are more protective than the numeric component of Vermont's MCL.¹⁶¹

| Chemical | Vermont (ppt) | Massachusetts (ppt) | New Jersey (ppt) | New Hampshire (ppt) | Michigan (ppt) | New York (ppt) |
|----------|------------------|---------------------|------------------|---------------------|----------------|----------------|
| PFOA | 20 (combined) | 20 (combined) | 14 | 12 | 8 | 10 |
| PFOS | | | 13 | 15 | 16 | 10 |
| PFNA | | | 13 | 11 | 6 | |
| PFHxS | | | | 18 | 51 | |
| PFHpA | | | | | | |
| PFDA | | | | | | |

RESPONSE: Since it is not possible to re-create the exact data set used to provide comments, below are the relevant numbers updated to include routine PFAS samples analyzed using 537.1 as of January 29, 2021. Please see elsewhere in the Agency's comments regarding analytic/laboratory methods, discussion of other state standards, and toxicological effects:

| | |
|--|-----|
| Total systems sampled: | 603 |
| Systems with any PFAS detection: | 97 |
| # Systems with Regulated PFAS detection: | 68 |
| # Systems with PFAS MCL Exceedances: | 10 |
| # of Systems with only non-detect results: | 506 |

- 1,308 PFAS samples for 603 systems have been received.
- 97 systems had at least one sample with a detectable level of one or more PFAS (16% of systems sampled).
- Of the 180 samples that had detectable levels of one or more PFAS, the total of the 18 analytes reported by EPA Method 537.1 for a given sample ranged from 2.00 to 335.04 parts per trillion (ppt), with an average of 16.55 ppt and a median of 6.88 ppt.
 - These statistics do not include the 1,128 samples that did not have detectable levels of any of the 18 PFAS analyzed due to the non-zero detection limit of the analytical method.
- Under the existing combined MCL of 20 ppt, 10 of the 97 (10%) public water systems with detectable levels of PFAS exceed the 20 ppt standard for the 5 regulated PFAS.
 - Subsequent sampling and confirmation samples is required to assess compliance with the MCL.

Care must be taken when reviewing data not to confuse the number of “systems” with the number of “samples” as was identified in the comments above which may have been off target due to that misunderstanding.

Comments were received stating that other state’s standards are more stringent than Vermont’s. Below identifies relative comparison of Vermont’s data with other state’s standards using Vermont data from 2019 (the only complete “set” of data currently available for analysis; 2020 sample data has not all been received or analyzed as of the time of this response)

| Description | Number of Systems | Comments/explanation |
|---|-------------------|--|
| Number of systems exceeding the current Vermont MCL | 6 | |
| How many systems would have exceeded Massachusetts’ | 6 | no change, PFDA was not identified in Vermont. |

| | | |
|--|---|---|
| standard of 6 compounds (adding PFDA) | | |
| How many systems would have exceeded New Jersey's Level | 3 | All 3 exceeded VT's MCL. This approach would have missed 3 other systems. |
| How many systems would have exceeded New Hampshire's Level | 4 | 3 of the 4 (same 3 as above compared to NJ's standard) exceeded VT's MCL. |
| How many systems would have exceeded Michigan's Level | 9 | Includes the 6 who exceeded Vermont's MCL plus 3 additional systems who did not. |
| How many systems would have exceeded New York's Level | 6 | 5 of the 6 were the same as those that exceeded VT's MCL with one substitution that did not exceed VT's MCL; one system that did exceed VT's MCL would have not exceeded NY's standard. |

COMMENT: PFAS have been found in drinking water, groundwater, and surface waters throughout Vermont. Not only can PFAS be toxic in very small amounts, PFAS can also be highly mobile in groundwater and surface water. PFAS, including compounds that are not currently regulated, have been found in waters throughout Vermont. Notably, the Advance Notice did not include a discussion of this data.

RESPONSE: See table below with Non-regulated PFAS detections with data as of January 29, 2021.

| Analyte | Systems with Detection |
|---|------------------------|
| (PFHXA) PERFLUOROHEXANOIC ACID | 31 |
| (PFBS) PERFLUOROBUTANESULFONIC ACID | 25 |
| (NETFOSAA) N-ETHYL PERFLUOROOCETANESULFON | 13 |
| (NMEFOSAA) N-METHYL PERFLUOROOCETANESULFO | 5 |

| | |
|--|---|
| (HFPODA)HEXAFLUOROPROPYLENEOXIDE DIMER A | 4 |
|--|---|

V. COMMENTS RELATED TO ANALYTIC METHODS AND LABORATORY METHODS

COMMENTS: 1) The analytical methods that capture the full range of synthetic organic fluorine chemicals have not been widely employed, especially outside areas of known PFAS contamination. In one intriguing study of tap water in five US cities, less than half the total “extractable” organic fluorine (EOF) measured in treated drinking water was accounted for by the sum of individually identified PFAS, indicating far more PFAS and other organofluorine compounds were present in the water than were identified with targeted analysis.¹³ The concentration of extractable organic fluorine ranged from 9.6 to 135.6 ng/L in 2016, an increase of 5 to 320 fold from samples collected roughly 25 years earlier (Table 2). The authors offered no additional information about potential sources for the five cities studied. Vermont Agency of Natural Resources (ANR) should consider the possibility that its efforts to measure and reduce exposure to a small subset of better-studied PFAS chemicals could be missing important opportunities to identify and reduce other synthetic organofluorine chemicals that could pose a similar hazard to human health and the environment.

2) Experts agree that PFAS should be regulated as a class in order to protect public health. In addition to high persistence, the accumulation potential and/or hazards (known and potential) of PFAS studied to date warrant treating all PFAS as a single class. The P-sufficient grouping is the most comprehensive, least resource intensive approach for managing/addressing PFAS as a class, as it requires no additional data to act. For source reduction efforts, such as product regulation, the essentiality framework is available to guide Vermont in phasing out all non-essential uses of PFAS. The question then becomes how best to regulate PFAS as a class once they have entered the environment, requiring remediation in drinking water, groundwater, and other matrices. As noted above, our focus begins with regulating PFAS as a class in drinking water and groundwater. Given current technical limitations, the most health protective approach available at this time is a two-pronged approach that involves 1) setting a treatment technique triggered by a set limit for total organic fluorine content

(TOF); as measured by combustion ion chromatography (CIC) AND 2) setting a combined standard for all quantifiable PFAS at the lowest, most health protective level achievable given current technical limitations (reporting limits for PFAS are between 2 - 5 ppt), following pre-oxidation of the sample in order to capture PFAA precursors.

3) We acknowledge that ANR may not yet have the capacity to evaluate the various commercially available methods and validate a TOF method with the required sensitivity, yet we argue that ANR should commit to adopting a treatment technique standard (based on TOF or another total PFAS method) once an agency-validated method has been published. Once a treatment technique is set, ANR should review the standard every two years to ensure standards reflect the latest scientific and technical information.

4) In the Review Team's evaluation of TOF, it stated:

"This approach does not reflect the reality that some PFAS are more biologically potent than others."

- Under the P-sufficient approach it is not necessary to know the relative biological potency of various PFAS.

"In addition, fluoride is naturally occurring in some Vermont aquifers and may complicate the interpretation of results."

- This is not accurate, as TOF assays examine organic fluorine and therefore distinguish between fluoride and organofluorine.

"This technique is not specific to PFAS, if there are other contaminants present that have fluorine (pharmaceuticals or pesticides) they would be reported in the results."

- While the potential to capture other chemicals containing organo-fluorine is possible when measuring TOF, this should not prohibit its use. We argue that these chemicals also do not belong in the drinking water or groundwater. Removing other organofluorine contaminants from the ground and drinking water is not detrimental to public health or the environment, and can be considered a co-benefit to regulating PFAS.³¹ USGS tracks pesticide use and can help screen for organofluorine

pesticide uses in the state (which are somewhat rare). Fluorine-based chemistry is relatively common in pharmaceutical drugs.³² USGS also monitors pharmaceuticals in water resources including metabolites of Ciprofloxacin and Prozac.

