AGENCY OF NATURAL RESOURCES
DEPARTMENT OF ENVIRONMENTAL CONSERVATION
DRINKING WATER AND GROUNDWATER PROTECTION DIVISION

ADVANCE NOTICE ON THE REGULATION OF PERFLUOROALKYL, POLYFLUOROALKYL SUBSTANCES (PFAS) AS A CLASS.

August 14, 2020

I. Background, legislative mandate, and initial findings.

No. 21 of the Acts and Resolves of 2019 directed the Agency of Natural Resources (the "Agency") to investigate and publish an advance notice of proposed rulemaking on the regulation of PFAS as a class or subclass. Sec. 3(b) No. 21 of 2019 (Act 21 or Act).

Vermont has no formal process for publishing an advance notice of proposed rulemaking and Act 21 does not require a process, in light of this, the following process will apply:

1. This notice of proposed rulemaking will be posted on the Department of Environmental Conservation website.

2. The Department will provide electronic notice to known interested persons, including drinking water systems, environmental nongovernmental organizations, trade associations representing drinking water systems and operators, and other interested persons.

3. The Department will have a 60-day public comment period which shall conclude on **Thursday, October 15, 2020.** All comments should be sent to ben.montross@vermont.gov and should include "Regulation of PFAS as a Class" in the subject line.

4. The Department will hold an informational meeting on the regulation of PFAS as a class on **Tuesday, September 15, 2020.** The informational meeting will be held via an electronic meeting platform (Microsoft Teams) and will allow participants to ask questions of the presenters via instant message / chat.

5. The Department will review all comments and make a final decision as to whether to regulate PFAS as a class or further regulate a class or subclasses of PFAS pursuant to the requirements of Sec. 3(c) of Act 21.

There are currently more than 4,000 PFAS compounds that are in commerce in the United States, and so far Vermont has established a regulatory standard for five PFAS compounds. In addition, there are only three promulgated US EPA analytical methods: USEPA 537, USEPA 537.1 and USEPA 533.

While only five PFAS compounds are regulated in Vermont, the known adverse health effects from PFAS generally include increases in cholesterol levels, high blood pressure, decreases in infant birth weight, decreased vaccine response in children, and increased risks of kidney and testicular cancer. PFAS are also persistent in the environment earning the nickname "the forever chemicals." Due to the chemistry of PFAS, they are chemically and thermally stable, and generally resistant to degradation and oxidation. See National Institutes of Health, Institute of Environmental Health Sciences.

In light of the high number of PFAS compounds in commerce, the Vermont Legislature directed the Agency of Natural Resources to evaluate whether PFAS could be regulated as a class or subclass of compounds.

In order to accomplish our review we assembled a team of scientists from the Vermont Departments of Environmental Conservation and Health that have expertise in analytical methods for the detection of substances in various environmental media, contaminated site investigation and remediation, drinking water, human health toxicology and risk assessment, and surface water (The Review Team). This team met over a year to develop the summary table below.

The Review Team consulted with other jurisdictions, interstate organizations, and literature on PFAS analytical methods and toxicology. The Review Team focused on groundwater (including drinking water), surface water, and soils when conducting its review. Analytical methods associated with airborne transmission of PFAS are under development, and as such were not available to review. The Review Team examined the following: (1) Does data exist to support regulating PFAS as a class in the same manner that other constituents are regulated as a class? (2) Are other jurisdictions regulating PFAS as a class or subclass? and (3) Do various analytical methods looking at total PFAS enable the Agency to better understand, for regulatory purposes, PFAS concentrations in various media to drive regulatory and risk management decisions?

Where chemicals are members of the same family or group have been shown to exhibit similar toxicological properties, it may be appropriate to regulate such chemicals as a class or group even though each individual chemical may differ in the degree of toxicity. In such cases, the reported concentrations of each member of the group may be evaluated using its relative toxicity to an index chemical for the group.

ANR currently regulates five PFAS compounds, in summation or separately, to a single health-based standard for groundwater, through the Groundwater Protection Rule and Strategy, drinking water through the Water Supply Rule, and soil through the Investigation and Remediation of Contaminated Properties Rule. Many states other than Vermont regulate groupings of PFAS, including Alaska, California, Colorado, Connecticut, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, Ohio, and Oregon. Any grouping of chemicals as a class must be carefully considered and supported by science that has been peer reviewed and/or adopted by authoritative agencies like the Environmental Protection Agency (EPA), World Health Organization (WHO), and other similar groups. The science surrounding the health effects of PFAS is constantly evolving and at a rapid pace. The State of Vermont will closely monitor the state of the science for grouping PFAS as a class.

