Oral comments of Dr. Katherine Pelch on LD164

Good morning, Chairs and Members of the Committee, and thank you for the opportunity to speak today.

I am Dr. Katherine Pelch, an Assistant Professor at the University of North Texas Health Science Center. I hold a PhD in biology, and have expertise in evaluating the health effects of PFAS and similar harmful chemicals. I have also been working in collaboration with scientists to systematically evaluate the decisions and judgements made by the 18 US federal and state agencies that have conducted risk assessments for PFAS in drinking water.

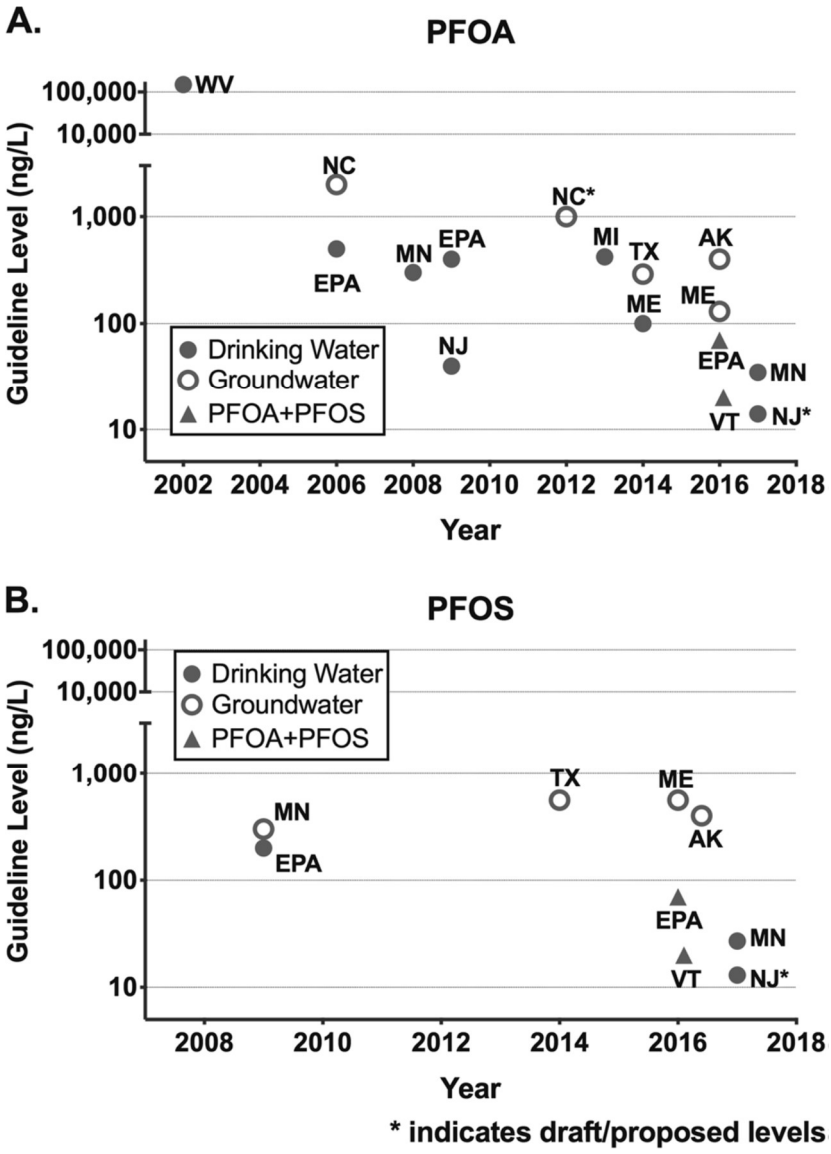
I am speaking today in favor of bill LD164 to set a combined maximum contaminant level (or MCL) for 6 PFAS at 20 ppt, and strongly urge you to include a provision to require monitoring of water supplies beyond these 6 PFAS.

Over time, proposed and adopted MCLs, notification levels, and health based guidance values for PFAS have continued to become stricter and more health protective as new scientific studies indicating health harms at lower exposure levels have become available. Leading scientists currently suggest that drinking water levels of several PFAS should be in the range of 1-2 ppt in order to account for a variety of health effects that have been observed at low levels of exposure, including disruption of immune system function. In line with this, many states have set values in the low ppt range for several PFAS. The states and agencies setting the strictest values have included considerations that more adequately protect infants and children, who represent a vulnerable and susceptible population for PFAS exposure. The young are vulnerable because they consume more water on a per body weight basis than adults. The young are also particularly susceptible to the harmful effects of PFAS due to their rapid growth and development and the potential for the establishment of long lasting health effects including decreased response to vaccines, and changes in hormonal signaling. It is important to note that the existing lifetime health advisory from EPA of 70 ppt for PFOA and PFOS is outdated and does not consider the effects of PFAS observed at low levels of exposure or account for the vulnerability and sensitivity of infants and children.

Many PFAS share similar toxicity concerns, indicating that combined or cumulative toxicity is of concern. To begin to address this, some states have set combined standards, for example, VT and MA, which have a combined standard of 20 ppt for 5 or 6 PFAS, respectively.

However, I would argue that the proposal to regulate 6 PFAS at 20 ppt does not go far enough considering there are many more PFAS in use and detected in the environment with known and unknown effects on health. I refer you to a technical guidance that my colleagues and I recently submitted to the Agency of Natural Resources in Vermont, outlining, in detail, how the state can take steps to more comprehensively regulate the class of PFAS in drinking water.

As more scientific evidence has become available, proposed and adopted MCLs, notification levels, and health based guidance values for PFAS have continued to become stricter and more health protective.



Timeline of Select PFOA and PFOS Drinking Water Guideline Levels. (a) PFOA and (b) PFOS water guideline levels have decreased over time. Several states have developed guidelines for PFOA or PFOS individually (circles), while Vermont (VT) and EPA have guidelines that apply to PFOA and PFOS individually or combined (triangles). PFOA and PFOS water guidelines can apply to different water types such as public drinking water (closed circles) or groundwater, e.g., at contaminated sites (open circles).

From: Cordner A, De La Rosa VY, Schaider LA, Rudel RA, Richter L, Brown P. 2019. Guideline levels for PFOA and PFOS in drinking water: The role of scientific uncertainty, risk assessment decisions, and social factors. Journal of exposure science & environmental epidemiology 29:157-171.

As states and agencies have over time better incorporated protections for vulnerable and susceptible populations such as infants and children as well as reports on health effects observed at low levels of exposure, there has also been a growing call from the scientific community on the need to address the growing class of PFAS that have been detected in the environment and in our bodies:

Helsingor Statement (2014)
Discusses the transition from long-chain PFASs to fluorinated alternatives and summarizes key concerns about the potential impacts of fluorinated alternatives on human health and the environment as well as the societal implications of continued exposure.

Madrid Statement (2015)
Consensus statement from over 200 scientists and experts documenting their concern over the persistence and potential for harm of PFAS, and calling on the international community to "cooperate in limiting the production and use of PFASs and in developing safer non-fluorinated alternatives."

Zurich Statement (2018)
Documents an action plan for the assessment and management of PFAS developed by a group of more than 50 international scientists and regulator. The group recommended a grouping approach to addressing PFAS, new approaches to assessing and managing highly persistent chemicals such as PFAS, a phase out of nonessential uses of PFAS and development of safer alternatives.

The Concept of Essential Use (2019)
Builds on the Madrid Statement and the Montreal Protocol to chart a path forward to phase out all non-essential uses of PFAS.

Persistence Alone is Major Cause of Concern (2020)
Concludes that the extreme persistence of PFAS due to the fluorocarbon bond is sufficient for management of the chemicals as a class, despite the diversity and large number of chemicals in the class. Further argues in favor of the application of the essential use framework to phase out the use of PFAS.

Scientific Basis for Managing PFAS as a Chemical Class (2020)
Presents a scientific basis for managing PFAS as one chemical class based on the shared physicochemical, environmental, and toxicological properties of PFAS.

Technical Comments of

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to the

Vermont Agency of Natural Resources

Re Advance Notice on the Regulation of Perfluoroalkyl, Polyfluoroalkyl Substances (PFAS) as a Class

November 16, 2020

Introduction

Over the past few decades per- and poly-fluoroalkyl substances (PFAS) contamination has grown into a serious global health threat. PFAS are extremely persistent, highly mobile in the environment and many have been found to bioaccumulate, or build up, in humans and animals. People are concurrently exposed to dozens of PFAS chemicals daily through their drinking water, food, air, indoor dust, carpets, furniture, personal care products, and clothing. As a result, PFAS are now present throughout our environment and in the bodies of virtually all Americans.

PFAS are associated with many serious health effects such as cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity - some of which occur at extremely low levels of exposure.[1, 2] Additionally, because PFAS are chemically related, they may have additive or synergistic effects on target biological systems within our bodies.

The number of chemicals in the PFAS class is growing rapidly. EPA Comptox Dashboard now indicates there are over 9,000 unique PFAS structures.[3] For most of these chemicals there is limited to no data on their potential toxicity to human health and the environment. However, evidence from known PFAS, including both legacy and replacement PFAS, is growing quickly that indicates that they collectively pose similar threats to human health and the environment, often at exceedingly low doses.[1] These 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.[4-9]

Vermont Public Water System Occurrence Data

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 detectible 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.[10] And in 2017, 40 new subclasses of PFAS were identified in aqueous film forming foam (AFFF) and AFFF-impacted groundwater.[11]

Most recently, new PFAS (chloroperfluoropolyether carboxylates) were identified around fluorochemical production facilities.[12] Importantly, these chemicals were also found up to 400 km away from the production source, indicating widespread airborne transport.[12] Therefore the potential exists for widespread contamination from fluorochemical use and production facilities beyond Vermont's border. None of these chemicals are included in US EPA Methods 537.1 or 533, however, these chemicals should not be assumed to be harmless. On the contrary, given the presence of carbon-fluorine bonds, these chemicals, at a minimum, are extremely persistent.

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.