“This technique has not been demonstrated that it can be used for solid matrices.”

- This is incorrect. The two most common TOF methods are AOF and EOF. AOF is used for aqueous samples. EOF is more versatile and can be used for water, blood serum, soil extracts and more. In fact, this method can be used for a range of solids including soil, product materials, paper goods, etc.³³

“This technique may not capture short-chained PFAS.”

- We acknowledge this is a limitation with AOF, as short-chain PFAS are not adsorbed as well as long-chain PFAS. However, with EOF this would not be an issue. Furthermore, this limitation can be partially addressed by applying the second prong of the proposed approach, as described in more detail below.

“There are no universal analytical standards for this technique. This method needs to be run in the lab and cannot be used in the field.”

- This is a logical fallacy. EPA Methods 537.1 and 533 are generally run in a laboratory, not in the field. There is no legal requirement that a method needs to be amenable to field use in order for it to be used in a regulatory setting.
- It is unclear why the Review Team needs a universal analytical standard to move forward with a particular method. ANR can specify a standard to be used, such as the current ASTM standard³⁴, or once published the EPA or EU standard.

5) Although TOF would be the most comprehensive approach to measuring synthetic organic fluorine compounds, current methods for measuring TOF are limited by high detection limits. Considering current risk assessments for individual known PFAS arrive at values in the single digit part per trillion (ppt) range, and that ANR set MCLGs for the 5 PFAS it currently regulates at zero, relying only on a high reporting limit from TOF for setting regulatory actions would not be health protective. Hence, ANR should additionally set a combined standard for all PFAS quantifiable with a validated method, which we discuss in more detail below. In order to be the most health protective, the validated method for measuring individual PFAS should be conducted following an

oxidation step in which PFAA precursors are oxidized to terminal PFAAs. At a minimum, a pre-oxidation step should be performed prior to a targeted analysis. It may not be necessary to perform targeted testing prior to the oxidation step (as is routinely done in the TOP assay) unless Vermont deems understanding the amount of precursor present in every sample important. This approach would reduce the cost of testing while providing the benefit of capturing a more accurate level of PFAS in water. It is important to note that the technology to achieve Prong 2 is currently available, therefore ANR should move forward in setting this health protective approach immediately.

6) In the Review Team's evaluation of the TOP assay, it stated,

"The TOP assay is "not indicative of environmental conditions, non-standardized, telomer-based short chain precursors biased low, larger molecular weight compounds may not be captured."

- It is correct that the TOP assay is not fully indicative of environmental conditions. However, because Approach 1 recognizes all PFAS as concerning for public health (including PFAA precursors themselves), the goal is not to precisely replicate environmental breakdown of PFAA precursors but rather to estimate precursor content in a sample. Importantly, the TOP assay does not generate MORE PFAS than what is already in a sample. Instead, the TOP assay makes the invisible, or not-tested for, PFAA precursors visible as terminal PFAA oxidation products, several of which are measured in currently available analytical tests.

"As TOP Assay is a qualitative technique and not a multi-laboratory verified method, there is a lot of variability in results and interpretation of data."

- The source of variability in results from the TOP assay comes mainly from differences in organic content from sample to sample, which can result in incomplete oxidation of a sample. Drinking water samples are not expected to have a lot of variability in the amount of organic matter, beyond PFAS, that would interfere with precursor oxidation. Reproducibility can be addressed by making sure the sample is well oxidized. When developing the pre-oxidation protocol that laboratories should follow, ANR can address this issue by overestimating the amount of oxidizing agent needed for drinking water and groundwater samples. Specifying how the pre-oxidation step is performed should not be beyond the technical abilities of ANR.

“Due to the process, this technique may provide false positives or skew the data high as compared to environmental conditions.”

- This possibility should be balanced with the possibility of retention and eventual conversion of precursors into PFAAs in the body. Metabolism of PFAA precursors has been shown to occur - the extent to which this occurs is not fully understood, but may skew the data from US EPA Method 537.1 or 533 low as compared to the amount of PFAAs a person is ultimately exposed to.^{11, 35, 36} In addition, without a pre-oxidation step or another more comprehensive test such as TOF or TOP, estimates of exposure are highly likely to skew low as compared to the total PFAS people are being exposed to.

“This technique would be used more as a screening tool and no standards are available to compare to.”

- Under the approach proposed in these comments, we recommend analysis of oxidized samples with a validated targeted analytical method, negating the need for additional standards to be developed or made available.

7) It is also important to note that many water providers find that they ultimately need to conduct one or both of these tests, the TOF and TOP assay, in order to better understand the kinetics of how a proposed treatment technique to remediate PFAS-contaminated water will operate. Better knowledge about the total amount of PFAS or TOF in a water system allows water providers to estimate how long treatment media will last before breakthrough occurs, thereby giving water providers more accurate data for budgeting and planning. There are several targeted analytical methods for ANR to consider, including US EPA Method 537.1, US EPA Method 533, or user defined 537-modified methods (537-M). There are no inherent differences in reporting limits among these three methods, and many labs can reliably report at 2 ppt for most PFAS and 5 ppt for the rest. US EPA Method 537.1 measures 18 specific PFAS and US EPA Method 533 measures 25 specific PFAS. There are 14 PFAS in common between the two methods. US EPA Method 533 is a newer method and includes several short-chain PFAS, including PFBA, PFPeA, and PFPeS, reflecting observed changes in PFAS use. These two drinking water validated methods are unique, requiring separate sample preparations and cannot be combined into a single analysis.

8) Given the above reviewed information, ANR should:

- Employ 537-M following DoD criteria for a pre-specified number of PFAS no less than those that are covered by US EPA Methods 537.1 and 533. Should ANR choose not to use 537-M following DOD criteria, the agency should at a minimum use US EPA Method 533;
- Set a combined standard at the lowest, most health protective level achievable given current technical limitations (current reporting limits are from 2-5 ppt). Considering the information provided on the known and potential harm of PFAS, and the fact that ANR has already set the maximum contaminant level goal (MCLG) at zero for the five PFAS it is currently regulating, it is logical to set a standard as close to zero as technically possible;
- Regardless of which analytical technique for individual PFAS is chosen, ANR should require a pre-oxidation step to be performed.

9) In further outlining why the Review Team determined it could not regulate additional PFAS beyond the 5 that are currently regulated, the team noted that: “As detection levels change it makes it difficult to determine what reported concentration should be included in the total concentration detected for a sample location. There are currently methods to analyze for 18 (USEPA 537.1) to 25 (USEPA 533) of the 4,000 PFAS.”

- We expect new validated methods to be continually developed as interest in PFAS continues to grow. This, however, is not a justifiable reason to delay health protective regulation. This problem is not unique to regulating PFAS as a class using a combined standard. Rather, Vermont should plan to consistently reevaluate the available technology to assess if greater health protections can be provided to the state’s residents.

10) As outlined here, adding the additional PFAS quantifiable with US EPA Methods 537.1, 533, or 537-M methods to a combined standard, is not only scientifically defensible, but also more health protective. Given the advantages of using 537-M following DoD criteria, ANR should use this method for a pre-specified number of PFAS no less than those that are covered by US EPA Methods 537.1 and 533 combined.

11) In addition to making great strides in protecting public health, the approaches outlined here also include several cost saving measures that ANR should take note of: 1) water utilities may ultimately perform TOF or TOP to

determine the total PFAS in a water system to support planning and budgeting activities, therefore this suggestion may not add a further cost burden; 2) we have suggested using a modified TOP assay that does not require targeted analysis prior to the oxidation step, reducing testing costs by half; 3) our suggestion to utilize 537-M following DoD criteria is more cost efficient than preparing two samples to be run with US EPA Method 537.1 and US EPA Method 533 while providing results on a larger number of individual PFAS.