When establishing a regulatory standard, ANR relies on health advisories set by the Vermont Department of Health (Health). A regulatory program takes an advisory level recommended by Health and determines to adopt it as a regulatory standard by rule. The Agency may consider other relevant factors when adopting a regulatory standard including the ability of analytical methods to detect a substance, the effectiveness of treatment techniques, and other considerations depending on the regulatory program.

The State of Vermont typically relies, in part, on EPA published guidance for establishing toxicity values for members of a chemical class, family, or group for classes of chemicals such as Dioxins, Polychlorinated Biphenyls (PCBs), and Polycyclic Aromatic Hydrocarbons (PAHs). Additionally, the State of Vermont typically relies on EPA and the WHO published guidance on regulation of these compounds as a class. However, no such guidance exists for regulation of PFAS as a class.

The State of Vermont does not have the resources to conduct the types of scientific and technical analyses that are normally provided by EPA or WHO to evaluate regulating PFAS as a class at this time. We plan 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. The NTP has published a framework for evaluating PFAS as a class using computational toxicology methods (Patlewicz, et al., 2019). These methods recognize that a chemical-by-chemical approach will not result in meaningful data to support regulation of PFAS as a class. The NTP approach starts with two lists of 75 PFAS that are evaluated for structural similarities and potency of biological response. The NTP plans to select "anchor" PFAS upon which to build classes or subclasses of PFAS. This work involves hundreds of NTP and EPA scientists, and reflects a level of effort and resources that the State could not independently invest in a similar process.

While scientists are assessing techniques that focus on measuring the total exposure of all PFAS instead of one or a limited set of PFAS substances, none of these techniques are ready for large-scale use or regulatory application. This is important to gain a better understanding of exposures to PFAS as a class (Hartmann et al. 2017; Poothong et al. 2017).

PFAS sampling in public drinking water systems in Vermont started in 2019 pursuant to the Act. Prior to that, select PFAS compounds had only been sampled in targeted areas of the State based on the potential for a release from industrial or other sources. Prior to 2013 there was limited to no sampling for PFAS compounds nation-wide.

The following tables provide a variety of assessed strategies to regulate PFAS as a class. Feasibility refers to the current potential to utilize a technique to regulate

PFAS as a Class above what currently exists, or in addition to, how we are currently regulating PFAS.

There are several analytical techniques to identify presence or likely presence of PFAS compounds, as identified below. From a regulatory standpoint, however, the granularity, standardization, uniformity, and repeatability across all media and waste streams (e.g., biosolids, leachate) in the State do not currently provide for adequate information to regulate PFAS as a class beyond the current class of five. ANR will continue to review ongoing and new research that may support future adoption of a health-based standard that applies to PFAS compounds beyond the five that are currently regulated.

As a result of this lack of information, the Agency of Natural Resources is not, at this time, recommending that PFAS be more broadly regulated as a class.

Findings of State Review of PFAS contaminants

<table>
<tr><th colspan="3">1. ADDITIVE</th></tr>
<tr><td>Description</td><td colspan="2">Additive is taking the sum of each individual PFAS detected and adding them together to compare to one health-based standard. An additive approach usually occurs with chemicals that are similar in structure and toxicological endpoints. This is the current method ANR uses to regulate the five PFAS for groundwater and drinking water. Currently, the following five PFAS compounds are included for summation:

• PFOA (perfluorooctanoic acid),
• PFOS (perfluorooctane sulfonic acid),
• PFHxS (perfluorohexane sulfonic acid),
• PFHpA (perfluoroheptanoic acid),
• PFNA (perfluorononanoic acid).</td></tr>
<tr><td colspan="3">Scientific Support, Analytical and Regulatory Pros and Cons</td></tr>
<tr><td rowspan="2">Scientific</td><td>PRO</td><td>The current Vermont process in place evaluates PFAS as a class using an additive method when individual toxicity values are available for the chemicals. The Vermont grouping process is applied when chemicals evaluated in Vermont have been released in the environment and are sufficiently similar, are found together, and elicit similar health effects.</td></tr>
<tr><td>CON</td><td>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.</td></tr>
<tr><td rowspan="2">Analytical Issues</td><td>PRO</td><td>PFAS have similar limits for lab detection via EPA Method 537.1, and there is a minimal cost difference between analyzing a few or 18 compounds. Regulating and requiring testing for more analytes does not increase the cost and lessens the potential for the need to resample in the future.</td></tr>
<tr><td>CON</td><td>As detection levels change it makes it difficult to determine what reported concentration should be included in the total concentration detected for a</td></tr>
</table>