Vermont has already taken important first steps to regulate PFAS as a class by enacting a combined MCL for 5 PFAS in drinking water. We appreciate this opportunity to respond directly to the questions examined by the Review Team. However, as detailed below, we disagree with the conclusion that it is currently not feasible to regulate PFAS as a class beyond the 5 PFAS presently regulated in the combined MCL. Following our response to the questions posed in the Advanced Notice on the Regulation of PFAS as Class, we provide options, organized by level of public health protection conferred, that ANR should consider for implementing and improving a class based approach to PFAS regulation.

Table 1. PFAS Summary

Acronym	Chemical Abstract Services Registry Number (CASRN)	Monitored in NHANES	Detected in Vermont Public Water Supplies	Detected in Other Environmental Media in Vermont	PFAS Currently Regulated in Vermont	Existing Federal Risk Assessment	Existing State Drinking or Ground Water Risk Assesment	20 PFAS on European List	Measured with EPA Method 537.1	Measured with EPA Method 533
PFBA	375-22-4			yes		EPA review in progress	yes	yes		yes
PFPeA	2706-90-3			yes			yes	yes		yes
PFHxA	307-24-4		yes	yes		EPA review in progress	yes	yes	yes	yes
PFHpA	375-85-9	yes	yes	yes	yes		yes	yes	yes	yes
PFOA	335-67-1	yes	yes	yes	yes	yes	yes	yes	yes	yes
PFNA	375-95-1	yes	yes	yes	yes	yes	yes	yes	yes	yes
PFDA	335-76-2	yes		yes		EPA review in progress	yes	yes	yes	yes
PFUnA	2058-94-8	yes		yes			yes	yes	yes	yes
PFDoA	307-55-1	yes		yes			yes	yes	yes	yes
PFTA	376-06-7			yes			yes	yes	yes	
PFTrDA	72629-94-8			yes			yes		yes	
PFBS	375-73-5	yes	yes	yes		yes	yes	yes	yes	yes
PFPeS	2706-91-4			yes				yes		yes
PFHxS	355-46-4	yes	yes	yes	yes	yes	yes	yes	yes	yes
PFHpS	375-92-8			yes				yes		yes
PFOS	1763-23-1	yes	yes	yes	yes	yes	yes	yes	yes	yes
PFNS	68259-12-1			yes				yes		
PFDS	335-77-3			yes			yes	yes		
PFUnS								yes		
PFDoS				yes				yes		
PFTS								yes		
PFOSA	754-91-6	yes		yes			yes			
HFPO-DA (GenX)	13252-13-6		yes			yes	yes		yes	yes
ADONA	919005-14-4								yes	yes
NEtFOSAA	2991-50-6	yes	yes	yes					yes	
NMeFOSAA	2355-31-9	yes	yes	yes					yes	
11Cl-PF3OUdS	763051-92-9								yes	yes
9Cl-PF3ONS	756426-58-1								yes	yes
4:2FTS	757124-72-4			yes						yes
6:2FTS	27619-97-2			yes						yes
8:2FTS	39108-34-4			yes						yes
PFEESA	113507-82-7									yes
NFDHA	151772-58-6									yes
PFMBA	863090-89-5									yes
PFMPA	377-73-1									yes
Total PFAS Evaluated/Identified		**12**	**10**	**25**	**5**	**6**	**17**	**20**	**18**	**25**

Table 2. Organic fluorine measurements in drinking water from five Massachusetts locations (ng/L or parts per trillion)

location:	**MA1**		**MA2**		**MA3**		**MA4**		**MA5**	
year:	**1989 1990**	**2016**	**1989 1990**	**2016**	**1989 1990**	**2016**	**1989 1990**	**2016**	**1989 1990**	**2016**
PFOA	0.2	6.2	0.5	1.7	0.9	4.8	0.6	0.9	1.3	0.9
PFOS	0.4	1.6	0.4	0.8	1.2	4.2	0.5	0.3	0.6	0.3
Other PFCAs	0.1	7.4	0.8	4.2	1.3	9.6	0.6	1.7	0	5.1
Other PFSAs	0.3	4.3	0.3	1.7	1.5	5.6	0.2	0.7	0.4	0.1
PFOS precursors	0	0	0.3	0	0	0	0	0	0	0
Un-identifiable organofluorines	6.7	135.6	19.8	105.2	2.9	39.4	0.2	58.5	5.4	9.6
Total Extractable Organic Fluorine	7.7	155.1	22.1	113.6	7.8	63.6	2.1	62.1	7.7	16
Percent of total fluorine that is unidentified chemicals	**87%**	**87%**	**90%**	**93%**	**37%**	**62%**	**10%**	**94%**	**70%**	**60%**

Source: Hu et al. 2019[13]

Response to the questions examined by the Review Team:

1. Does data exist to support regulating PFAS as a class in the same manner that other constituents are regulated as a class?

PFAS present a unique public health crisis and should be approached in a manner that best protects public health. **Regulation of PFAS, and the resulting health protections, should not depend on the ability to act on them in the exact manner other chemicals have been regulated.** Action on PFAS as a class is supported by the scientific community, which has provided scientific justification for why a class-based approach is appropriate and necessary for PFAS:

- Helsingor Statement[4]

  This scientific statement discusses the transition from long-chain PFASs to fluorinated alternatives. It summarizes key concerns about the potential impacts of fluorinated alternatives on human health and the environment including, "amongst others, the likelihood of fluorinated alternatives or their transformation products becoming ubiquitously present in the global environment; the need for more information on uses, properties and effects of fluorinated alternatives; the formation of persistent terminal transformation products including PFCAs and PFSAs; increasing environmental and human exposure and potential of adverse effects as a consequence of the high ultimate persistence and increasing usage of fluorinated alternatives; the high societal costs that would be caused if the uses, environmental fate, and adverse effects of fluorinated alternatives had to be investigated by publicly funded research; and the lack of consideration of non-persistent alternatives to long-chain PFASs."

- Madrid Statement[5]

  This scientific consensus statement from over 200 scientists and experts documents their concern over the persistence and potential for harm of PFAS, and calls on the international community to "cooperate in limiting the production and use of PFASs and in developing safer non-fluorinated alternatives." The statement then provides a list of suggested actions for various stakeholders to prevent further harm.

- Zurich Statement[6]

  This scientific statement documents an action plan for the assessment and management of PFAS developed by a group of more than 50 international scientists and regulators in a two-day workshop in November, 2017. The group identified respective needs, common goals, and recommended cooperative actions including, among others, a grouping approach to addressing PFAS, new approaches to assessing and managing highly persistent chemicals such as PFAS, a phase out of nonessential uses of PFAS and development of safer alternatives.

- Cousins et al. 2019[7]

  This article builds on the Madrid Statement and the Montreal Protocol to chart a path forward to phase out all non-essential uses of PFAS. The authors describe three categories essentiality:

  Category 1: "Non-essential" Uses that are not essential for health and safety, and the functioning of society. The use of substances is driven primarily by market opportunity.

  Category 2: "Substitutable" Uses that have come to be regarded as essential because they perform important functions, but where alternatives to the substances have now been developed that have equivalent functionality and adequate performance, which makes those uses of the substances no longer essential.

  Category 3: "Essential" Uses considered essential because they are necessary for health or safety or other highly important purposes and for which alternatives are not yet established.

The authors conclude that category 1 and 2 should be phased out as quickly as possible. For category 3, authors note that, "this essentiality should not be considered as permanent; rather, constant efforts are needed to search for alternatives."

- Cousins et al. 2020[8]

  According to authors of this article, "Given the number of substitutions of long-chain PFAAs with other PFAS that are now also considered to be problematic, there is a need for more effective grouping strategies for the regulation of PFAS than the current approach of regulating only long-chain PFAAs and related substances." This article 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). The extent that these approaches are already in use in regulatory contexts throughout the world is discussed. There are data requirements and limitations to implementing each grouping approach, yet interestingly, the most comprehensive grouping requires the least amount of data *a priori*.

- Kwiatkowski et al. 2020[9]

  This article presents a scientific basis for managing PFAS as one chemical class.The basis for the class approach is presented in relation to their physicochemical, environmental, and toxicological properties. Specifically, the high persistence, accumulation potential, and/or hazards (known and potential) of PFAS studied to date warrant treating all PFAS as a single class. Options are also provided for how governments and industry can apply the class-based approach moving forward. The authors conclude, "Without effective risk management action around the entire class of PFAS, these chemicals will continue to accumulate and cause harm to human health and ecosystems for generations to come. As demonstrated above, managing PFAS as a class is scientifically sound, will provide business innovation opportunities, and will help protect our health and environment now and in the future."

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.

2. Are other jurisdictions regulating PFAS as a class or subclass?

The Review Team reports that no guidance exists for regulation of PFAS as a class. However, in addition to the scientific guidance as detailed in the above resources provided in response to the Review Team's first question, there are other jurisdictions that are or are proposing to regulate PFAS as a class or as subclasses, detailed below.

The EU Drinking Water Directive[14, 15] was not mentioned by the Review Team. In October 2020, the EU Council adopted a proposal for the EU's Drinking Water Directive that 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 monitoring method for total PFAS, which within five years should be enforceable at the level of 500 ppt. The family approach (total PFAS) will be an additional alternative to the list approach (sum of 20 PFAS), as soon as the total PFAS monitoring method becomes available.[15] The EU is currently performing a pilot study to develop technical guidelines for monitoring total PFAS. In general, EU member countries are free to adopt stricter regulations than the EU's minimum standards, if the regulations are health-based. Therefore, it is expected that these total PFAS limits will be used in conjunction with stricter individual or combined PFAS limits set by member countries. For example, the European Food Safety Agency has performed a risk assessment for four PFAS and derived a group tolerable weekly intake for the four that would convert to a much stricter drinking water standard than 100 ppt.[16]

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:

- 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;
- address PFAS with a group approach, under relevant legislation on water, sustainable products, food, industrial emissions, and waste;
- address PFAS concerns on a global scale through the relevant international fora and in bilateral policy dialogues with third countries;
- 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;
- provide research and innovation funding for safe innovations to substitute PFAS under Horizon Europe."[18]

The National Institute for Public Health and the Environment in the Netherlands (RIVM) derived a relative potency factor approach for 19 PFAAs, including PFOA and PFOS.[19] In this approach the exposure to a PFAS mixture is expressed as a comparable amount of PFOA. RIVM states, "Measured PFAS quantities are simply expressed in PFOA units, so that they can be compared with PFOA standards for soil or (drinking) water.[19]" The relative potency approach developed by RIVM is based on liver hypertrophy, for which data is available for at least 11 PFAS. One advantage of this approach is that it can allow regulators to translate environmental standards developed for PFOA and PFOS to other PFAS compounds, including matrices other than drinking water.[19] Another benefit is it allows for the consideration of the additive impact of exposure to multiple PFAS compounds.