12) The Agency should employ user defined 537-modified methods following DoD criteria to establish a pre-specified number of PFAS that is no less than those covered by US EPA Methods 537.1 and 533.²⁰² In addition, this combined standard should establish a test method that captures the maximum number of quantifiable PFAS and requires an oxidation step in which PFAA precursors are oxidized to terminal PFAAs before measuring individual PFAS.²⁰³

13) As the Technical Comments note, there are several targeted analytical methods that can reliably detect between 18 – 40 individual PFAS to 2 – 5 ppt.²⁰⁴ In addition,

[i]n order to be most health protective, the validated method for measuring individual PFAS should be conducted following an oxidation step in which PFAA precursors are oxidized to terminal PFAAs. At a minimum, a pre-oxidation step should be performed prior to a targeted analysis. It may not be necessary to perform targeted testing prior to the oxidation step (as is routinely done in the TOP assay) unless Vermont deems understanding the amount of precursor present in every sample important. This approach would reduce the cost of testing while providing the benefit of capturing a more accurate level of PFAS in water.²⁰⁵

14) Total Oxidizable Precursor (TOP) Assay is commercially available, and we do not agree with the Agency's characterizations of its limitations for the reasons outlined in the Technical Comments.²⁰⁶

15) While we recognize there may be current limitations with TOF, the Technical Comments note: Commercial laboratories like Eurofins and Bureau Veritas offer TOF by CIC with detection limits in the low (single digit) part per billion range. Commercially validated methods are already available in Australia and Europe. Bureau Veritas (located in Canada) released a commercially validated TOF method this year and Eurofins expects to have a commercially validated TOF method in the US by the end of the year. This approach has been validated by academic institutions in the U.S. as well. In addition, efforts are currently underway to develop and validate more sensitive methods for TOF analysis.²²³ Thus, we recommend that the Agency establish a treatment technique using this analytical method as soon as an international, federal, or state agency validates a method. Once a treatment technique is set, ANR should review the standard every two years to ensure standards reflect the latest scientific and technical information.²²⁴ As discussed previously, existing treatment technologies are able to remove long and short chain PFAS to concentrations below 2 ppt.²²⁵

16) In the alternative, the Agency should establish new rules for subclasses of PFAS that protect Vermonters from the PFAS class. The Agency should establish new drinking water rules for PFAS subclasses in the alternative. As the Technical Comments note, there are numerous different approaches for grouping PFAS based on intrinsic properties or technical capabilities.²²⁶ The Review Team did not consider many of these approaches and did not fully evaluate the few approaches they did identify.²²⁷

17) The Review Team also appeared to dismiss potential approaches out-of-hand for a variety of reasons, including because not all PFAS can be quantified at this time, regulations would need to be regularly reviewed and updated to account for new information, and there would be a "learning curve" associated with certain programs.²²⁸ However, none of these reasons provide justification for delaying health protections to Vermonters. As noted previously, commercial laboratories can reliably detect up to 40 PFAS between 2 – 5 ppt and,

“alternative methods, such as TOF and TOP, greatly increase our ability to protect drinking water and ground water from PFAS.”²²⁹ Further, as part of a core mission to protect public health, it is not unreasonable to expect that the Agency and the Department of Health will regularly review drinking water rules to ensure they are current with the latest science and that agency staff are responsible for learning how to implement new technical and regulatory approaches that are necessary to protect Vermonters. The review conducted by the Agency does not support its finding that there is insufficient scientific and technical information to regulate PFAS subclasses.

18) “Not all of the 4,000+ PFAS are detectable with current analytical methods.”

- This is true, however, alternative methods, such as TOF and TOP, greatly increase our ability to protect drinking water and ground water from PFAS. Furthermore, as detailed above, laboratories across the country are already reliably quantifying up to 40 individual PFAS using 537-M following DoD criteria.

RESPONSE: TOF, TOP, and the DoD nonstandard method are not suitable methods to use for purposes of regulating PFAS in a permitting environment at this time. These methods are not suitable because: (1) all these methods are nonstandard and do not have accompanying laboratory certifications that ensure appropriate quality assurance and quality control at the laboratories processing a sample. This nonstandard approach may lead to differing results of the same drinking water by different labs. It also creates significant issues with respect to the enforceability of violations of any of these standards; and (2) both methods are qualitative methods or screening techniques that do not provide a quantitative result that is suitable for use in the Drinking Water Program.

To set forth a sampling program relying on either total organic fluorine (TOF), total oxidizable precursor (TOP), or Department of Defense modifications to existing standard methodologies, the method would need to be something that minimal qualifications for use in a regulatory program. This means that an existing accrediting agency, such as NELAP, would need to grant a certification first. To be certified, the laboratories would need an established standard to which the analysis would be based. This is necessary to ensure that the analytical results of a sample are accurate, replicable, and consistent between laboratories. None of

the approaches described above (TOF, TOP, or DOD) meet these minimal standards and therefore are not suitable for the basis of a regulatory program.

In addition to these methods not being standard, Total organic fluorine (TOF) measured by combustion ion chromatography (CIC) is a qualitative technique as it measures fluorine content, and is not specific to PFAS, nor is it quantitative. Qualitative or screening techniques are not relied upon for quantifying PFAS, nor for meeting regulatory requirements. VT ANR will consider this in the future if a multi-laboratory validated method is promulgated utilizing this technology.

Total organofluorine Analysis using Combustion Ion Chromatography (TOF) is noted as a high priority for USEPA, and ORD is working with OW-OST to develop a draft method.

As identified above, all laboratories performing analysis must be certified/accredited. The Department of Health is the accrediting body for laboratories in Vermont and can only certify analysis under the NELAP or other equivalent framework. There are only a few labs nationally who are currently certified for DoD validation standards. Prior to requiring this analytic standard be employed in Vermont, additional laboratories would need to be accredited by DoD to perform the analysis.

Modifications of USEPA Methods present challenges with reproducibility, quality control and assurance, and data validation. The Department of Defense Quality Systems Manual Table B-15 is a robust set of quality control measures, but it is not a method. Modifications of USEPA 537.1 are not endorsed by the USEPA, and are not standardized or validated, thus are not able to be used for regulatory decision-making. The EPA states that if modifications are made that are not explicitly listed in the method, the method is not considered USEPA 537.1. The VT ANR does not have the resources (time, money, capacity) to generate a new method utilizing the DoD QSM Table B-15 quality control parameters and undergo a multi-laboratory validation process.

USEPA Method 537.1 and USEPA Method 533 collectively analyze for 29 PFAS. If SW846 8327 is included then 40 analytes, however SW-846 8327 is not intended for drinking water, and additionally, the target quantitation limit is 10 ng/L, and is not accepted at DoD sites.

TOP is not suitable for use in a regulatory program. Oxidation of PFAAs does not represent biotransformation under natural conditions. Additionally, PFAA precursors would be primarily abiotically oxidized to PFCAs, whether the precursors contained telomer or sulfonamido functionalities. For instance, a precursor that would likely form PFOS in the environment would be oxidized to PFOA under the conditions of the TOP assay. Other limitations of the TOP Assay are that telomer-based short chain precursors are biased low, larger molecular weight compounds may not be captured, and this assay does not close the mass balance on PFAS.

There is not currently a multilaboratory validated method for Total Oxidizable Precursor, as it is still considered a qualitative technique. Decisions pertaining to enforcement of standards cannot be made from qualitative (as opposed to quantitative) techniques.

See Agency comments elsewhere in this document regarding the discussion of a treatment technique for PFAS.

