

October 7, 2020

Lori Miyasato, Ph.D. Liaison to the Scientific Review Panel on Toxic Air Contaminants Air Resources Board P. O. Box 2815 1001 "I" Street Sacramento, California 95812

Subject: October 9, 2020 Meeting, Agenda Item 4, Part II - Update from the Office of Environmental Health Hazard Assessment on Development of Provisional Values

Dear Dr. Miyasato:

W.L. Gore and Associates (Gore) is a global materials science company focused on discovery and product innovation. Gore combines industry expertise with product versatility, creating solutions for the most challenging environments, from implants in the human body, to clothing worn on expeditions to Mt. Everest, to electronic cables transmitting signals from Mars. Gore conducts original research on the potential health effects of PFAS used in our product lines and is actively engaged with authoritative bodies and public health agencies around the world on evaluation and regulation of PFAS generally, and fluoropolymers in particular.

The attached documents are relevant to OEHHA's work on development of provisional health reference values (PHRV) for PFAS. The first document addresses challenges related to potential adaptation of health reference values from other authorities, discussed during the July 9, 2020 SRP meeting. The second document proposes a methodology for grouping PFAS by relative risk. These documents were submitted to CARB on August 19, 2020, for their consideration in updating the Air Toxics Hot Spots Program Emissions Inventory Criteria and Guidelines Regulation. The third document identifies impediments to applying "essential use" criteria as a factor in prioritizing PFAS for assessment and potential regulation. The fourth document addresses the role of persistence in chemical risk assessment, and by extension to PFAS, use of this criterion as a weighting factor in prioritizing development of health reference values for individual substances.

We request that the SRP consider these materials in the advice it provides to CARB and OEHHA on development of PHRVs for PFAS. There is a strong scientific basis and a practical policy need to differentiate sub-classes of PFAS for future evaluation and regulation. Just as OEHHA has determined that certain substances have low toxicity or are not bioavailable (e.g., some metal alloys) and therefore do not warrant development of health reference values, certain PFAS are not inherently toxic and do not degrade to or leach toxic metabolites, even under extreme laboratory conditions. These substances do not warrant the commitment of public resources necessary to develop health reference values. It is similarly inappropriate to include these substances in large groupings for data gathering, health risk screening, health risk assessment or regulatory purposes, especially if those groupings are based on data for substances with fundamentally different chemical properties and health risk profiles.

Gore appreciates your consideration of our comments on this agenda item. If you have any questions, please contact me at 443-907-2938.

Sincerely,

Barbara J. Henry, Ph.D.

W.L. Gore and Associates

cc: Members of the Scientific Review Panel on Toxic Air Contaminants Melanie Marty, Ph.D., OEHHA David Edwards, CARB

Proposal for Grouping PFAS by Relative Risk

August 12, 2020

This document provides an in depth look at a PFAS grouping proposal based on relative risk originally published online. See <u>https://news.bloomberglaw.com/environment-and-energy/insight-finding-a-middle-ground-on-pfas-using-a-four-step-process</u>

All substances with at least one fully fluorinated carbon would be screened for biological, chemical and physical properties, shown in the brown boxes below. This screening should occur at each stage of the PFAS' life cycle.



Biological properties include toxicity (mammalian and ecological, human, animal, aquatic), potency (comparing the lowest effect level in the same species for the same toxicity endpoint to other substances), bioaccumulation potential and biodegradation data. Chemical properties include reactivity and potential to leach from a landfill by a standard EPA test. Physical properties impacting substance behavior include molecular weight, vapor pressure, environmentally relevant thermal stability, biotic and abiotic stability, water solubility, potential for long range environmental transport, and potential to partition to air, water or soil.

The chemical, physical and biological screening (Step 1) would create health and environmental hazard categories of PFAS meeting the definition (e.g., health hazards: acute toxins, chronic toxins, carcinogens, mutagens, reproductive/developmental toxins, sensitizers, bioaccumulative substances; environmental hazards: acute or chronic aquatic toxins, persistent and water soluble, degrading into persistent and water soluble substances, volatile or adsorbing to soil, mobile with air or soil in the environment, etc.) In the absence of data to the contrary, these chemical, physical and biological questions should be assumed to present the hazard for grouping purposes.

The uses of the PFAS are identified in Step 2. These could be widely dispersive (e.g., cosmetics, pesticides, children's products) or more restricted (e.g., medical device, durable article, processing agent). This step provides insight into the exposure potential of the PFAS in its intended uses.