Germany and Sweden proposed and the EU adopted a restriction under REACH (a 2006 European regulation that addresses the registration and production of chemical substances) to cover six PFAS (C9-C14 PFCAs) and any substance that can degrade into one of the six.[20] The European Chemicals Agency lists over 500 PFAS precursors that fall under this restriction. Though this particular regulation focuses specifically on PFAS use, it highlights a mechanism that has been adopted by a jurisdiction to group related PFAS, namely by their terminal breakdown products.

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]

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?

In the advanced notice the Review Team focused on evaluating whether or not existing analytical methods or grouping approaches could fit into traditional risk assessment and regulatory paradigms. **The nature of the PFAS problem Vermont and the world is facing cannot be sufficiently addressed with traditional regulatory approaches.** This is why PFAS experts from around the world are advocating for more aggressive, "out-of-the-box" approaches to managing PFAS as a class.

For each method evaluated by the Review Team, the scientific support, analytical issues and regulatory issues were highlighted. It appears that the Review Team was looking for a one-size fits all solution to regulating PFAS as a class across many varied types of environmental media. The Review Team stated, "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 should not, however, be looking for a one-size fits all approach to regulating PFAS as a class.** It is not expected that a single regulatory decision or approach should be made to regulate all PFAS across all types of media and waste streams. On the contrary, it is likely that different approaches will be needed to regulate PFAS in different matrices and media. For example, approaches for remediating existing PFAS will necessarily be different from efforts to prevent future environmental releases, as evidenced by the multiple approaches the EU is taking to address PFAS as a class.

Looking for a solution across all media streams that fits into traditional, data intensive regulatory paradigms will paralyze ANR for an indefinite amount of time. **Delaying regulations until a single approach that does not have limitations is developed denies health protections to Vermont residents.** As there are available treatment methods to remediate PFAS from drinking water and groundwater, and

drinking water becomes the main source of PFAS exposure for the community when a community's water is contaminated with PFAS, a logical place to begin is with regulating PFAS as a class in drinking water and groundwater.

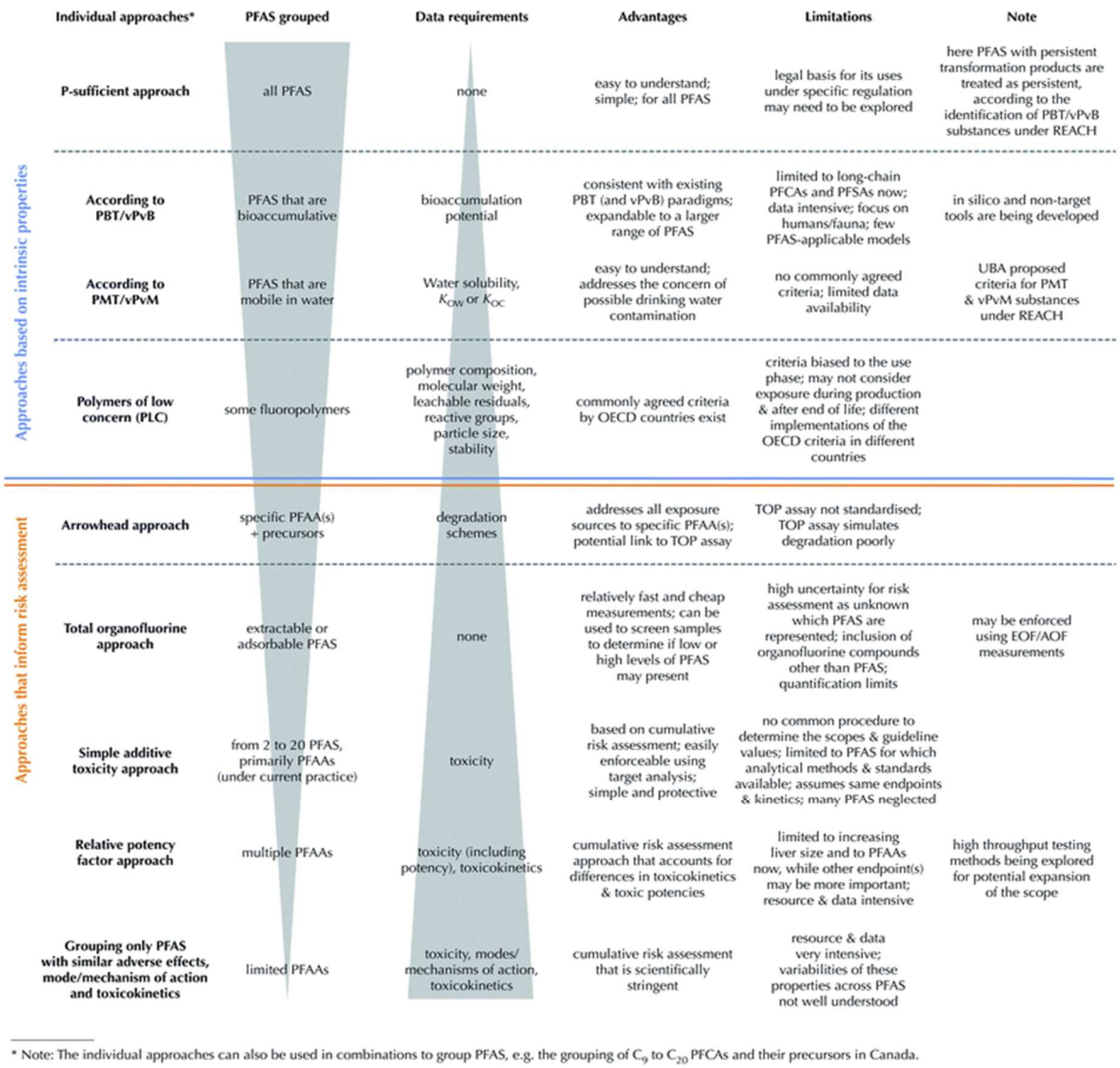
ANR has broad authority to regulate unsafe chemicals in drinking water.[22] Pursuant to 10 V.S.A. § 1672, the Secretary "shall regulate" drinking water "to prevent and minimize public health hazards."[22] The Secretary may adopt a Health Advisory Level set by the Vermont Department of Health as an MCL 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.[22, 23] In addition, ANR has the authority to adopt a treatment technique drinking water standard for PFAS.[22] "A treatment technique is an enforceable procedure or level of technological performance which public water systems must follow to ensure control of a contaminant."[24] Therefore ANR has the authority to regulate PFAS as a class, and the legislature has directed ANR to initiate a rulemaking process to regulate PFAS as a class or subclasses.

Options for Class Management in Drinking Water and Groundwater: A Tiered Approach

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.

Figure. Grouping Approaches for PFAS



	Individual approaches*	PFAS grouped	Data requirements	Advantages	Limitations	Note
Approaches based on intrinsic properties	**P-sufficient approach**	all PFAS	none	easy to understand; simple; for all PFAS	legal basis for its uses under specific regulation may need to be explored	here PFAS with persistent transformation products are treated as persistent, according to the identification of PBT/vPvB substances under REACH
	According to PBT/vPvB	PFAS that are bioaccumulative	bioaccumulation potential	consistent with existing PBT (and vPvB) paradigms; expandable to a larger range of PFAS	limited to long-chain PFCAs and PFSAs now; data intensive; focus on humans/fauna; few PFAS-applicable models	in silico and non-target tools are being developed
	According to PMT/vPvM	PFAS that are mobile in water	Water solubility, K_{OW} or K_{OC}	easy to understand; addresses the concern of possible drinking water contamination	no commonly agreed criteria; limited data availability	UBA proposed criteria for PMT & vPvM substances under REACH
	Polymers of low concern (PLC)	some fluoropolymers	polymer composition, molecular weight, leachable residuals, reactive groups, particle size, stability	commonly agreed criteria by OECD countries exist	criteria biased to the use phase; may not consider exposure during production & after end of life; different implementations of the OECD criteria in different countries	
Approaches that inform risk assessment	**Arrowhead approach**	specific PFAA(s) + precursors	degradation schemes	addresses all exposure sources to specific PFAA(s); potential link to TOP assay	TOP assay not standardised; TOP assay simulates degradation poorly	
	Total organofluorine approach	extractable or adsorbable PFAS	none	relatively fast and cheap measurements; can be used to screen samples to determine if low or high levels of PFAS may present	high uncertainty for risk assessment as unknown which PFAS are represented; inclusion of organofluorine compounds other than PFAS; quantification limits	may be enforced using EOF/AOF measurements
	Simple additive toxicity approach	from 2 to 20 PFAS, primarily PFAAs (under current practice)	toxicity	based on cumulative risk assessment; easily enforceable using target analysis; simple and protective	no common procedure to determine the scopes & guideline values; limited to PFAS for which analytical methods & standards available; assumes same endpoints & kinetics; many PFAS neglected	
	Relative potency factor approach	multiple PFAAs	toxicity (including potency), toxicokinetics	cumulative risk assessment approach that accounts for differences in toxicokinetics & toxic potencies	limited to increasing liver size and to PFAAs now, while other endpoint(s) may be more important; resource & data intensive	high throughput testing methods being explored for potential expansion of the scope
	Grouping only PFAS with similar adverse effects, mode/mechanism of action and toxicokinetics	limited PFAAs	toxicity, modes/ mechanisms of action, toxicokinetics	cumulative risk assessment that is scientifically stringent	resource & data very intensive; variabilities of these properties across PFAS not well understood	

* Note: The individual approaches can also be used in combinations to group PFAS, e.g. the grouping of C_9 to C_{20} PFCAs and their precursors in Canada.