COMMENT: With respect to analytical methods, the Advance Notice does not even mention—much less discuss the results of—the pilot project that the Agency was required by Act 21 to conduct to evaluate methods to quantify total PFAS. Act 21 states that “the Secretary shall conduct a pilot project at public water systems to evaluate PFAS that are not quantified by standard laboratory methods using a total oxidizable precursor assay or other applicable analytical method to evaluate total PFAS.”⁴⁶ The Agency was required to publish a plan by June 1, 2019 explaining how it intended to conduct this pilot as part of its statewide investigation of PFAS sources and implement the plan by July 1, 2019.⁴⁷ The Agency has not met this timeline and our understanding is that the pilot project has not been conducted and the Agency has no specific plans to do so at this time. Yet the legislature included

this requirement and specific timeline for completion in Act 21 in order for those results to inform the Agency’s development of new drinking water rules for PFAS.⁴⁸

RESPONSE: Act 21 requires the Secretary to conduct a pilot project at public water systems to evaluate PFAS that are not quantified by standard laboratory methods using a total oxidizable precursor assay or other applicable analytical method to evaluate total PFAS. The pilot project does not fit into the existing work of the regulatory program and is better suited to a contract with academia or a scientific research institution. A study of this nature would require financial resources, which have not been identified or appropriated. The Agency would like to engage with the legislative committees of jurisdiction to evaluate relative priority of this pilot project and determine how to complete this work if deemed important.

VI. COMMENTS RELATED TO CLASS/SUB-CLASS APPROACH OR CHEMICAL SIMILARITY

COMMENT: Approach 1: Regulate the Entire Class of PFAS Based on Persistence, or “P-Sufficiency”

All PFAS share a common structural feature, the carbon-fluorine bond, which is the strongest single bond in organic chemistry and confers environmental persistence to all PFAS. In addition, PFAS can also share several other problematic properties, including bioaccumulation, environmental mobility and toxicity. Experts agree that persistence alone is a major cause for concern and sufficient for regulation.

RESPONSE: See elsewhere in the Agency response re: toxicological research and information available.

COMMENT: In the Advanced Notice, the Review Team “determined that at the current time it is not feasible to regulate PFAS as a Class, other than the five compounds presently regulated to the health- based standard.” However, we disagree and see no reason why ANR cannot add the additional PFAS covered in targeted

analytical methods to the existing combined standard in order to increase health protections for Vermont residents (Table 1). This is based on:

1. “The chemical or group of chemicals is found or being investigated in Vermont” All of the chemicals evaluated with US EPA Method 537.1 are currently being investigated in Vermont. Importantly, PFHxA, PFBS, HFPODA, NtEtFOSAA, and NMeFOSAA have been detected in Vermont drinking water. Further, there are many PFAS that have not yet been investigated, so one cannot say with certainty that additional PFAS do not occur in Vermont drinking water. In addition, PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnA, PFDoA, PFTA, PFTrDA, PFBS, PFPeS, PFHxS, PFHpS, PFDS, PFDoS, PFOSA, NtEtFOSAA, NMeFOSAA, 4:2 FTS, 6:2 FTS, and 8:2 FTS have been found in other environmental media in Vermont (leachate, sludge) (Table 1).
2. “The chemicals are sufficiently similar.” To this point, the Review Team stated that “The Vermont grouping process is still a one-by-one approach and has been applied as supported by science. Limited data currently exists upon which to allow for the inclusion of additional PFAS.”

As outlined above, there is ample scientific support to consider all PFAS as a class and for inclusion in ANR’s regulations. Further, no definition of “sufficient” similarity is provided in the memo dated May 3, 2019.³⁹ As detailed above, the PFAS quantified with US EPA Methods 537.1, 533, and 537-M also belong to the PFAS family, share similar chemical structures and attributes and therefore can be considered sufficiently similar.

3. “The chemicals are often found together.” Several of the PFAS detected with US EPA Method 537.1 were found together in the drinking water with PFAS that are currently regulated in Vermont. Furthermore, many of the PFAS monitored for in Vermont’s leachate and sludge occur together with the PFAS currently regulated in Vermont. Although some of these have yet to be detected in Vermont’s drinking water, it will only be a matter of time before these PFAS will affect drinking water given their high mobility in the environment.
4. “The chemicals elicit similar health effects.” The Review Team did not evaluate whether or not additional PFAS, including those evaluated with US EPA Methods 537.1, 533, and 537-M elicit similar health effects to currently regulated PFAS. Similarities for a number of individual PFAS have already been noted (Table 3).

RESPONSE: As stated elsewhere in these comments, based on the current understanding of the toxicology PFAS compounds, limitations for methodologies for analysis and

detection, we are unable to adopt a class-based approach to adopting a MCL for PFAS. We will continue to review existing literature as information evolves to see if/when it becomes feasible. Other comments pertaining to impact to the environment are outside of the scope of this notice.

COMMENTS: 1) In the alternative, the State should establish new drinking water rules for PFAS with the subclass approach. At a bare minimum, the Agency should establish a combined MCL below 20 ppt at the lowest, most health protective level technically achievable for the maximum number of quantifiable PFAS pursuant to the additive approach currently utilized.³ Under any of these approaches, the new rules should be reviewed at least once every two years to ensure drinking water standards reflect the latest science. New rules that remove additional PFAS from drinking water are necessary to protect public health and will result in significant avoided costs and benefits for Vermonters and the State. The State and public water systems have options to address the financial costs associated with the clean-up of PFAS contamination in drinking water.

2) While a class-based approach to chemical management can pose challenges to the traditional paradigm of individual chemical risk assessment, the extreme persistence and potential for harm from thousands of PFAS demand a more efficient and effective approach. Lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent public health protections and environmental degradation. Furthermore, no chemical management approach is perfect, including individual risk assessments. Alternative chemical management approaches have been proposed and will be covered in detail below. ANR has broad authority to regulate unsafe chemicals in drinking water. As a state agency, it is your mandate to use the approach best fitted to provide the greatest amount of health protections for the residents of Vermont.

3) Although PFOA and PFOS have now been phased out of production in the United States,¹⁵ these compounds will remain in our drinking water, groundwater, and surface waters, as well as our bodies, for decades. In addition, manufacturers have rushed to produce thousands of alternative PFAS, and all of the alternatives tested pose comparable health risks as legacy PFAS.¹⁶ The thousands of untested PFAS are likely to pose comparable

health risks as well due to similarities in chemical structure.¹⁷ There are currently over 9,000 different kinds of PFAS.¹⁸

4) The Agency must establish drinking water standards for the PFAS class. The Agency has broad authority to protect drinking water, and the legislature has directed the Agency to promulgate new rules to remove PFAS from public water supplies. PFAS are harmful to public health even in very small concentrations. These toxic “forever chemicals” have been found in drinking water, groundwater, and surface water throughout Vermont. It is critical that the Agency establish strong state standards for the PFAS class in order to protect Vermont communities from these dangerous chemicals.

5) As discussed below and in greater detail in the Technical Comments, there is a strong scientific basis for regulating PFAS as a class.¹⁶⁴ The significant toxicity and the unique characteristics of the PFAS class of chemicals, along with the potential combined and synergistic effects from exposure to multiple PFAS chemicals, demand a class, subclass, or grouping approach to regulation. Vermont communities should not be forced to continue to bear the health risks associated with these unsafe chemicals while regulators take decades to chase down these chemicals one by one. For all these reasons, the combined 20 ppt MCL for PFOA, PFOS, PFHxS, PFHpA, and PFNA does not fully protect public health.

6) If the Agency refuses to establish standards for the PFAS class despite a clear scientific basis for regulation, the State should establish new drinking water rules for all subclasses of PFAS.¹⁷² At a bare minimum, the Agency should establish a combined MCL below 20 ppt at the lowest, most health protective level technically achievable for the maximum number of quantifiable PFAS pursuant to the additive approach currently utilized.¹⁷³ Under any of these approaches, the Agency should review these rules at least once every two years and revise drinking water standards for PFAS to ensure standards reflect the latest scientific and technical information.¹⁷⁴

7) The MCLG for the PFAS class should be zero. The MCLG for the PFAS class of chemicals should be zero. Vermont has already established an MCLG of

zero for PFOA, PFOS, PFHxS, PFHpA, and PFNA.¹⁸³ PFAS share similar structures and properties, including extreme persistence and high mobility in the environment.¹⁸⁴ Many PFAS are also associated with similar health endpoints, some at extremely low levels of exposure.¹⁸⁵ There is additional potential for additive or synergistic toxicity among PFAS.¹⁸⁶ Given the similarity among chemicals of the PFAS class and the known risk of the well-studied PFAS, there is reason to believe that other members of the PFAS class pose similar risk.¹⁸⁷ Therefore, health-protective standards for PFAS should be based on the known adverse effects of the well-studied members of the PFAS class.