The third step identifies available and effective control measures (e.g., effective environmental controls/Best Available Technology such as thermal oxidizers, occupational hygiene programs, recycling, reuse, buy/take back, labeling, permitting, incineration).

In this four-step process for PFAS grouping, at each stage of the lifecycle (e.g., raw material manufacture, processing to intermediate forms, intermediate processing to final articles/products, and end of life), the hazard(s), plus the use(s) (exposure potential), plus effective control measures should be identified. Hazard plus use plus effective control measures will identify the residual risk (Step 4) of the PFAS to be managed. Management may include restrictions on use or additional control measures to decrease exposure potential. Ultimately, those PFAS with the same hazard (e.g., carcinogen, mobile, water soluble, low molecular weight, not biodegradable) and uses (e.g., manufacturing aid or food contact material) and control measures could be considered "PFAS subgroup", such as PFAAs, precursor to PFAA, or low hazard polymers, etc. for regulation/restriction/management.

This approach should be used by the California Air Resources Board and the Office of Environmental Health Hazard Assessment to prioritize various PFAS for development of Health Reference Values for use in California's air toxics regulatory programs. This prioritization process is relevant to both the ChemSet 1 and ChemSet 2-designated PFAS in CARB's revised Appendix A list for the Air Toxics Hot Spots Emissions Inventory Criteria and Guidelines regulation (July 29, 2020). It may indicate that agency resources should be focused on a subset of PFAS rather than trying to encompass all known substances in commerce regardless of their potential human health or environmental risk.

The Role of Persistence in Chemical Risk Assessment

Persistence is an intrinsic trait or characteristic of a substance indicating relative longevity in the environment and a degree of resistance to degradation or environmental transformation. Persistence means stability, durability and longer life, which are desirable characteristics in a product and are design features in essential products like critical electronics, medical devices, protective clothing for health care workers, first responders, firefighters, police and the military. Persistence does not, however, define the ability of a substance to partition to air, water, sediment or soil or widespread distribution of chemical contaminants in these media. Persistence in the environment does not equate to mobility, bioaccumulation or toxicity. Persistent substances released into the environment will remain for a relatively long time, and if those substances are bioavailable, they can also result in longer term exposure. However, a persistent substance that is neither bioavailable nor inherently hazardous cannot present a human or ecological risk. Therefore, proposals to restrict or phase out substances based on persistence alone are not science-based and should be avoided.

Risk is, by definition, a function of hazard and exposure. Toxicity (a type of hazard) is the intrinsic ability of the substance to harm a living organism. Exposure refers to the presence of a substance in the same environment as the human or living organism. In order for the substance to have any effect on the living organism it must first be present in a form that can be taken up by the living organism at the cellular level; in other words, the substance must be "bioavailable."¹ Persistence does not contribute to exposure potential if the substance is not bioavailable.

What then is meant by hazard and how have widespread hazards historically been addressed? As previously stated, a substance is deemed to be a toxicity hazard if there is evidence that it causes adverse impact or harm to a living organism. Historically, international and intergovernmental treaties have targeted hazardous chemicals for restriction. These include:

- The Helsinki Convention and HELCOM protecting the Baltic Marine Environment²
- <u>The Oslo and Paris Conventions and OSPAR protecting the Northeast Atlantic Marine</u> <u>Environment³</u>

¹ To enter a cell through the cell membrane the atomic mass of the substance must be less than about 3,000 Da. De Mello WC., Ed., Cell-to-Cell Communication, Plenum Press, NY, 1987, p34; Beyer EC, Gap Junctions. Inter. Rev. Cytol. 137, 1993 p2; Molecular Biology of the Cell, 3rd Ed., Alberts B, Bray D, Lewis J et al., Garland Science, NY, 1994, pp 958, 963 ² HELCOM protects the Baltic Sea from introduction by man of substances or energy resulting in such deleterious effects as hazard to human health, harm to living resources and marine line, hindrance to legitimate uses of the sea including fishing, impairment of the quality for use of sea water, and reduction of amenities. Substances agreed upon by the Convention signatories were listed in Annex I to the Convention: DDT (1,1,1-trichloro-2,2-bis-(chlorophenyl)-ethane) and its derivatives DDE and DDD; PCB's (polychlorinated biphenyls); PCT's (polychlorinated terphenyls). Substances agreed to be listed in Annex II of the Convention were not to be introduced into the marine environment of the Baltic Sea Area in significant quantities *without a prior special permit* and included: mercury, cadmium, and their compounds; antimony, arsenic, beryllium, chromium, copper, lead, molybdenum, nickel, selenium, tin, vanadium, zinc, and their compounds; persistent halogenated hydrocarbons; persistent and toxic organosilicic compounds; persistent pesticides, such as organophosphorics and organotins; radioactive materials; etc. Exceptions were agreed upon by signatories in the original convention and subsequent updates. <u>https://helcom.fi/about-us/convention/</u>