Source: Cousins et al., 2020[8]

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.[25] In 2019, a group of PFAS experts demonstrated that "if a chemical is highly persistent, its continuous release will lead to continuously increasing contamination irrespective of the chemical's physical–chemical properties." They argue that, "increasing concentrations will result in increasing probabilities of the occurrence of known and unknown effects and that, once adverse effects are identified, it will take decades, centuries or even longer to reverse contamination and therefore effects." Based on their findings they propose the "P-sufficient approach" - that high persistence alone is sufficient to regulate a chemical or group of chemicals. They note that the "P-sufficient approach" is not over-precautionary given the historical and ongoing problems that have been caused by persistent chemicals to date.

For the same reasons outlined by Cousins et al., (2019), the European Commission held a sub-study within its 7th EAP (Study for the Strategy for a Non-toxic Environment) to investigate the case for regulating substances solely on the basis of their persistence in the environment.[26] The sub-study concludes that, "in the context of an increasingly resource-constrained world, preserving the usefulness of essential natural and material resources and ecosystem services is important. From the standpoint of public health, environmental protection and economic growth, it thus appears desirable to take a precautionary, hazard-based approach and to prevent and/or minimize all releases of vP [very persistent] chemicals in the future."[26]

Experts agree that PFAS should be regulated as a class in order to protect public health.[9] 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.[8] 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.[7] **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.

Prong 1:

There are several methods to determine the amount of TOF compounds in environmental media. Commercial laboratories like Eurofins and Bureau Veritas offer TOF by CIC with detection limits in the low (single digit) part per billion range.[27, 28] Commercially validated methods are already available in Australia and Europe.[29, 30] 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. The recast of the EU drinking water directive already calls for regulation of Total PFAS at 500 ppt. The EU will be performing a pilot study to develop and validate a specific testing method that can support this regulatory goal. **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.**

In the advanced notice, the Review Team explored the pros and cons of using TOF (listed as Adsorbable Organic Fluorine (AOF) and Extractable Organic Fluorine (EOF)). In doing so the Review Team seemed to evaluate whether or not TOF is a suitable one-size-fits-all solution to regulating PFAS across all matrices. Here we address the concerns raised by the Review Team for the use of TOF, but specifically in regards to its use in drinking water and ground water as described above.

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. If 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 standard[34], or once published the EPA or EU standard.

Prong 2:

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.**

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.

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.

537-M methods have been developed by various labs for the targeted analysis of PFAS in potable, non-potable and solid matrices, including those compounds identified with US EPA Methods 537.1 and 533 and more. Because these are user defined methods, there is not a standard method and there is a possibility that methods would vary from lab to lab. However, the Department of Defense (DoD) relies upon these user defined methods for testing of non-potable water and solid matrices at military sites. In order to ensure consistent and comparable data are being generated across program labs, the DoD established quality assurance criteria for PFAS in Table B-15 of the DoD QSM (Quality Systems Manual).[37] With the lack of federal standards, these criteria are generally considered the gold standard. Several labs across the country are certified by DoD to meet these criteria. Because of its acceptance and use by DOD, several states (CA, NH, and CO) are already using 537-M in compliance with DoD criteria. An added benefit of using this approach is that any data collected is consistent and comparable with data collected by DoD.

537-M methods are capable of reliably quantifying more individual PFAS than either US EPA verified drinking water method alone or in combination. Furthermore, they have the added advantage of being able to analyze PFAS in both US EPA Methods 537.1 and 533 with the same test, reducing the costs required to analyze these PFAS by approximately half. Eurofins, along with several other labs, can reliably quantify up to 40 PFAS using the 537-M following DoD criteria. In addition, 537-M methods are appropriate for use across a wide range of matrices beyond drinking water (including in groundwater, soil, sludge, leachate, and biosolids).

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.**

The approach that we have outlined here is the most cost effective and health protective approach for regulating PFAS as a class in the long term. A socioeconomic analysis of environmental and health impacts linked to exposure to just a subgroup of PFAS (C4-14 non-polymer fluorosurfactants) demonstrated that the cost of inaction on these PFAS is greater than the cost of remediating PFAS-contaminated water.[38] The potential long-lasting harm the full class could have on public health and the environment is likely far greater. Furthermore, the more piece-meal PFAS regulations are, the greater

potential for increased cost and resource requirements. For example, the current trend suggests that there will be a continual need to set new regulations as more and more PFAS are demonstrated to put the public at risk. There is also the likelihood of water systems investing in treatment technology that will not be sufficient for regulations set in the future (e.g. some treatment technologies are not well suited for capturing short-chain PFAS). As we have stated previously, PFAS pose a unique and serious problem; thus, novel approaches are urgently needed for addressing PFAS exposures.

Approach 2: Regulate Specific Subclasses of PFAS Based on Intrinsic Properties or Technical Capabilities

Several different subclass-based options for regulating PFAS have been proposed or put in place, as outlined above, many of which the Review Team did not cover in its analysis. Please refer to Cousins et al., (2020) and the other resources provided in these comments for further details.[8] Although subclass-based approaches are not as health protective as Approach 1, they will provide greater health protections than Vermont's current health advisory.

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.

"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.

"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."

- This is assuming that subclasses are based on biological potency. There are other grouping opportunities available as discussed in Cousins et al. (2020).[8]
- The fact that regular review is required for this approach should not be used as justification for delaying putting in place necessary health protections. To the contrary, in order to meet its mandate to protect the public from dangerous chemicals in drinking water, the Agency and Department of Health should be expected to regularly review and revise standards to keep pace with new scientific and technical information.

"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. [19]

"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.

Regulating PFAS based on subclasses is an alternative, more health protective, approach than currently used by ANR. However, the possibilities of applying these methods were not fully and adequately explored by the Review Team.

Approach 3: At Minimum, Expand Currently Utilized Additive Approach

At the very minimum, ANR should expand the number of PFAS included in its combined drinking water and ground water standard for PFAS. It is important that the combined standard include all PFAS that are currently reliably quantified and should be set at the most health protective level currently achievable given current technical limitations. The merits of US EPA Methods 537.1 and 533 and 537-M methods are described in Approach 1, Prong 2, above; as outlined, 537-M following DoD criteria is preferable to 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. Furthermore, the risk assessment used by ANR to establish its 20 ppt combined standard is outdated and does not reflect the MCLG of zero set by ANR and the more recent science and analyses that show the need for a significantly stricter standard.

In 2016 ANR set an enforceable drinking water health advisory for PFOA and PFOS based on available toxicity data and risk assessments for each chemical (EPA derived Reference Dose for PFOA and PFOS with infant drinking water exposure parameters). In 2018, ANR added PFHpA, PFNA, and PFHxS to this standard based on similarity to PFOA and PFOS, stating that these three additional PFAS met the criteria outlined by Vermont Department of Health.[39] The Vermont Department of Health provides the following guidance for grouping chemicals when no toxicity values are available:

"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.

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, NEtFOSAA, 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, NEtFOSAA, 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).[1, 40]

Table 3. Summary of ATSDR's Findings on Health Effects from PFAS Exposure

	Immune e.g. decreased antibody response, decreased response to vaccines, increased risk of asthma diagnosis	Developmental & Reproductive e.g. pregnancy-induced hypertension/pre-eclampsia, decreased fertility, small decreases in birth weight, developmental toxicity	Lipids e.g. increases in serum lipids, particularly total cholesterol and low-density lipoprotein	Liver e.g. increases in serum enzymes and decreases in serum bilirubin levels	Endocrine e.g. increased risk of thyroid disease, endocrine disruption	Body Weight e.g. decreased body weight	Blood e.g. decreased red blood cell count, decreased hemoglobin and hematocrit levels
PFOA	x	x	x	x	x	x	x
PFOS	x	x	x	x	x	x	x
PFHxS	x	x		x	x		x
PFNA	x	x	x	x	x	x	
PFDeA	x	x	x	x	x	x	
PFDoA	x	x		x		x	
PFUA	x	x		x		x	x
PFHxA		x		x			x
PFBA		x		x	x		x
PFBS				x			x

This table summarizes ATSDR's findings on the associations between PFAS exposure and health outcomes in human and animal studies (not an exhaustive list of health outcomes, includes both "serious" and "less serious" effects, as defined by ATSDR). Note x's in black represent PFAS for which ATSDR considers their liver effects to be specific to animals.

EPA has published health assessments for HFPODA (GenX) and PFBS, highlighting their similarity to PFOA, PFOS, and other PFAS, and is in the process of conducting similar reviews on PFBA, PFHxA, and PFDA. Further, there exists a growing body of evidence for these PFAS.[41, 42] We and others are working to build an online, interactive, database of the existing health and

toxicological data for 29 PFAS of emerging concern.[43] Though the process is ongoing, we have identified numerous human epidemiological, experimental animal, and mechanistic and/or in vitro studies for the majority of PFAS included in US EPA Method 537.1, indicating the presence of more than "limited data."

For example, though our analyses based on literature searches conducted in PubMed in May 2019 are still ongoing, we have already identified at least:

- 232 studies on PFDA (detected in Vermont's leachate/sludge)
- 124 studies on PFUnA (detected in Vermont's leachate/sludge)
- 91 studies on PFDoA (detected in Vermont's leachate/sludge)
- 73 studies on PFBS (detected in Vermont's water and leachate/sludge)
- 47 studies on PFHxA (detected in Vermont's water and leachate/sludge)
- 38 studies on PFTrDA (detected in Vermont's leachate/sludge)
- 35 studies on PFBA (detected in Vermont's leachate/sludge)
- 28 studies on PFTA (detected in Vermont's leachate/sludge)
- 19 studies on PFHpS (detected in Vermont's leachate/sludge)
- 12 studies on NMeFOSAA (detected in Vermont's water and leachate/sludge)
- 9 studies on NEtFOSAA (detected in Vermont's water and leachate/sludge)
- 8 studies on HFPODA (GenX; detected in Vermont's water)
- 3 studies on 6:2 FTSA (detected in Vermont's leachate/sludge)
- 2 studies on ADONA

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.

"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."

- The fact that regular review is required for this approach or that regulated entities could incur costs should not be used as justification for delaying putting in place necessary health protections. To the contrary, in order to meet its mandate to protect the public from dangerous chemicals in drinking water, ANR and the Department of Health should regularly review and revise standards to keep pace with new scientific and technical information. In addition, it is not

appropriate for ANR to delay rules due to the economic impacts to public water supply operators. Further, the Review Team did not include discussion of the significant avoided costs and benefits associated with removing additional PFAS from drinking water.