8) VT has already taken important first steps to regulate PFAS as a class by enacting a combined standard for 5 PFAS in drinking water. PFHpA, PFNA, and PFHxS were added to the existing standard for PFOA and PFOS because of their known similarities to these chemicals. There is no reason to, at a minimum, add the remaining 13 PFAS that are measured with EPA Method 537.1 to the combined standard. Several of these PFAS are already detected in VT drinking water, including PFHxA, PFTTrDA, PFBS and others. Is ANR confident that these are not associated with human health or environmental health concerns? This is why a class based approach is not only needed for protecting public health, but is also conservative of VT's resources and time.

9) But this is still just the tip of the iceberg, and really, the minimum which should be done. While a class-based approach to chemical management can pose challenges to the traditional paradigm of individual chemical risk assessment, the extreme persistence and potential for harm from thousands of PFAS demand a more efficient and effective approach. Lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent public health protections and environmental degradation.

10) Ultimately, it is now widely understood that the wisest approach would demand that PFAS be regulated as a class. The time and expense required to research each PFAS chemical individually would present an indefensible barrier to protecting the public health and that of our environment and natural resources on which that health depends. Both long-chain or short-chain PFAS molecules are proving to have common chemical properties, negative and severe health effects, and long lasting

and destructive environmental consequences even at the lowest measurable limits in parts per trillion (ppt).

11) The argument leveled against a class approach is that each PFAS chemical has a different chemical structure, intended use, and environmental and health profile (Bowman 2019). However, there is precedent for EPA regulating a family of chemicals as a class, even when there is a lack of toxicity data pertaining to certain chemicals of the class. In 1998, EPA established an MCL for five haloacetic acid disinfection byproducts (HAA5), which are a byproduct of drinking water chlorination and associated with an increased risk of cancer (Griefen et al. 2018; US EPA 2019e). Due to the challenges surrounding the regulation of these individual chemicals separately, EPA determined that a group MCL for these compounds would better protect public health.

RESPONSE: As stated above, Vermont currently regulates PFAS as a subclass looking at five long chain PFAS compounds. The modification of that existing subclass continues to represent a one-by-one approach. As stated by the commenter and by the Agency and Department of Health, a one-by-one approach is not sufficient to address PFAS as a class. As illustrated by the recent publication of the toxicity assessment for PFBS by EPA then subsequent removal of that final assessment, the toxicities of certain PFAS included in EPA Method 537.1 are still being researched by authoritative bodies. Vermont relies on the assessment by these authoritative bodies to provide a solid basis for standards. The steps outlined in the Final Decision on Regulating PFAS as a Class outlines specific steps the Agencies will take while authoritative bodies produce more toxicity assessments and work toward a framework for regulating PFAS as a class.

Vermont's current advisory of 20 ppt for the sum of five PFAS is a health-protective approach. Significantly increasing the number of PFAS in the grouped advisory would necessitate a higher advisory level to account for reporting levels for the individual PFAS since the lowest possible level at which to establish a health advisory would be detection. For example, if there are 15 compounds identified in a new health advisory number, each with a reporting level of 2 ng/L, it would not be possible to quantify results under 30 ng/L combined, so it would

effectively raise the current health advisory level/MCL. This would lead to less protection for Vermonters. See Agency responses pertaining to analytic methods and toxicological information for further related information.

COMMENT: The Review Team also did not consider the scientific justification for a class-based approach, jurisdictions that are or are proposing to regulate PFAS as a class or subclasses, possible approaches to subclass regulation, and a comprehensive discussion of analytical methods.⁴⁵

RESPONSE: See elsewhere in this response document for information pertaining to other jurisdictions, analytic methods, and toxicological justification.

COMMENTS: 1) The advanced notice provided by ANR stated that no guidance exists for regulation of PFAS as a class. However, ANR failed to discuss existing approaches that do just that. For example, the EU Drinking Water Directive, in December 2019, called for two things: 1) the immediate regulation of the sum of 20 PFAS in drinking water at 100 ppt and 2) the development of a treatment technique for total PFAS within five years, enforceable at the level of 500 ppt. ANR also did not mention the derived relative potency factor approach for 19 PFAAs, including PFOA and PFOS, that has been proposed for use by the National Institute for Public Health and the Environment in the Netherlands. These approaches can be used as models by VT as they are defensible steps in taking action to regulate PFAS as a class in drinking water.

2) You note in your Advance Notice on Regulating PFAS as a Class, “As the field is rapidly evolving, the State strives to stay current, however the scientific studies and toxicology data necessary to regulate PFAS as a Class is not feasible at this time.” “At this time” is the key phrase, as researchers continue to compile a greater body of evidence that may well soon provide the necessary data you maintain does not currently exist. While we recognize the role of peer review in setting policy, broader review in the literature, including the articles provided, lends credence to the argument that regulating PFAS as a class is the forward-looking approach our State should adopt.

RESPONSE: See elsewhere in the Agency's comments re: needing to use peer-reviewed, authoritative research/determinations regarding PFAS and comparing Vermont's data to other jurisdictions and standards.

COMMENT: 1) The American Chemistry Council (ACC) supports the Agency's decision not to develop a regulation for the class of chemicals referred to as per- and polyfluoroalkyl substances (PFAS). The Advance Notice developed by the Agency provides a comprehensive analysis of the reasons why such a class regulation is not possible. The Notice reviews the approaches that have been suggested both for quantifying such a large number of substances and for assessing the potential environmental and health effects and finds that there is not a sufficient basis for a class regulation.

2) The conclusions reached by the Agency in the Advance Notice are echoed in a February 2020 white paper from the Environmental Council of the States (ECOS), in presentations made as part of a recent National Academies of Sciences, Engineering and Medicine (NASEM) workshop on federal human health research on PFAS, and in a recent publication evaluating possible assessment frameworks for grouping of PFAS.

3) PFAS are a large and diverse group of chemicals whose exact definition is not agreed upon by experts worldwide. In 2018, the Organization for Economic Cooperation and Development (OECD) identified 4,730 substances that meet the definition of PFAS proposed by Buck et al. (2011). Of these, OECD indicated that only one-third (1,616 substances) were listed under at least one national/regional chemical inventory considered. More recently, the available information suggests that the US Environmental Protection Agency (USEPA) has identified about 600 PFAS that are actively in commerce as of February 2020. Among these 600 are substances in the solid (e.g., fluoropolymers), liquid (e.g., fluorotelomer alcohols) and gaseous (e.g., hydrofluorocarbon refrigerants) forms. Consequently, the physical and chemical properties within this group vary widely and cannot be readily grouped together, including the likelihood that the substances will be found in air and water and the tendency for biological uptake and retention. Moreover, the stability in the environment of the substances within the group varies considerably, as does the tendency to be metabolized. As observed in the ECOS white paper referred to in Appendix A of the Advanced

Notice, “[g]iven that there are nearly 5,000 PFAS, most of which have little known information about their toxicities, many regulators and subject-matter experts advise against grouping PFAS as an entire class.”

4) Most of the publicly available information on non-polymeric PFAS comes from studies conducted with perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), two legacy products that are no longer manufactured in the United States. In addition to PFOA and PFOS, USEPA has conducted assessments for two other PFAS — perfluorobutane sulfonic acid (PFBS) and hexafluoropropylene oxide (HFPO) dimer acid — and has indicated its plan to review five other PFAS in 2021. After assessing the available information for 14 PFAS, the Agency for Toxic Substances and Disease Registry (ATSDR) proposed minimum risk levels (MRLs) for only four, concluding that insufficient information was available for the remaining 10 substances. In addition, a comprehensive toxicity assessment has been conducted for perfluorohexanoic acid (PFHxA).