³OSPAR protects the northeast Atlantic from the "introduction by man, directly or indirectly, of substances or energy into the maritime area which results, or is likely to result, in hazards to human health, harm to living resources and marine ecosystems, damage to amenities or interference with other legitimate uses of the sea". <u>https://www.ospar.org/convention</u>

- <u>The Basel Convention, controlling transboundary movements of hazardous wastes and their</u> <u>disposal</u>⁴
- <u>The Montreal Protocol protecting the ozone layer by phasing out the production of numerous</u> <u>substances that deplete stratospheric ozone</u>⁵
- <u>The Stockholm Convention on Persistent Organic Pollutants (POPs) eliminating/restricting the</u> production and use of persistent organic pollutants.⁶

No existing treaty or regulatory framework seeks to restrict or classify a chemical on the basis of persistence alone. Persistence is always paired with a hazard such as bioaccumulation and/or toxicity. "Persistent" (P) and "very persistent" (vP) are defined as follows by the U.S Environmental Protection Agency (EPA), the German Umweltbundesamt (UBA), the United Nations Environment Programme's Stockholm Convention, and the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH):

Category	US EPA PBT Profiler	UNEP Stockholm Convention	REACH (Chapter R.11: PBT/vPvB assessment version 2.0, 11/2014)	UBA PMT (May, 2017)	
			>60 days (marine water), >40 days	>60 days (marine water), >40 days	
Persistence, P	>60 days (soil, water, sediment)	>60 days (water)	(estuarine water), >120 days (fresh &	(estuarine water), >120 days (fresh &	
			estuarine sediment or soil)	estuarine sediment or soil)	
Very Persistent, vP	>180 days (soil, water, sediment)	>180 days (soil, sediment)	>180 days		
		half life >2 days, potential for long			
		range transport			

Table 1. Comparison of criteria for persistence and very persistent

Notably P and vP are always paired with T (toxicity) and/or B (bioaccumulation).

Not all persistent PFAS are bioavailable or toxic in the first instance. Moreover, not all PFAS are mobile in the environment or capable of concentrating in the tissues of living organisms. Polymeric PFAS that meet the Organisation for Economic Co-operation and Development Polymer of Low Concern (OECD PLC) criteria, such as those fluoropolymers detailed in Henry et al, 2018, are not bioavailable, toxic, bioaccumulative, water soluble or mobile in the environment. Therefore, their presence in the environment or in proximity to living organisms cannot, by definition, constitute a risk to those organisms.

Fluoropolymers are highly valued for their durability and resistence to physical, chemical and biological breakdown and reaction (transformation). Fluoropolymers meeting the OECD PLC criteria are not subject to photolysis, hydrolysis, oxidation, or thermal degradation under environmentally relevant conditions. They are among the most inert substances known to man and will not chemically transform

⁴ The Basel Convention is the most comprehensive global environmental treaty on hazardous and other wastes. It has 170 member countries (Parties) and aims to protect human health and the environment against the adverse effects resulting from the generation, management, transboundary movements and disposal of hazardous and other wastes. The transboundary movements of hazardous and other wastes are permitted with the "Prior Informed Consent" procedure and are illegal unless there is a special agreement. Annexes listed substances agreed upon as hazardous and subject to the terms of the convention including: biomedical and healthcare wastes; used oils; used lead acid batteries; Persistent Organic Pollutant wastes; polychlorinated biphenyls (PCBs),etc. <u>http://www.basel.int/Portals/4/Basel%20Convention/docs/convention/bc_glance.pdf</u>

⁵ The Montreal Protocol is a multilateral environmental agreement that regulates the production and consumption of nearly 100 man-made chemicals referred to as ozone depleting substances (ODS), including: CFCs, halons, other fully halogenated CFCs, carbon tetrachloride, methyl chloroform, HCFCs, methyl bromide and HFCs. It has been estimated that the Montreal Protocol is saving an estimated two million people each year by 2030 from skin cancer.