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 537.1of 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.[16, 40, 44-46]

It should be noted that using US EPA method 533 or 537-M methods that incorporate more PFAS will provide greater health protections to Vermont residents. 537-M methods have the added advantage of being able to analyze PFAS in both US EPA Methods 537.1 and 533 with the same test, reducing the costs required to cover these PFAS by approximately half. **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.**

Furthermore, as noted before, ANR has already set a MCLG of zero for the 5 PFAS currently under regulation. A MCL should be set as close to the MCLG as technically feasible, yet Vermont's current standard is set at 20 ppt, above what is achievable both in terms of monitoring and treatment capabilities. **Any standard set by ANR must be set at the most health protective level currently achievable given current technical limitations.** Finally, for all of these approaches, ANR should review these rules every two years and revise drinking water protections for PFAS to ensure standards reflect the latest scientific and technical information.

Conclusions

The current approach of only regulating individual PFAS or small groups of PFAS is the most resource intensive and least health protective. Under the current chemical-by-chemical approach, the amount of data needed to sufficiently regulate all individual PFAS is overwhelming, and for each PFAS includes several animal studies conducted for various lengths of time in multiple species and is exceedingly expensive and subject to factors beyond the control of the state agency. Yet the science shows that we must act now to protect public health, and Vermont's legislature has requested the state find a way forward to regulate PFAS as a class. We have provided many options for ways in which to do so.

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.

The environmental and public health threat of PFAS contamination and exposure is growing. Waiting until the perfect solution is available unnecessarily delays needed safeguards to protect public health. As NAS stated in its 2009 report *Science and Decisions:* "The design of a risk-assessment process should balance the pursuit of individual attributes of technical quality in the assessment and the competing attribute of timeliness of input into decision-making."[47] Decisions delayed are health protections denied. We urge ANR to move quickly to consider and incorporate our recommendations, so that critical public health protections can be enacted in a timely manner.

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7. Cousins, I.T., et al., *The concept of essential use for determining when uses of PFASs can be phased out.* Environ Sci Process Impacts, 2019. doi: 10.1039/c9em00163h. PubMed PMID: 31204421.
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11. Barzen-Hanson, K.A., et al., *Discovery of 40 Classes of Per- and Polyfluoroalkyl Substances in Historical Aqueous Film-Forming Foams (AFFFs) and AFFF-Impacted Groundwater.* Environ Sci Technol, 2017. **51**(4): p. 2047-2057. doi: 10.1021/acs.est.6b05843. PubMed PMID: 28098989.
12. Washington, J.W., et al., *Nontargeted mass-spectral detection of chloroperfluoropolyether carboxylates in New Jersey soils.* Science, 2020. **368**(6495): p. 1103-1107. doi: 10.1126/science.aba7127. PubMed PMID: 32499438.
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15. EC. *Safe and clean drinking water: Council adopts strict minimum quality standards*. 2020. Last updated: October 23, 2020; Available from: https://www.consilium.europa.eu/en/press/press-releases/2020/10/23/safe-and-clean-drinking-water-council-adopts-strict-minimum-quality-standards/.
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19. Zeilmaker, M.J., et al. *Mixture exposure to PFAS: A Relative Potency Factor approach*. 2018 National Institute for Public Health and the EnvironmentRIVM Report 2018-0070. Available from: https://www.rivm.nl/bibliotheek/rapporten/2018-0070.pdf.
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21. Associated Press. *Wisconsin officials offer water quality standards for PFAS*. Associated Press 2020 November 6; Available from: https://apnews.com/article/water-quality-wisconsin-archive-d86bbc23f26bf27bb17a1e31dad7f873#:~:text=(AP)%20%E2%80%94%20Wisconsin%20health%20officials,dozen%20types%20of%20PFAS%20chemicals.&text=The%20chemicals%20have%20been%20used,foam%20and%20stain%2Dresistant%20sprays.
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32. Inoue, M., Y. Sumii, and N. Shibata, *Contribution of Organofluorine Compounds to Pharmaceuticals.* ACS Omega, 2020. **5**(19): p. 10633-10640. doi: 10.1021/acsomega.0c00830. PubMed PMID: 32455181.
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40. NRDC. *Scientific and Policy Assessment for Addressing Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water*. 2019. p. 105. Available from: https://www.nrdc.org/sites/default/files/assessment-for-addressing-pfas-chemicals-in-michigan-drinking-water.pdf.
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42. US EPA. *Systematic Review Protocol for the PFAS IRIS Assessments*. 2019 US Environmental Protection Agency: Washington DCEPA/635/R-19/050. Available from: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=345065.
43. Pelch, K.E., et al., *PFAS health effects database: Protocol for a systematic evidence map.* Environ Int, 2019. **130**: p. 104851. doi: 10.1016/j.envint.2019.05.045. PubMed PMID: 31284092.
44. Birnbaum, L., Testimony before the Senate Committee on Environment and Public Works Hearing on “Examining the Federal response to the risks associated with per- and polyfluoroalkyl substances (PFAS)”. 2019.
45. Grandjean, P. and E. Budtz-Jorgensen, *Immunotoxicity of perfluorinated alkylates: calculation of benchmark doses based on serum concentrations in children.* Environ Health, 2013. **12**(1): p. 35. doi: 10.1186/1476-069X-12-35. PubMed PMID: 23597293.
46. CA OEHHA. *Notification level recommendations: Perfluorooctanoic acid and perfluorooctane sulfonate in drinking water*. 2019, Office of Environmental Health Hazard Assessment. p. 70. Available from: https://oehha.ca.gov/media/downloads/water/chemicals/nl/final-pfoa-pfosnl082119.pdf.
47. National Research Council, *Science and Decisions: Advancing Risk Assessment*. 2009, Washington, DC: The National Academies Press. 404.

Katherine E. Pelch, PhD

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ACADEMIC BACKGROUND

Education

PhD 2011 University of Missouri, Department of Biology (Developmental Toxicology)

BS 2005 University of Missouri, Department of Biology (Biology), Departmental Honors, General

Honors, and Magna Cum Laude

BS 2005 University of Missouri, Department of Chemistry (Medicinal Chemistry)

Appointments

2020 **Assistant Professor**, University of North Texas Health Science Center

2016-2019 **Senior Scientist**, The Endocrine Disruption Exchange

2012-2016 **Postdoctoral Fellow**, National Toxicology Program Laboratories, National Toxicology Program and Office of Health Assessment and Translation, National Institutes of Environmental Health Sciences, Research Triangle Park, NC

2006-2011 **Research Assistant**, University of Missouri

2005-2006 **Senior Research Laboratory Technician**, University of Missouri

2004-2004 **Undergraduate Laboratory Research Assistant**, University of Missouri

TEACHING

Courses Taught

Assistant Professor, University of North Texas Health Science Center, School of Public Health, Spring 2020 to present

- EOHS 5300 (in person: spring semester 2020; online summer and fall semester 2020). Environmental Determinants of Health I. A masters-level course on the environmental determinants that influence human health.
- EOHS 5313 (online: fall semester 2020). Topics in Global Food Security and Sustainability. A masters-level course exploring the complexities of global and local food systems.

Teaching and Mentoring Professional Development

Teaching Internship, Introductory Biology, University of Missouri, 2010

Preparing Future Faculty, University of Missouri, 2010

College Science Teaching, Division of Biological Sciences, University of Missouri, 2010

Entering Mentoring Workshop, University of Missouri, 2006

Guest Lectures & Invited Presentations

"Urgent evaluation of links between chlorpyrifos and autism development needed." The Health and Environment Alliance: webinar, 2019.

"Protecting Communities from Exposure to Harmful PFAS Chemicals: The Urgent Need for Safe Drinking Water Standards in the Absence of Federal Action." Alaska Collaborative on Health & the Environment: webinar, 2019.

"Endocrine Disruption: What Can You Do?" Invited guest lecture, The Evergreen State College, 2018.

"Is your trip to the store secretly harming marine wildlife?" Science and Cocktails: Lightning Talks: Seattle Aquarium, 2017.

"Endocrine Disruption in Plastics." Plastics Summit, 2017.

"The Endocrine Disruption Exchange." University of California – Los Angeles Toxics in Everyday Life Symposium, 2017.

"Systematic literature review of bisphenol A (BPA) structural and functional analogues." US Environmental Protection Agency Emerging Topics Forum, 2016.

"Developmental programming by xenoestrogens." US Environmental Protection Agency Endocrine Disrupting Contaminant Seminar, 2012.

"Real-time quantitative PCR and gene expression." University of Missouri Obstetrics, Gynecology and Women's Health Resident Research Conference, 2008.

Student Research Supervision

Supervised Undergraduate Students (co-author on presentation* or publication†)
University of Missouri (2005-2011)

Audrey Bailey*	Joseph Beeman†	Alison Ghormley†
Bridgett Niebruegee†	Emily Milford	Jake Redel*
Amy Schroder*†	Maija Steinberg*	Stacey Winkeler†

RESEARCH AND CREATIVE ACTIVITY

Peer Reviewed Publications

Kwiatkowski C, Andrews D, Birnbaum L, Bruton T, DeWitt J, Knappe D, Maffini M, Miller M, **Pelch KE**, Reade A, Soehl A, Trier X, Venier M, Wagner C, Wang Z, Blum A. 2021. Response to Comment on Scientific Basis for Managing PFAS as a Chemical Class. Environmental Science & Technology Letters. DOI: 10.1021/acs.estlett.1c00049.

Kwiatkowski C, Andrews D, Birnbaum L, Bruton T, DeWitt J, Knappe D, Maffini M, Miller M, **Pelch KE**, Reade A, Soehl A, Trier X, Venier M, Wagner C, Wang Z, Blum A. 2020. The Scientific Basis for Managing PFAS as a Chemical Class. Environmental Science & Technology Letters, 7(8). DOI: 10.1021/acs.estlett.0c00255.

Merrick BA, Phadke DP, Bostrom MA, Shah RR, Wright GM, Wang X, Gordon O, **Pelch KE**, Auerbach SS, Paules RS, DeVito MJ, Waalkes MP, Tokar EJ. 2020. KRAS-retroviral fusion transcripts and gene amplification in arsenic-transformed, human prostate CAsE-PE cancer cells. Toxicology and Applied Pharmacology, 397. DOI: 10.1016/j.taap.2020.115017.