5) Consideration of the available information on the handful of substances for which information is publicly available indicates that the observed health effects vary considerably — both in terms of the target organ and the severity of effect. Even for PFOA and PFOS, the developmental effects selected by USEPA for its analysis, were observed in different biological systems and in different animal species. Although EPA has suggested that its 2016 health advisories for these substances can be applied to the combined concentration of the two PFAS, that suggestion has not been subject to rigorous peer review and is not consistent with the Agency’s historic approach to consideration of mixtures (see below). Of the dozen or so states that have established standards for PFAS, only three (Massachusetts, Minnesota and Vermont) employ an additive summing approach for more than two PFAS compounds. Among the reasons given for this approach is that “their toxicity is assumed to be additive based on a substantial body of publicly available data indicating that they cause similar toxicological effects, have long serum half-lives in humans (long-chain PFAS only), and are associated with similar health effects in humans.” (Emphasis added.) However, as noted by ECOS, “these PFAS do still present differences (e.g., different levels at which toxicity occurs, different toxicological effects and modes of action) that a state might acknowledge as a reason not to group the chemicals, but rather to regulate

them individually.” As set out among the counter- balancing reasons for the majority of the states that do not employ an additive approach, there are ample bases to question and not follow such an approach, including that “toxicological studies demonstrate differences in the potency and bioaccumulation (i.e., physiological half-lives) between individual PFAS.” USEPA and other federal agencies currently are evaluating approaches for prioritizing non-polymeric PFAS for toxicity testing based on chemical identifiers. The analysis is complicated, however, by the surfactant properties interfering with the interpretation of in vitro, high-throughput assays conducted with PFAS.

6) The grouping of substances under a single regulatory approach is justified only when the substances are believed to cause adverse health effects by acting on the same biological system. While a full understanding of the mode of action (MoA) for toxicity is not essential, grouping of substances does require the identification of a biologically plausible sequence of key events (e.g., an adverse outcome pathway, or AOP) leading to an observed effect supported by robust experimental observations and mechanistic data. Based on comprehensive evaluations of multiple lines of evidence supporting quantitative estimates of cumulative risks, a chemical-class approach has been applied to a very limited number of chemical groups including total petroleum hydrocarbons, polychlorinated biphenyls, organophosphates, and dioxin-like compounds. Such assessments involving co-exposure to chemical mixtures require simplifying assumptions be made regarding dose additivity, response additivity, and interactions (e.g., synergism or antagonism) and involve inferences about responses at relatively low doses based on dose-response information collected from studies with single components administered at relatively high doses. Such information does not exist for the non-polymeric PFAS. In particular, there are fundamental data gaps because toxicity values have been developed for only a handful of nonpolymeric PFAS and plausible MoAs or AOPs have not yet been defined. Among the data that have been collected, moreover, there is evidence of qualitative and mechanistic differences that preclude extrapolating findings across non-polymeric PFAS chemicals. For example, while the liver appears to be a target organ for many non-polymeric PFAS, recent 28-day studies conducted by the National Toxicology Program (NTP) suggest that hepatotoxic effects of non-polymeric PFAS are mediated through multiple nuclear receptors. Other health endpoints have not been reported consistently for studies with non-polymeric PFAS that can be used as a basis for assessing exposures to multiple substances.

7) To date USEPA has developed validated methods for measuring 29 non-polymeric PFAS in drinking water. While that number will likely increase over time and the Agency is developing validated methods for measuring these substances in air, solids, and other water sources, the universe of non-polymeric substances for which analytical methods exist is likely to remain limited. As observed in the Advanced Notice, with respect to some analytical methods and techniques, “operating conditions for analyzing PFAS have not been standardized. Extraction methods for environmental samples is still under development and [have] not been published in peer-reviewed literature.”

8) The limitations of methods to analyze for individual non-polymeric PFAS has prompted the development of techniques for measuring total organic fluorine. As noted in the Advance Notice, these techniques include the adsorbable/extractable organic fluorine (AOF/EOF) and total oxidizable precursor (TOP) assays, and non-targeted analytical approaches including PIGE and qTOF. These techniques are not widely available in commercial laboratories and are only semi-quantitative or have higher detection limits than those for the individual substances. While they may be helpful for screening purposes, these methods do not provide information on the specific substances that can allow for a robust exposure assessment.

9) Until it has been demonstrated that large groups of these varied PFAS/PFOA share toxicology and detrimental effects for consumers, class regulation seems to lack merit. By no means does this mean that future class regulation should be ruled out, but I feel that it’s reasonable to say that increased regulation should be followed by increased aid to those affected by, but not responsible for, the failure to meet regulatory requirements.

RESPONSE: Noted. The Agency commits to working with the Health Department as documentation becomes available pertaining to toxicological studies.

VII. COMMENTS RELATED TO LIMITED SCOPE/REVIEW OR INSUFFICIENT REVIEW

COMMENTS: 1) The review does not include a comprehensive discussion of scientific and technical information and other relevant factors that support a class or subclass approach to regulation of PFAS.

2) The Agency falls far short of the rigorous review required by Act 21 and, in fact, did not perform even basic due diligence when it conducted this review. Although the Review Team—scientists from the Departments of Health and Environmental Conservation—claims there is limited or insufficient information to justify regulating PFAS beyond the five currently regulated,³⁹ they did not consider or fully consider critical scientific and technical information and other relevant factors. Although the Advance Notice states that “[t]he Review Team consulted with other jurisdictions, interstate organizations, and literature on PFAS analytical methods and toxicology,” there is no record of who the Review Team consulted with, what exactly was discussed, or how that informed the Agency’s preliminary determination.⁴⁰ Further, the literature review is shockingly limited in scope.⁴¹

3) In addition to these major deficiencies, the Agency fails to articulate a specific timeline or plan for action in light of what they perceive to be a lack of scientific studies and toxicology data.⁴⁹ For example, the Review Team states that it “plan[s] to closely monitor the work by the National Toxicology Program (NTP) and the Agency for Toxic Substances and Disease Registry (ATSDR) to evaluate PFAS as a class.”⁵⁰ There is no estimated timeline for the completion of the NTP and ATSDR process and no explanation as to what “closely monitor” means.

4) Similarly, the Advance Notice states that the State lacks resources to conduct certain scientific and technical analyses, but does not provide support for these statements or identify what level of resources they believe would be necessary.⁵¹ While this may be true, the Agency must provide support and a more complete explanation for these statements.⁵² Moreover, as set forth below, the Agency may not use costs to regulated entities as a rationale for not promulgating new rules for PFAS.⁵³ There is a scientific basis for regulation of PFAS as a class and technology is available to detect and

treat PFAS in drinking water.⁵⁴ For all these reasons, the Agency has not met its obligation to conduct a rigorous review of all scientific and technical information and other relevant factors related to class or subclass regulation of PFAS.

RESPONSE: The Department of Health and Agency are not research toxicology programs. There are currently no staff devoted to performing basic research to characterize the effects of chemicals on the human body. The cost to develop the facilities, staff, and capacity to perform such research are beyond the scope of this report. The VDH uses information from authoritative agencies to develop Vermont specific guidance. Such authoritative agencies include The National Toxicology Program (NTP) which is a part of the National Institute of Health. NTP is the preeminent toxicology agency in the US and publishes detailed toxicology reports on chemicals. The NTP is staffed by hundreds of scientists. Based on the publications to date from NTP, they are working to characterize PFAS as a class. As is typical in scientific research, findings are published for the scientific community to read. Vermont expects that NTP will publish the results of their work to characterize PFAS as a class. We do not and cannot articulate a timeframe within which NTP will complete this work.

The PFAS health advisory follows the Vermont process to take into account exposure to the most vulnerable population. Infants 0–1-year-old drink more water per body weight than other age groups. This means that they receive a higher dose of contaminants from drinking water than other age groups. Vermont health advisories are derived using the drinking water intake of this most highly exposed group. The Vermont PFAS MCL is based on the most vulnerable population, which is the infant 0–1-year-old who is drinking formula made with tap water.