		sample location. There are currently methods to analyze for 18 (USEPA 537.1) to 25 (USEPA 533) of the 4,000 PFAS.
Regulatory Issues	PRO	This approach is currently utilized with other compounds in the Drinking Water and Groundwater Protection Division and Sites program and is an accepted scientific strategy.
	CON	This approach could lead to the need to regularly update regulatory levels for PFAS in various media as the level of scientific support for grouping additional PFAS becomes available. This method also may need a significant level of outreach and education to stakeholders to gain acceptance for this method because of the increased costs for regulatory entities. This method is also complicated and labor intensive when evaluating new compounds to include in this strategy.
2. SUBCLASS		
Description	Regulating PFAS as a subclass is a way to categorize PFAS into groupings based on chemical properties and structure, toxicologic properties, precursors that transform into other PFAS, manufacturing processes, commercial use, and available data.	
Scientific Support, Analytical and Regulatory Pros and Cons		
Scientific Support	PRO	Subclasses may be decided based on biological potency, so that the most toxic PFAS are grouped together as the highest priority to monitor.
	CON	There are no existing templates from peer-reviewed and authoritative sources on how to regulate PFAS as a subclass.
Analytical Issues	PRO	Analytical methods exist to sample up to 25 PFAS and achieve low detection limits.
	CON	Not all of the 4,000+ PFAS are detectable with current analytical methods.
Regulatory Issues	PRO	Regulating and focusing on a smaller group of PFAS that have the highest likelihood to cause impacts to human health or the environment, rather than trying to regulate and create standards for all 4,000 PFAS.
	CON	This approach could lead to the need to regularly update regulatory levels for PFAS in various media as the scientific support for new groupings or changes in relative biological potency in PFAS become available.
3. TEQ- Toxicity Equivalence		
Description	The TEQ concept has been developed to facilitate risk assessment and regulatory control. A group of chemicals is ranked 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, based upon years of scientific research. Vermont does not have the current capacity to develop TEQs for PFAS compounds.	
Scientific Support, Analytical, and Regulatory Pros and Cons		
Scientific Support	PRO	A TEQ is a science-based approach to evaluate chemicals as a class based on potency.
	CON	No peer-reviewed authoritative bodies have published TEQs to evaluate PFAS as a class.

Analytical Issues	PRO	Not all PFAS are detectable with current analytical methods, but as TEQs are developed for newly analyzable compounds they can be integrated into this approach.
	CON	TEQs don't yet exist, therefore achievable analytical Minimum Detection Limits (MDL) for the labs are unknown
Regulatory Issues	PRO	Could be used for regulatory programs. Consistency amongst the programs for different media would be a benefit. Adding new PFAS into this technique would allow for the same standard to be used (20 ppt).
	CON	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).
4. Non-targeted Analytical Techniques: AOF/EOF with CIC		
Description	Adsorbable or extractable organic fluorine (AOF/EOF) paired with combustion ion chromatography (CIC) measures the combusted organofluorine content in a sample. The total fluorine is measured as fluoride.	
Scientific Support, Analytical, and Regulatory Pros and Cons		
Scientific Support	PRO	Could be used as rapid screening tool to assess if fluorine-containing compounds are present in aqueous samples.
	CON	This approach does not reflect the reality that some PFAS are more biologically potent than others. In addition, fluoride is naturally occurring in some Vermont aquifers and may complicate the interpretation of results.
Analytical Issues	PRO	If this method were less expensive than the LC/MS this technique could be used to quantify PFAS in a groundwater or surface water. Laboratories are getting better at quantifying concentration of AOF in a sample to a total PFAS concentration
	CON	Not specific to PFAS, so if samples contain fluorine, this could bias results high. 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. This technique has not been demonstrated that it can be used for solid matrices. This technique may not capture short-chained PFAS. 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.
Regulatory Issues	PRO	If existing conditions of PFAS or Fluoride were known at a site this could be an alternative indicator to determine fate and transport of PFAS in groundwater. Most useful for Sites program.
	CON	This technique would be used more as a screening tool as it does not analyze for PFAS compounds specifically. Total PFAS concentration identified would most likely contain more PFAS than are regulated in VT. A lot of work would need to be conducted to determine existing concentrations of fluorine in the aquifer.
5. Non-targeted Analytical Techniques: PIGE		