Muncke J, Andersson A-M, Backhaus T, Boucher JM, Almroth BC, Castillo AC, Chevrier J, Demeneix BA, Emmanuel JA, Fini J-B, Gee D, Geueke B, Groh K, Heindel J, Houlihan J, Kassotis CD, Kwiatkowski C, Lefferts LL, Maffini MV, Martin OV, Myers JP, Nadal A, Nerin C, **Pelch KE**, Rojello Fernández S, Sargis RM, Soto AM, Trasande L, Vandenberg L, Wagner M, Wu C, Zoeller RT, Scheringer M. 2020. Impacts of food contact chemicals on human health: a scientific consensus statement. Environmental Health, 19(25). DOI: 10.1186/s12940-020-0572-5.

Akter S, Xu D, Nagel SC, Bromfield J, **Pelch KE**, Wilshire GB, Joshi T. 2019. Machine learning classifiers for endometriosis using transcriptomics and methylomics data. Frontiers in Genetics, 10(766). DOI: 10.3389/fgene.2019.00766.

Pelch KE, Li Y, Perera L, Thayer KA, Korach KS. 2019. Characterization of Estrogenic and Androgenic Activities for Bisphenol A-like chemicals (BPs): *In Vitro* Estrogen and Androgen Receptors Transcriptional Activation, Gene Regulation, and Binding Profiles. Toxicological Sciences. DOI: 10.1093/toxsci/kfz173.

Pelch KE, Reade A, Wolffe TAM, Kwiatkowski CF. 2019. PFAS Health Database: A Protocol for a Systematic Evidence Map. Environment International, 130. DOI: 10.1016/j.envint.2019.05.045.

Pelch KE, Wignall JA, Goldstone AE, Ross PK, Blain RB, Shapiro AJ, Holmgren SD, Hsieh J-H, Svoboda D, Auerbach SS, Parham FM, Masten SA, Walker VR, Rooney AA, Thayer KA. 2019. A scoping review of the health effects and toxicological activity of bisphenol A (BPA) structural analogues and functional alternatives. Toxicology, 424. DOI: 10.1016/j.tox.2019.06.006.

Merrick BA, Phadke DP, Bostrum MA, Shah RR, Wright GM, Wang X, **Pelch KE**, Waalkes MP, Auerbach SS; Paules RS, DeVito MJ, Tokar EJ. 2019. Arsenite malignantly transforms human prostate epithelial cells in vitro by gene amplification of mutated KRAS. PLoS ONE 14(4):e0215504. DOI: 10.1371/journal.pone.0215504.

Pelch KE, Bolden AL, Kwiatkowski CF. 2019. Environmental Chemicals and Autism: A Scoping Review of the Human and Animal Research. Environmental Health Perspectives, 127(4). DOI: 10.1289/EHP4386.

Bolden AL, Schultz K, **Pelch KE**, Kwiatkowski CF. 2018. Exploring the endocrine activity of air pollutants associated with unconventional oil and gas extraction. Environmental Health, 17(26). DOI: 0.1186/s12940-018-0368-z.

Walker VR, Boyles AL, **Pelch KE**, Holmgren SD, Shapiro AJ, Blystone CR, Devito MJ, Newbold RR, Blain R, Harman P, Thayer KA, Rooney AA. 2018. Human and animal evidence of potential transgenerational inheritance of health effects: An evidence map and state-of-the-science evaluation. Environment International, 115:48-69. DOI: 10.1016/j.envint.2017.12.032.

Li Y, Perera L, Coons LA, Burns K, Ramsey JT, **Pelch KE**, Houtman R, van Beuningen R, Teng CT, Korach KS. 2018. Differential in vitro biological action, coregulator interactions, and molecular dynamic analysis of bisphenol A (BPA), BPAF, and BPS ligand–ERα complexes. Environmental Health Perspectives, 126(1). DOI: 10.1289/EHP2505.

Rochester RR, Bolden A, **Pelch KE**, Kwiatkowski CF. 2017. Potential developmental and reproductive impacts of triclocarban (TCC): a scoping review. Journal of Toxicology, 2. DOI: 10.1155/2017/9679738.

Pelch KE, Wignall JA, Goldstone AE, Ross PK, Blain RB, Shapiro AJ, Holmgren SD, Hsieh J-H, Svoboda D, Auerbach SS, Parham FM, Masten SA, Thayer KA. 2017. NTP research report on biological activity of bisphenol A (BPA) structural analogues and functional alternatives. NTP RR4. Research Triangle Park, NC: National Toxicology Program. 4:1-78. DOI: 10.22427/NTP-RR-4

NTP (National Toxicology Program). 2016. Monograph on immunotoxicity associated with exposure to perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Research Triangle Park, NC: National Toxicology Program.

Howard BE, Phillips J, Miller K, Tandon A, Mav D, Shah MR, Holmgren S, **Pelch KE**, Walker V, Rooney AA, Macleod M, Shah RR, Thayer K. 2016. SWIFT-Review: a text-mining workbench for systematic review. Systematic Reviews, 5(87). DOI: 10.1186/s13643-016-0263-z.

Thayer KA, **Pelch KE,** Birnbaum LS, Bucher JR. 2015. Bisphenols: more unnecessary surprises. Endocrine Disruptors, 4(1):e1131032. DOI: 10.1080/23273747.2015.1131032.

Pelch KE, Tokar EJ, Merrick BA, Waalkes MP. 2015. Differential DNA methylation profile of key genes in malignant prostate epithelial cells transformed by inorganic arsenic or cadmium. Toxicology and Applied Pharmacology, 286:159-167. DOI: 10.1016/j.taap.2015.04.011.

Pelch KE, Sharpe-Timms KL, Nagel SC. 2012. Mouse model of surgically-induced endometriosis by auto-transplantation of uterine tissue: lesion characteristics. Journal of Visualized Experiments, 59. e3396. DOI: 10.379/3396.

Pelch KE, Carleton SM, Schroder AL, Phillips CL, Nagel SC. 2011. Developmental exposure to low dose xenoestrogens alters femur length and tensile strength in adult mice. Biology of Reproduction, 86(3):69. DOI: 10.1095/biolreprod.111.096545.

Syrcle SM, **Pelch KE,** Schroder AL, Nichols BM, Mills MP, Barrier BF, Havey AD, Nagel SC. 2011. Altered gene expression profile in vaginal polypoid endometriosis resembles peritoneal

endometriosis and is consistent with increased local estrogen production. Gynecologic and Obstetric Investigation, 71(2):77-86. DOI: 10.1159/000320736.

Pelch KE, Schroder AL, Kimball PA, Sharpe-Timms KL, Davis JW, Nagel SC. 2010. Aberrant gene expression profile in a mouse model of endometriosis mirrors that observed in women. Fertility and Sterility, 93(5):1615-1627. DOI: 10.1016/j.fertnstert.2009.03.086.

Schroder AL, **Pelch KE**, Nagel SC. 2009. Estrogen modulates the expression of putative house keeping genes in the mouse uterus. Endocrine, 35(2):211-219. DOI: 10.1007/s12020-009-9154-6.

Hajduch M, Casteel JE, **Hurrelmeyer KE**, Song Z, Agrawal GK, Thelen JJ. 2006. Proteomic analysis of seed filling in *Brassica napus*: Developmental characterization of metabolic isozymes using high-resolution two-dimensional gel electrophoresis. Plant Physiology, 141(1):32-46. DOI: 10.1104/pp.105.075390.

Scientific and Policy Reports, Comments and Resources

Technical comments on *Vermont Agency of Natural Resources: Advance Notice on the Regulation of Perfluoroalkyl, Polyfluoroalkyl Substances (PFAS) as a Class.* November 2020. (**lead co-author**)

Comments on *Washington Department of Health's Draft Recommended State Action Levels for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water: Approach, Methods and Supporting Information (Chapter 246-290 WAC)*. January 2019 (**lead co-author**)

Comments on *New Hampshire Department of Environmental Services Proposed Rulemaking to Set Public Drinking Water and Groundwater Standards for PFOA, PFOS, PFNA, & PFHxS (Env-Dw 700-800 and Env-Or 603.03)*. April 2019. (**lead author**)

Comments on the *U.S. Environmental Protection Agency's Draft Toxicity Assessments for Perfluorobutane Sulfonic Acid (PFBS) and Hexafluoropropylene Oxide Dimer Acid (GenX Chemicals), November 2018*. Joint comments by The Endocrine Disruption Exchange, Natural Resources Defense Council, Sierra Club, Environmental Working Group, and Center for Environmental Health, January 2019. (**lead co-author**)

Comments to New York Department of Health regarding setting public drinking water standards for PFOA and PFOS. November 2018. (**lead author**)

Comments on *New Hampshire Department of Environmental Services Stakeholder Input for Setting Public Drinking Water and Groundwater Standards for PFOA, PFOS, PFNA, & PFHxS*. November 2018. (**lead author**)

Protocol for a systematic map of the evidence of migrating and extractable chemicals from food contact articles. 2018. DOI: 10.5281/zenodo.2525277. (**contributor and expert reviewer**)

Comments on Washington State's *Safe Firefighting Foam Bill "Reducing the use of certain toxic chemicals in firefighting activities" (Senate Bill 6413).* January 2018. (**lead author**)

Comments on *Washington State's Healthy Food Packaging Bills (House Bill 2658 and Senate Bill 6396).* January 2018. (**lead author**)

Comments on *Washington State Department of Ecology Children's Safe Product Act (CSPA) rule (WAC 173-334).* May 2017. (**lead author**)

The Endocrine Disruption's *FrackHealth Database* of peer-reviewed literature on health effects associated with unconventional oil and gas drilling. 2017-2019. (**co-creator and contributor**)

The Endocrine Disruption Exchange's *List of Potential Endocrine Disruptors*. 2016-2019. (**contributor**)

The Endocrine Disruption Exchange's *Endocrine disruption fact sheet*. 2017. (**co-creator**)

Literature review of bisphenol A (BPA) analogues. Extended abstract submitted to the European Chemicals Agency (ECHA) in response to data call-in related to use of BPA in thermal paper. December 11, 2014. (**lead author**)

Book Chapters

Pelch KE, Niebrugee BA, Beeman JM, Winkeler SR, Nagel SC. 2010. Endocrine Disruption in Mammals. In Norris DO and Lopez KH (Ed.), *Hormones and Reproduction of Vertebrates – Volume 5 Mammals* (pp. 329-371). San Diego, CA: Elsevier Publishing.