IIX. COMMENTS RELATED TO TREATMENT TECHNIQUE APPROACH

COMMENTS: 1) Existing treatment technologies are able to remove long and short chain PFAS to concentrations below 2 ppt, including granular activated carbon, ion exchange, and reverse osmosis.²⁰⁷ Reverse osmosis appears to be the most robust technology for preventing exposure to PFAS and other unidentified contaminants.²⁰⁸ These treatment technologies will also confer significant co-

benefits for public health because the same technologies that are effective in removing PFAS are also effective in removing a host of other dangerous chemicals, including RDX, arsenic, benzene, cryptosporidium, MTBE, mercury, perchlorate, tetrachloroethylene, trichloroethylene, 1,4-dioxane, alachlor, chromium, malathion, and nitrates.²⁰⁹ Thus, the technology is available to put these health-protective standards in place immediately.²¹⁰

2) The Agency should establish a treatment technique standard based on TOF as measured by CIC for the PFAS class of chemicals as soon as an international, federal, or state agency validates a method. The Agency should establish a treatment technique drinking water standard for the PFAS class of chemicals based on TOF as measured by CIC as soon as an international, federal, or state agency validates a method. As discussed previously, the Agency has broad authority to adopt a treatment technique drinking water standard. “A treatment technique is an enforceable procedure or level of technological performance which public water systems must follow to ensure control of a contaminant.”²¹¹ In other words, the Agency has the authority to develop a procedure that would require the use of specific drinking water treatment technologies under certain circumstances.²¹²

3) EPA has adopted several treatment technique drinking water standards in lieu of an MCL where EPA has determined that it is “not economically or technologically feasible to ascertain the level of [a] contaminant.”²¹³ For example, the Lead and Copper Rule is a treatment technique.²¹⁴ This rule requires public water systems to test drinking water in the homes of consumers and undertake additional treatment measures to control lead if 10 percent of the samples exceed 15 ppb.²¹⁵ The Surface Water Treatment Rule is also a treatment technique.²¹⁶ Under this rule, most public water systems that obtain water from surface water or groundwater under the direct influence of surface water must use filters and disinfectants to reduce pathogens.²¹⁷ In both cases, EPA had to establish a unique procedure to address the risks posed by a specific contaminant because an MCL would not have been practical or protective of public health due to the unique characteristics of the contaminants.

4) Similarly, the unique characteristics of the PFAS class pose a public health threat that cannot be adequately addressed with the establishment of an MCL for one or a few PFAS chemicals.²¹⁸ The Agency should require the installation of treatment technologies to remove long and short- chain PFAS where total organic fluorine is detected as measured by CIC as soon as an international, federal, or state agency validates a method.²¹⁹ The Review Team noted that TOF would be over-inclusive and capture other contaminants like pharmaceuticals or pesticides.²²⁰ However, “these chemicals also do not belong in the drinking water or groundwater. Removing other organofluorine contaminants from the ground and drinking water is not detrimental to public health or the environment, and can be considered a co-benefit to regulating PFAS.”²²¹ Further, the Agency could utilize USGS data to screen for pharmaceuticals and pesticides.²²²

RESPONSE: The Agency strongly disagrees with the comment that we should implement a treatment technique-based approach based on TOF. As noted above, TOF is a qualitative, non-standard, analytical technique that is unsuitable for use in the Drinking Water Program (see Agency’s responses re: analytic methods). A treatment technique may only follow from receipt of data via an accredited laboratory. Given the complexity and expense of treatment, including the expenses of managing treatment in a comprehensive manner to account for disinfection byproducts and corrosion, setting a treatment technique at detection is not an appropriate approach to manage PFAS in Vermont. Treatment techniques are employed separate and apart from MCLs, which Vermont already employs regarding PFAS.

The response below examines three techniques to treat PFAS compounds as raised by the comments. It should be noted that there is no source to show that these techniques are effective for all PFAS compounds and no analytical methodology to determine when a PFAS compound that cannot be detected by EPA Method 537.1 breaks through the treatment media.

GAC filtration presents expensive and complex problems for public water systems, especially when accounting for the size of the systems where treatment is needed, both presently and in the future, especially if MCLs are lowered or if short-chain PFAS is added to MCLs based on future toxicological data. At the most basic level, in

Vermont installation of GAC treatment requires an increase operational expertise from Class 2 to Class 3 based on the system classification criteria established in the Water Supply Rule. Small water systems, for the most part, cannot find these operators and must contract out to get them. This is expensive and the result can be a Class 3 operator who visits the water system infrequently, leaving a lower-classified or non-certified operator to do the daily work. GAC filtration requires post disinfection (usually via chlorine), so a system that has not previously disinfected will now analyze daily for chlorine and produce water with disinfection byproducts at a level usually proportional to dissolved inorganic carbon. Disinfection Byproducts will have their own deleterious health effects if not properly managed. Chlorine will also increase the corrosivity of the water, potentially increasing lead corrosion. If iron or manganese is present in the water, even in low levels, any dissolved oxygen in the water will oxidize the iron and manganese that is adsorbed onto the GAC potentially clogging the GAC filter. Iron and manganese pre-treatment may therefore be required. The resulting treatment scheme would be oxidation, iron and manganese filtration, possible dechlorination, and GAC filtration and disinfection.

Anionic exchange resins work similarly to GAC filtration. The anionic resin substitutes an anion (usually chloride) for a PFAS anion. Once all the exchange capacity is exceeded, PFAS will bleed through. The resin is then discarded, and new resin is loaded. As with GAC, other contaminants (competing ions) must be addressed as part of the treatment process. We have no experience with this anionic resin treatment in Vermont and no framework to understand its lifespan in a Vermont system. Research shows that it is superior to GAC with some PFAS and inferior with others. Just as with GAC filtration, performance is poorer with short-chain PFAS. The resin is reported to be more costly than GAC with fewer manufacturers. Handling spent media poses handling, storage, and cost challenges. It is loaded with PFAS when exhausted, leaving it to be managed through the waste stream, at a considerable expense.

Commenters state that high pressure membrane filtration, namely reverse osmosis, is the best method to remove PFAS from water. The molecules are simply too large to pass through the membrane and removal is nearly complete whether they are short-chain or long-chain. For small Vermont water systems, this method, is not the preferred treatment alternative. The process wastes water. Conservative estimates report it to waste between 5-30%. This water has rejected PFAS in it with concentrations three to twenty times greater than the raw water. This water must be

properly disposed of. Current EPA guidance is to provide “interim storage” until the time comes when disposal options become available. Centralized RO is nothing like an under-sink unit that treats a small amount of water. The efficiency of the units will require more water be pumped from the sources (mostly groundwater wells) which has a deleterious effect on the aquifer. RO membranes are subject to fouling or “clogging” and must be rejuvenated with strong acids and other chemicals which also must be managed and disposed of properly. Centralized RO also requires the elevation to Class 3, which has concerns previously addressed above. The RO process would remove PFAS and other contaminant compounds, but it also removes alkalinity and hardness, leaving a low pH and extremely corrosive water. Corrosion control would be needed, likely with two or more of lime, carbon dioxide, sodium hydroxide, or sodium bicarbonate to not create a situation with metals, including lead, corrosion within the distribution system and local plumbing. These all come with respective additional costs, storage and operation requirements, and need for time and attention from the water system operator. Under-sink RO units are not feasible in the vast majority of systems, because each individual treatment device creates its own quality of water and must be sampled for various contaminants to ensure efficacy of treatment. This can be at considerable additional cost.

The comments refer to other treatment technique levels in drinking water and reference the lead action level of 15 ppb. An MCL is based on health effects and feasibility; whereas an action level is a screening tool for determining when certain treatment technique actions are needed. The lead action level is not a health-based number, but a trigger for action to address treatment efficacy to reduce corrosion. Vermont already has an MCL for PFAS, substituting that for a Treatment Technique is not in the best interest of public health.