Description	PIGE is a nondestructive analytical technique that measures the unique gamma-ray wavelength emission of fluorine when it's impacted with a proton ion beam. The technique assesses total fluorine content of a variety of materials (Ritter et al. 2017). In the published literature, PIGE has been used to demonstrate total organofluorine concentrations in papers and textiles (Ritter et al. 2017; Robel et al. 2017) and food packaging (Schaider et al. 2017). It has also been used on an experimental basis to evaluate organofluorine concentrations in extracted water and soils, but those results are not yet available in the peer-reviewed literature.	
Scientific Support, Analytical, and Regulatory Pros and Cons		
Scientific Support	PRO	In peer-reviewed, published literature, PIGE is a technique demonstrated to measure total organofluorine on surfaces.
	CON	Operating conditions for analyzing PFAS have not been standardized. Extraction methods for environmental samples is still under development and has not been published in peer-reviewed literature.
Analytical Issues	PRO	Rapid screening tool. Non-destructive. Minimal sample preparation required for analysis of commercial products. Can be used to analyze for organofluorine if inorganic fluoride removed from sample.
	CON	Not specific to PFAS, and may not be specific to organofluorine. Does not include chain length information in results. This technique would be used more as a screening tool as it does not analyze for PFAS compounds specifically. Not widely available in commercial laboratories.
Regulatory Issues	PRO	Could be used as a screening tool when more widely available.
	CON	This technique would be used more as a screening tool as it does not analyze for PFAS compounds specifically and no standards are available to compare to.
6. Non-targeted Analytical Techniques: qTOF		
Description	Quadrupole time-of-flight mass spectrometry (qTOF/MS) can be used to determine both the chemical formula and structure of unknown PFAS in a sample. Separate analytical standards are required for unequivocal structural identification.	
Scientific Support, Analytical, and Regulatory Pros and Cons		
Scientific Support	PRO	Semi-quantitative analysis for PFAS
	CON	High probability for false positives
Analytical Issues	PRO	This technique can be used to forensically differentiate between two different sources of PFAS in a sample.
	CON	This technique involves the need for well-trained lab technicians to interpret data. Identification of PFAS structures can't happen without comparison to reference materials or analytical standard. False positives are more likely with this technique than with PIGE, TOP, or AOF.
Regulatory Issues	PRO	This technique would be used more as a screening tool as it does not analyze for PFAS compounds specifically and no standards are available to compare to.
	CON	There are no standards to compare to, quantification of PFAS in a sample still seems to have a lot of inaccuracies

7. Non-targeted Analytical Techniques: TOP		
Description	Total Oxidizable Precursor (TOP) Assay is a qualitative technique that measures Perfluoralkyl acids (PFAAs) precursors, or polyfluorinated compounds that can be converted to PFAAs, by Liquid Chromatography tandem mass spectrometry (LC/MS/MS).	
Scientific Support, Analytical, and Regulatory Pros and Cons		
Scientific Support	PRO	TOP Assay may provide information on what precursors are present, however there is a lot of variability in the interpretation of the data. Qualitative technique to estimate PFAA precursors
	CON	Not indicative of environmental conditions, non-standardized, telomer-based short chain precursors biased low, larger molecular weight compounds may not be captured.
Analytical Issues	PRO	TOP Assay is available in certain commercial labs. The oxidation step forces all precursors to their terminal PFAA compounds.
	CON	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. Due to the process, this technique may provide false positives or skew the data high as compared to environmental conditions. This technique would be used more as a screening tool as it is not quantitative.
Regulatory Issues	PRO	Could be used as a screening tool. Not well suited for regulatory purposes.
	CON	This technique would be used more as a screening tool and no standards are available to compare to.

Conclusions:

The Review Team spent over a year deliberating, researching, and discussing the potential to regulate PFAS as a Class. After reviewing the current peer-reviewed literature, as well as the available toxicology data for PFAS, 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. 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.