Pelch KE, Allison JL, Nagel SC. 2011. Fetal Programming. In Winn H, Chervenak FA, Romero R (Ed.), *Maternal-Fetal Medicine, 2nd Edition* (pp. 45.1-45.15). New York: Informa Healthcare.

Presentations

"Database of PFAS Health and Toxicology Research." The Navigation Guide Workgroup: webinar 2020.

"Database of PFAS Health and Toxicology Research." The National PFAS Contamination Coalition: webinar 2020.

"Environmental influences on the epigenome: Using SWIFT text mining tool to explore the state of the science." National Toxicology Program's Board of Scientific Counselors Meeting, 2015.

"Using SWIFT text mining tool to explore the state of the science: environmental influences on the epigenome." National Toxicology Program's Concept Review Meeting, 2015.

"Using SWIFT text mining tool to explore the state of the science: environmental influences on the epigenome." NIEHS Data Science Interest Group Meeting, 2015.

"Upcoming *in vitro* and *in vivo* analyses of BPA analogues." NIEHS Intramural Research on Bisphenol A Analogues, 2015.

"Biological activity of BPA structural analogues and functional alternatives." NIEHS Intramural Research on Bisphenol A Analogues, 2015.

"Environmental influences on the epigenome: using SWIFT text mining tool to assess the current state of the science." NIEHS Cross-divisional Minisymposium on Epigenetics, 2015.

Scientific Meeting Abstracts

Akter S, Xu D, Nagel SC, Bromfield J, **Pelch KE**, Wilshire GB, Joshi T. GenomeForest: An Ensemble Machine Learning Classifier for Endometriosis. American Medical Informatics Association Summit, 2020.

Akter S, Xu D, Nagel SC, Bromfield J, **Pelch KE**, Wilshire GB, Joshi T. Machine Learning Classifier for Endometriosis Using Transcriptomics and Methylomics Data. International Society for Computational Biology, 2019.

Akter S, Xu D, Nagel SC, Bromfield J, **Pelch KE**, Wilshire GB, Joshi T. A machine learning approach for the prediction of endometriosis using multi-omics next generation sequencing data. BIO International Convention, 2019.

Merrick BA, Phadke D, Shah RR, **Pelch KE**, Auerbach SS, Paules RS, DeVito M, Waalkes MP, Tokar EJ. Oncogenic KRAS occurs after prolonged *in vitro* arsenite exposure of human prostate epithelial cells. Society of Toxicology's 58th Annual Meeting, 2019.

Akter S, Bromfield J, Pelch KE, Wilshire G, Crowder S, Schust D, Barrier B, Davis W, Nagel S, Joshi T. An Integrative Multi-Omics Diagnostic Predictive Model as a Biomarker of Endometriosis. BIO International Convention, 2018.

Pelch KE, Bolden AL, Kwiatkowski CF. 2018. Reviewing the Environmental Origins of Autism. Society of Toxicology's 57th Annual Meeting, 2018.

Waidyanatha S, Foster P, Gray L, Mcintyre B, Conley J, Sutherland V, **Pelch KE**. 2017. A comparison of the in vivo reproductive and developmental toxicity (DART) endpoints for bisphenol AF and bisphenol A. Society of Toxicology's 56th Annual Meeting, 2017.

Pelch KE, Li Y, Teng C, Thayer KA, Korach K. 2016. Characterization of estrogenic and anti-androgenic activity for 21 bisphenol A analogues *in vitro*. Gordon Research Conference on Environmental Endocrine Disruptors, 2016.

Pelch KE Wignall JA, Goldstone AE, Ross PK, Blain RB, Shapiro AJ, Holmgren SD, Hsieh J-H, Svoboda D, Auerbach SS, Parham FM, Masten SA, Thayer KA. 2016. Systematic review of bisphenol A (BPA) analogues and analysis of high throughput screening data. Gordon Research Seminar on Environmental Endocrine Disruptors, 2016. *oral presentation

Sutherland V, **Pelch KE**, McIntyre B, Conley JM, Gray LE, Hsieh JH, Truong RT, Lundby Z, Allard P, Foster PM. 2016. Bisphenol AF: correlation of in vitro endocrine responses with in vivo developmental outcomes (a case example). Society of Toxicology's 55th Annual Meeting, 2016.

Pelch KE, Li Y, Teng C, DeVito M, Thayer K, Korach K. 2015. Characterization of estrogenic activation for 21 bisphenol A analogues *in vitro*. National Institute of Environmental Health Sciences Science Day, 2015.

Walker VR, Holmgren S, **Pelch KE,** Howard B, Shah RR, Thayer KA, Rooney AA. 2015. Utilizing text-mining strategies to address challenges of a literature-based evaluation of transgenerational inheritance of health effects. Genetics and Environmental Mutagenesis Society, 2015.

Pelch KE, Walker VM, Hsieh JH, Auerbach SS, Svoboda D, DeVito M, Holmgren S, Tice R, Thayer KA. 2015. Systematic review of bisphenol A (BPA) analogues and analysis of high throughput screening data. Society of Toxicology's 54th Annual Meeting, 2015.

Walker VM, Holmgren S, **Pelch KE**, Howard B, Shah R, Thayer K, Rooney A. 2015. Problem formulation of complex environmental health questions: utilizing text mining to address challenges of a literature-based evaluation of transgenerational health effects. Society of Toxicology's 54th Annual Meeting, 2015.

Pelch KE, Auerbach SS, DeVito M, Holmgren S, Tice R, Thayer KA. 2014. Literature review of bisphenol A (BPA) analogues and analysis of high throughput screening data. National Institute of Environmental Health Sciences Science Day, 2014.

Pelch KE, Tokar EJ, Merrick BA, Waalkes MP. 2014. Differential DNA methylation in arsenic- or cadmium- transformed malignant prostate epithelial cells. Society of Toxicology's 53rd Annual Meeting, 2014.

Merrick BA, Tokar EJ, Phadke DP, Shah RR, Wang X, Bostrom MA, Gordon O, Wright GM, Burke M, **Pelch KE**, Auerbach SS, Tice RR Waalkes MP. 2014. Genome-wide DNA methylation changes influence gene expression in arsenic-transformed human prostate cells. Society of Toxicology's 53rd Annual Meeting, 2014.

Bromfield JJ, **Pelch KE**, Nagel SC. 2013. Perinatal exposure to low dose Bisphenol A (BPA) or diethylstilbestrol (DES) have similar and yet unique effects on adult gene expression in experimental endometriosis. University of Missouri Health Science Research Day, 2013.

Bromfield JJ, **Pelch KE**, Nagel SC. 2013. Gestational exposure to low dose BPA and DES alters endometrial gene expression in response to induced endometriosis and reduces the ovarian follicle reserve. Seventh Copenhagen Workshop on Endocrine Disruptors, 2013.

Merrick BA, Tokar EJ, Phadke, DP, Shah RR, Wang M, Gordon O, Wright GM, Burke M, Baxter SA, **Pelch KE**, Tice RR, Waalkes MP. 2013. Epigenetics of arsenic carcinogenesis and location of methylated DNA sites underlying gene expression changes. Society of Toxicology's 52nd Annual Meeting, 2013.

Pelch KE, Davis JW, Nagel SC. 2012. Developmental xenoestrogen exposure permanently programs expression of endometriosis related genes in a mouse model. Gordon Research Conference on Environmental Endocrine Disruptors, 2012.

Drobnis EZ, Nabli H, Sharpe-Timms KL, Schulz LC, Nagamatsu T, **Pelch KE**, Schlitt JM, Sherwood RS, Wright SG, Schust DJ. 2012. Establishment of an IUI program for HIV-discordant couples in the United States. American Association of Bioanalysts Annual Meeting and Educational Conference, 2012.

Pelch KE, Bailey AM, Kassotis CD, Lin R, Spearow JL, Nagel SC. 2011. Differential strain sensitivity to prepubertal xenoestrogen disruption. University of Missouri Health Sciences Research Day, 2011.

Pelch KE, Bailey AM, Kassotis CD, Lin R, Spearow JL, Nagel SC. 2011. Differential strain sensitivity to prepubertal xenoestrogen disruption. Society for the Study of Reproduction's 44th Annual Meeting, 2011.

Pelch KE, Carleton S, Schroder AL, Phillips C, Nagel SC. 2011. Developmental xenoestrogen exposure alters femur length and tensile strength in adulthood. University of Missouri Obstetrics, Gynecology and Women's Health David G. Hall Symposium, 2011. *oral presentation

Pelch KE, Carleton SM, Schroder AL, Phillips CL, Nagel SC. 2010. Developmental estrogen exposure alters femur length and tensile strength in mice in adulthood. Society for the Study of Reproduction's 43rd Annual Meeting: Milwaukee, WI, July 30-August 3, 2010.

Pelch KE, Schroder AL, Redel J, Ghormley A, Sharpe-Timms KL, Nagel SC. 2010. Developmental xenoestrogen exposure permanently programs cytokine gene expression in a mouse endometriosis model. University of Missouri Obstetrics, Gynecology and Women's Health David G. Hall Symposium 2010. *oral presentation

Pelch KE, Schroder AL, Nagel SC. 2010. Developmental xenoestrogen exposure permanently programs inflammatory cytokine gene expression in mouse endometriosis model. Gordon Research Conference on Environmental Endocrine Disruptors, 2010.

Pelch KE, Schroder AL, Sharpe-Timms KL, Nagel SC. 2010. Aberrant gene expression in a mouse model of endometriosis mirrors that in women. University of Missouri's Graduate Professional Council's Research and Creative Arts Forum, 2010. *oral presentation

Hurrelmeyer KE, Carleton S, Schroder AL, Phillips C, Nagel SC. 2008. Developmental exposure to DES alters bone geometry and biomechanical properties. University of Missouri Obstetrics, Gynecology and Women's Health Division Retreat, 2008. *oral presentation

Hurrelmeyer KE, Schroder AL, Kimball P, Niebruegee B, Beeman J, Ghormley A, Sharpe-Timms KL, Nagel SC. 2008. Aberrant gene expression in a mouse model of endometriosis mirrors that in women. University of Missouri Obstetrics, Gynecology and Women's Health David G. Hall Symposium, 2008. *oral presentation

Hurrelmeyer KE, Carleton SM, Schroder AL, Phillips CL, Nagel SC. 2008. Developmental exposure to DES alters bone geometry and biomechanical properties. Gordon Research Conference on Environmental Endocrine Disruptors, 2008.