The Division’s Draft PFAS Response Plan, developed under contract with Weston and Sampson Engineers identifies some of the details of the various treatment methodologies mentioned in the comments. The document is available here: <https://dec.vermont.gov/sites/dec/files/PFAS/Draft-Final-PFAs-Response.pdf>

IX. ANALYSIS OF TREATMENT COSTS

Continuing from the Treatment Technique responses above, the Agency provides the following, based on the Draft PFAS Response Plan and on actual observed costs experienced by public water systems that have needed to address PFAS treatment to date. Each system has its own set of circumstances, available space for treatment, and unique water quality which all factor into the overall cost. “Installing” treatment is far more than simply connecting pieces of pipe and equipment together. Systems may need to provide additional space, reconfigure existing infrastructure to be optimized to provide treatment, and provide pre-treatment to maximize efficacy of the treatment targeting PFAS. A small system implementing GAC filtration is expected to spend \$15,000 – \$40,000 on equipment purchase and installation, without the need to re-configure the water system or build a new building to accommodate the infrastructure. This does not account for permitting or design work. A new building would cost tens of thousands of dollars. Once operational, annual costs range from \$10,000 to \$20,000 for GAC, Reverse Osmosis, or Ion Exchange equipment. This does not account for pre-treatment or wastewater disposal issues, both of which add significantly higher costs. Depending on system sizes, pre-treatment would cost tens of thousands to millions of dollars, based on the individual water quality and size of the system. The initial costs coupled with the on-going operation and maintenance expenses lead to very high user rates, especially for smaller systems like those in Vermont.

As discussed above, Reverse Osmosis (RO) generates a waste stream of water with PFAS concentrations much greater than the source water. This waste stream must be treated and disposed of in a manner that does not pass on the PFAS contamination. A feasible method for treating this waste stream is to install GAC treatment to concentrate the PFAS contamination. Therefore, any RO treatment is more expensive than GAC treatment since it may require implementation both courses of treatment.

X. COMMENTS RELATED TO SUMMATION/OVERALL POSITION

COMMENTS: 1) To protect Vermont communities, the Agency should promulgate new rules for the PFAS class and establish a (1) maximum contaminant level goal (MCLG) of zero for the PFAS class; (2) combined MCL below 20 ppt at the lowest, most health protective level technically achievable¹ for the maximum number of quantifiable PFAS; and (3) treatment technique standard for the PFAS class based on total organic fluorine (TOF) measured by combustion ion chromatography (CIC) as soon as an analytical method is validated by an international, federal, or state agency. With respect to the combined MCL, the standard should include all PFAS that can be quantified with a

user defined 537-modified method following the Department of Defense (DoD) criteria.² In addition, the Agency should require a pre-oxidation step in which perfluoroalkyl acids (PFAA) precursors are oxidized to terminal PFAAs before measuring individual PFAS to capture a more accurate accounting of PFAS in the public water supply.

2) The Agency must conduct a rigorous review of all scientific and technical information and other relevant factors regarding regulation of PFAS as a class or subclasses. Act 21 directs the Agency to initiate a formal rulemaking process to regulate PFAS as a class or subclasses in recognition of the fact that the current MCL for just five PFAS out of more than 9,000 compounds is not adequate to protect Vermonters.³¹ The statute sets forth deadlines for the publication of the Advance Notice, as well as proposed and final rules to ensure additional drinking water protections are put in place expeditiously.³² If the Agency does not publish a proposed rule by March 1, 2021, the Agency must “at a minimum, identif[y] . . . all legal, technical, or other impediments to regulating PFAS compounds as a class or subclasses and a detailed response to all public comments received.”³³ The Agency does not have unlimited discretion to choose whether or not to propose and finalize additional drinking water rules for PFAS.³⁴ Under Act 21, the Agency must move forward with new rules unless it demonstrates there is a scientific, technical, or legal impediment that prevents the Agency from doing so.³⁵ Inherent in this mandate to the Agency is the requirement for the Agency to conduct a rigorous review of all scientific and technical information and other relevant factors regarding regulation of PFAS as a class or subclasses.³⁶ Agencies must articulate a reasonable explanation for a decision that is consistent with legislative policy, and these decisions must be supported by substantial evidence.³⁷ Courts have held that an agency must evaluate all substantial scientific and technical information, consider all relevant factors, and provide a detailed and rational explanation for its conclusion.³⁸ These are basic principles of administrative law, and the Agency is required to meet this same test with respect to new rules to protect Vermonters from PFAS compounds in drinking water.

3) The Agency has broad authority to regulate unsafe chemicals in drinking water.⁵⁵ Pursuant to 10 V.S.A. § 1672, the Secretary “shall regulate” drinking water “to

prevent and minimize public health hazards.”⁵⁶ The Secretary may adopt a Health Advisory Level set by the Vermont Department of Health as an MCL⁵⁷ or establish other standards or requirements for drinking water quality so long as the standards or requirements are at least as stringent as the national primary drinking water regulations.⁵⁸ In addition, the Agency has the authority to adopt a treatment technique drinking water standard for PFAS.⁵⁹ “A treatment technique is an enforceable procedure or level of technological performance which public water systems must follow to ensure control of a contaminant.”⁶⁰

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When promulgating drinking water rules, the Agency is obligated, first and foremost, to establish drinking water standards that fully protect public health.⁶⁶ The Agency is not required to conduct a cost-benefit analysis.⁶⁷ That said, the benefits that stem from preventing exposure to harmful PFAS—as well as other unregulated contaminants that are removed in the process—in drinking water would far outweigh the costs associated with compliance.⁶⁸

There are substantial societal costs avoided and benefits gained from preventing PFAS exposure. There are significant environmental and human health costs associated with PFAS, and exposure can lead to massive, lifelong health-related costs on individuals exposed (including decreased wages and increased medical bills), a lower quality of life, and premature death. For

example, with respect to low birth weight alone, a recent study estimated the economic burden of PFOA contamination at \$13.7 billion for the period 2003-2014 in the U.S.⁶⁹ Low birth weight may be associated with a higher risk of developing diseases in adulthood such as cardiovascular disease, respiratory disease and diabetes,⁷⁰ and is associated with impaired cognitive development. In addition, low birth weight can be associated with a 25% lower likelihood of passing high school exit exams; a higher risk of unemployment at age 33 years;⁷¹ and lower income for men 30 years of age and for women between 50 and 60 years of age.⁷²

Additionally, a recent report by the Nordic Council estimates that health costs from exposure to PFAS costs far outweigh the costs of remediation.⁷³ Many of the findings from this report came from studies conducted in the United States. Notably, the economic impacts in the Nordic Council study do not include indirect costs, such as psychological or emotional impacts. Therefore, the total societal costs are likely underestimated in the report. While the exact health-related costs associated with PFAS exposure have not been comprehensively quantified, such costs will undoubtedly far outweigh the costs of monitoring and treatment to remove PFAS from drinking water.⁷⁴ In conclusion, the Agency has the authority to establish drinking water regulations for the PFAS class or subclasses, including setting a treatment technique standard.

4) The time and money saved by regulating PFAS as a class must instead be immediately directed to developing and employing effective measures to mitigate and prevent further damage to the public health, our environment, and the natural resources that are the foundation of life itself- our drinking water, our food supply, and the air that we breathe.

RESPONSE: The most appropriate way to manage per and polyfluoroalkyl (PFAS) is to develop a class-based approach to the regulation of PFAS. A class-based approach provides greater protection to the public, decreases the burden on regulatory agencies, and provides greater certainty to the operators of public community water systems.

In evaluating whether this advisory should include other PFAS, several barriers were identified which are described in the final decision and elsewhere in this response. Notwithstanding the clear advantages of adopting a class based maximum contaminant level (MCL) for a broad range of PFAS compounds, it is technically infeasible at this time to do so. The primary technical barrier to adopting a MCL for PFAS as a class is the lack of the comprehensive comparative or relative toxicological information necessary and framework to develop a class based regulatory standard. An important secondary consideration are the significant limitations that exist surrounding the ability to quantify all PFAS in drinking water and the unreliability in a drinking water regulatory setting of using qualitative methods to require enhanced management of all PFAS.