II. Questions and focus areas for comment

1. The Agency has provided a list of peer reviewed technical articles that served as the basis of the research summarized in this Notice in Attachment A. If there are additional peer reviewed articles that address the toxicology of PFAS compounds please provide a copy or a link to that article.

2. Any PFAS compound that you believe is not currently regulated under Vermont's grouping and that you believe should be regulated. Provide any supporting documentation for this request.

Appendix A

PFAS as a Class References List for 8/15/2020 Notice of Advance Rulemaking

Agency for Toxic Substances and Disease Registry (ATSDR) https://www.atsdr.cdc.gov/

ECOS. (February 2020). Processes & Considerations for Setting State PFAS Standards. https://www.ecos.org/documents/ecos-white-paper-processes-and-considerations-for-setting-state-pfas-standards/

Hartmann, C., Raffesberg, W., Scharf, S., & Uhl, M. (2017). Perfluoroalkylated substances in human urine: results of a biomonitoring pilot study. *Biomonitoring*, *4*(1), 1-10.

ITRC (Interstate Technology & Regulatory Council). 2020. *PFAS Technical and Regulatory Guidance Document and Fact Sheets* PFAS-1. Washington, D.C.: Interstate Technology & Regulatory Council, PFAS Team. https://pfas-1.itrcweb.org/

Michigan PFAS Science Advisory Panel. (December 2018). Scientific Evidence and Recommendations for Managing PFAS Contamination in Michigan.

National Toxicology Program (NTP) https://ntp.niehs.nih.gov/

OECD. (May 2018) Toward a New Comprehensive Global Database of Per-and Polyfluoroalkyl Substances (PFASs): Summary Report on Updating the OECD 2007 List of Per-and Polyfluoroalkyl Substances (PFASs).

Patlewicz, G., Richard, A. M., Williams, A. J., Grulke, C. M., Sams, R., Lambert, J., & Guiseppi-Elie, A. (2019). A chemical category-based prioritization approach for selecting 75 per-and polyfluoroalkyl substances (PFAS) for tiered toxicity and toxicokinetic testing. *Environmental health perspectives*, *127*(01), 014501.

Poothong, S., Thomsen, C., Padilla-Sanchez, J. A., Papadopoulou, E., & Haug, L. S. (2017). Distribution of novel and well-known poly-and perfluoroalkyl substances (PFASs) in human serum, plasma, and whole blood. *Environmental science & technology*, *51*(22), 13388-13396.

Ritter, E. E., Dickinson, M. E., Harron, J. P., Lunderberg, D. M., DeYoung, P. A., Robel, A. E., & Peaslee, G. F. (2017). PIGE as a screening tool for Per-and polyfluorinated substances in papers and textiles. *Nuclear Instruments and Methods in Physics Research Section B: Beam Interactions with Materials and Atoms*, *407*, 47-54.

Robel, A. E., Marshall, K., Dickinson, M., Lunderberg, D., Butt, C., Peaslee, G., & Field, J. A. (2017). Closing the mass balance on fluorine on papers and textiles. Environmental Science & Technology, 51(16), 9022-9032.

Schaider, L. A., Balan, S. A., Blum, A., Andrews, D. Q., Strynar, M. J., Dickinson, M. E., & Peaslee, G. F. (2017). Fluorinated compounds in US fast food packaging. *Environmental science & technology letters*, *4*(3), 105-111.

USEPA. (December 2010). Recommended Toxicity Equivalence Factors (TEFs) for Human Health Risk Assessments of 2,3,7,8-Tetrachlorodibenzo-p-dioxin and Dioxin-Like

Compounds. https://www.epa.gov/sites/production/files/2013-09/documents/tefs-for-dioxin-epa-00-r-10-005-final.pdf

USEPA. (2019). EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan. https://www.epa.gov/pfas/epas-pfas-action-plan

Vermont Department of Health. (May 2019). https://www.healthvermont.gov/sites/default/files/documents/pdf/ENV_ECP_GeneralScreeningValues_Water.pdf

Wang, Z., DeWitt, J. C., Higgins, C. P., & Cousins, I. T. (2017). A never-ending story of per-and polyfluoroalkyl substances (PFASs)?.

Washington Department of Ecology. (February 2019) Interim Chemical Action Plan for Per-and Polyfluorinated Alkyl Substances. https://fortress.wa.gov/ecy/publications/summarypages/1804005.html