Kimball PA, **Hurrelmeyer KE**, Schroder AL, Spearow JL, Nagel SC. 2008. Characterization of estrogen sensitivity in C57Bl6 and CD10 ERIN Mice. Gordon Research Conference on Environmental Endocrine Disruptors, 2008.

Schroder AL, **Hurrelmeyer KE**, Nagel SC. 2008. Estrogen regulation of common house keeping genes in the mouse uterus. Gordon Research Conference on Environmental Endocrine Disruptors, 2008.

Hurrelmeyer KE, Ghormley AL, Redel JM, Schroder AL, Steinberg ML, Sharpe-Timms KL,

Nagel SC. 2007. Developmental exposure to xenobiotic estrogens permanently programs expression of extracellular matrix and adhesion molecules in a mouse endometriosis model. Society for the Study of Reproduction's 40th Annual Meeting, 2007. *oral presentation

Hurrelmeyer KE, Ghormley AL, Redel JM, Schroder AL, Steinberg ML, Sharpe-Timms KL, Nagel SC. 2007. Developmental exposure to xenobiotic estrogens permanently programs expression of extracellular matrix and adhesion molecules in a mouse endometriosis model. University of Missouri Life Sciences Week, 2007.

Nagel SC, **Hurrelmeyer KE**, Sharpe-Timms KL, Schroder AL, Redel JM, Ghormley AL, Myears HE. 2007. Developmental exposure to DES permanently programs Timp-1 gene expression and exacerbates endometriosis in a mouse model. Society for Gynecologic Investigation, 2007.

Hurrelmeyer KE, Ghormley AL, Myears HE, Redel JM, Schroder AL, Sharpe-Timms KL, Nagel SC. 2006. Developmental exposure to DES permanently programs expression of endometriosis related genes in a mouse model. University of Missouri Health Science Research Day, 2006.

Hurrelmeyer KE, Ghormley AL, Sharpe-Timms KL, Nagel SC. 2006. Prenatal exposure to DES permanently programs expression of TIMP-1 in a mouse endometriosis model. Society for the Study of Reproduction's 39th Annual Meeting, 2006. *oral presentation

Hurrelmeyer KE, Ghormley AL, Nagel SC, Sharpe-Timms KL. 2006. Prenatal exposure to DES permanently programs expression of TIMP-1 in a mouse endometriosis model. Gordon Research Conference on Environmental Endocrine Disruptors, 2006.

Hurrelmeyer KE, Ghormley AL, Nagel SC, Sharpe-Timms KL. 2006. Prenatal exposure to DES permanently programs expression of TIMP-1 in a mouse endometriosis model. University of Missouri Life Sciences Week, 2006.

Ghormley AL, **Hurrelmeyer KE**, Sharpe-Timms KL, Nagel SC. Prenatal exposure to xenoestrogens and the development of endometriosis in adulthood. American Association for the Advancement of Science Annual Meeting, 2006.

Hajduch M, Casteel JE, **Hurrelmeyer KE**, Song Z, Agrawal GK, Thelen JJ. Proteomics of seed filling in oilseeds: a proteomics perspective on carbon assimilation in *Brassica napus*. International Plant & Animal Genomes XIV Conference, 2006.

Hajduch M, Casteel JE, **Hurrelmeyer KE**, Song Z, Agrawal GK, Thelen JJ. 2005. Integrated proteomics approach for analysis of *Brassica napus* seed filling - high protein identification rate with limited database resources. NSF-VBI-Noble Workshop, 2005.

Hurrelmeyer KE, Thelen JJ. Proteomics of integral membrane proteins from developing *Brassica napus.* University of Missouri Summer Undergraduate Research Conference, 2004.

Hurrelmeyer KE, Thelen JJ. Isolation and profiling of integral membrane proteins form developing *Brassica napus*. University of Missouri Undergraduate Research Conference, 2004.

AWARDS

Funded External Grant Proposals

Sigma Xi Grant in Aid of Research, 2010. Towards the development of a non-invasive

diagnostic test for endometriosis. $400. Katherine Pelch.

Funded Internal Fellowship

University of Missouri Clinical Biodetectives Training Grant (NIH T90), 2007-2010. Understanding the etiology of endometriosis. $42,000. Katherine Pelch and Susan Nagel.

Research Awards

3rd Place Postdoctoral Research Award for "Differential DNA methylation in arsenic- or cadmium- transformed malignant prostate epithelial cells" by Pelch KE, Tokar EJ, Merrick BA, Waalkes MP; Metals Specialty Section of the Society of Toxicology's 53rd Annual Meeting, 2014.

Larry Ewing Memorial Trainee Travel Award for "Differential strain sensitivity to prepubertal xenoestrogen disruption" by Pelch KE, Bailey AM, Kassotis CD, Lin R, Spearow JL, Nagel SC; Society for the Study of Reproduction Annual Meeting, 2011.

Larry Ewing Memorial Trainee Travel Fund, for "Developmental estrogen exposure alters femur length and tensile strength in mice in adulthood" by Pelch KE, Carleton SM, Schroder AL, Phillips CL, Nagel SC; Society for the Study of Reproduction Annual Meeting, 2010.

Research Presentation Award for "Developmental xenoestrogen exposure permanently programs cytokine gene expression in a mouse endometriosis model" by Pelch KE, Schroder AL, Redel J, Ghormley A, Sharpe-Timms KL, Nagel SC; David G. Hall Symposium University of Missouri, 2010.

Graduate Professional Council Travel Grant, for "Developmental xenoestrogen exposure permanently programs inflammatory cytokine gene expression in mouse endometriosis model" by Pelch KE, Schroder AL, Nagel SC; Gordon Research Conference on Environmental Endocrine Disruptors, 2010.

University of Missouri Biology Graduate Student Association Travel Grant for "Developmental exposure to xenobiotic estrogens permanently programs expression of extracellular matrix and adhesion molecules in a mouse endometriosis model" by Hurrelmeyer KE, Ghormley AL, Redel JM, Schroder AL, Steinberg ML, Sharpe-Timms KL, Nagel SC; Society for the Study of Reproduction Annual Meeting, 2007.

SERVICE

University and Professional Service

Member, HEEDS Mentoring Advising Work Group, 2018-present

Member, CHE EDC Strategies Partnership Webinars Planning Committee, 2018-2019

Co-chair, Gordon Research Symposium on Environmental Endocrine Disruptors, 2018

Coordinator, NIEHS Intramural Research on Bisphenol A Analogues Meeting, 2015

Rapporteur, Shift Work at Night, Artificial Light at Night, and Circadian Disruption Workshop, National Institute of Environmental Health Sciences, 2016

Rapporteur, Expert Panel Meeting: Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid, National Institutes of Health, 2015

Member, National Toxicology Program Laboratories Seminar Series Committee, 2013

Co-coordinator, Endocrine Disruptor Discussion Group, 2010-2011

Discussion Group Leader for Mizzou's One Read Program, University of Missouri, 2010

Professional Affiliations

Society of Toxicology, Member, 2014-present

Lone Star Society of Toxicology Member 2019-present

The Griffith's Leadership Society for Women, member, 2010-2011

Sigma Xi Scientific Research Society, member, 2009-2011

Society for the Study of Reproduction, member, 2005-2011, 2015

Other Professional Service Activities

Manuscript referee

Birth Defects Research; Chemosphere; Current Research in Toxicology; Environment International; Environmental Health Perspectives; Environmental Pollution; Environmental Research, Frontiers in Public Health

Community Outreach

Expert discussion panelist for A Teach-In Discussing PFAS in Vermont, online event hosted by Conservation Law Foundation, 2020

Expert discussion panelist for Dark Waters Screening: Panel Discussion, online event hosted by Environment Texas, 2020

Expert discussion panelist for Plastics and Covid-19: Panel Discussion, online event hosted by Environment Texas, 2020

Expert discussion panelist for The Devil We Know Film Series, NH, 2019

Presenter at Timberlane Regional School District Science, Technology, Engineering, Arts, and Mathematics (STEAM) Event, Plaistow, NH, 2018

Guest Blog for Toxic Free Future, "The Problem With D4: A Science in Policy Action Brief," May 8, 2007

Case study leader for "BPA and Its Replacements" for NIEHS Science, Teachers & Research Summer (STaRS) Institute, 2015

Facilitator for hands on DNA isolation workshop for NIEHS Family Day, 2013

MEDIA

Samsel, Haley. “Grand Prairie Fire Is out, but Concerns about Air Quality, Water Contamination Remain.” Star-Telegram, 21 Aug. 2020, https://www.star-telegram.com/news/local/article245146670.html.

Samsel, Haley. “Cancer-Causing Chemicals Found in Fort Worth Well. Could They Be in City Water?” *Star-Telegram*, 10 July 2020, https://www.star-telegram.com/article244096547.html

Nicole Wendee. “Getting the Lay of the Land: Human and Animal Evidence on Environmental Chemicals and Autism.” Environmental Health Perspectives, vol. 127, no. 9, p. 094002. ehp.niehs.nih.gov (Atypon), doi:10.1289/EHP5674.

Bienkowski, Brian. “BPA-Free? Substitutions Mimic Hormones in Breast Cancer Cells.” EHN, 15 Mar. 2017, https://www.ehn.org/bpa-free_substitutions_mimic_hormones_in_breast_cancer_cells-2497125325.html.

Samantha, Hall. “Former NIEHS Trainee Transitions to Nonprofit Work.” Environmental Factor, January 2017. National Institute of Environmental Health Sciences, https://factor.niehs.nih.gov/2017/1/awards-recognition/nonprofit/index.htm.

Katherine Pelch
University of North Texas Health Science Center

Please find attached my oral and written testimony and supporting documents.