⁶ The Stockholm Convention initially recognized twelve POPs as causing adverse effects on humans and the ecosystem and these can be placed in 3 categories: pesticides: aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene; industrial chemicals: hexachloroenzene, hexachlorobenzene, polychlorinated biphenyls (PCBs); and byproducts: hexachlorobenzene; polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans (PCDD/PCDF), and PCBs. Other POPs have been added by the UN Environment Programme since the convention origination.

or react in the environment or in the tissues of living organisms to create substances of concern. The inherent stability of a fluoropolymer meeting the PLC criteria means it will not leach substances of concern. These findings are supported by analytical data presented in the supplement to Henry et al., 2018. Therefore, while they are long-lived, fluoropolymers meeting the PLC criteria lack the basic properties necessary to present a human health or ecological risk.

Analytical data on a fine powder polyterafluoroethylene (PTFE; used by Gore) meeting the OECD Polymer of Low Concern criteria, presented in the Supplement to Henry et al., 2018, demonstrated that even with chemical extraction methods, it is not possible to separate any polymerization aid, surfactant, catalyst, chain transfer agent, modifier or monomer out of the polymer.

The analytical data developed by W.L. Gore (Gore) was approved by the US Food and Drug Administration as the basis for registering use of PLC fluoropolymers and polymerization aids in our medical devices. The PLC fluoropolymers will not leach to biota or the environment or transform to substances of concern under relevant biological or environmental conditions. PLC fluoropolymers have been demonstrated to be impervious to microbial degradation as demonstrated in medical device explant analyses discussed in Henry et al., 2018. Over 40 years and 40 million W.L. Gore implanted medical devices confirm the *in vivo* stability of fluoropolymers meeting the PLC criteria. In fact, stability is one of the important features of the PLC fluoropolymers that imparts high societal value to a wide array of products including medical devices, automobiles, wiring and cabling for satellites and aircraft and protective gear for first responders, among other applications.

Chemical analyses have demonstrated that polymerization aids do not migrate from Gore fluoropolymer intermediates and downstream finished products. Short chain alternatives to PFOA are volatile and are captured by thermal oxidizers during processes to convert the incoming fluoropolymer resin to intermediate physical forms (e.g., tapes, films, fibers, tubes) used in downstream final product manufacture. The absence of quantifiable polymerization aid residuals in Gore intermediates means final products will also have residuals below the limit of quantitation (LOQ) because those substances are not added during fluoropolymer processing or final article creation. Therefore, because the polymerization aid cannot be detected in the intermediate and does not leach from either the polymer or the intermediate, the final product in customer use or end of life situations (e.g., recycling, reuse, landfill, etc.) cannot be a source of any polymerization aids found in the environment.

While persistence alone does not define health or environmental risk, persistent materials will endure after the useful life of the products they enable, and will need thoughtful end of life management strategies to minimize their contribution to the solid waste stream and to enable the material reuse/recycling streams envisioned for the Circular Economy.

With regard to the growing global burden of solid waste management, use and control measures should be carefully considered for all persistent materials, *not just substances meeting the structural chemical definition of a PFAS*. To reduce the environmental impact of global solid waste, control measures (reuse, recycling, upcycling, take back/buy back, etc.) should be implemented for all persistent materials as much as possible in accordance with the transition to a Circular Economy.

• There is great concern over microplastics and plastic solid waste in the environment. According to the UN Environment Programme, 300 million tons of plastics are produced per year: 9% is recycled, 12% is incinerated; 79% ends up in landfills, and the environment.⁷ Although the UN

⁷UNEP 2018 https://www.unenvironment.org/interactive/beat-plastic-pollution/

Environment Program does not list any polymeric PFAS among those most frequently found in plastic waste, the minimization of environmental release of fluoropolymers, and all plastics, is critical.

- Glass bottles are very persistent materials believed to take over a million years to breakdown in the environment.
- Aluminum or steel cans may take 80-100 years to decompose. Aluminum cans consist primarily of aluminum (~97%) with about 1% each of magnesium and manganese, and 1% of iron, silicon and copper.⁸

When alternatives to persistent materials are considered, the alternatives should be evaluated to determine their efficacy in performing their intended function, as well as chemical, physical, biological properties and control measures. Alternatives typically involve tradeoffs in performance potentially resulting in use of higher material volumes or compromised product efficacy. It should be noted that alternatives should be scrutinized to identify hazards other than those that may be associated with the presence of per- or polyfluoroalkyl substances because the tradeoffs may present greater public health or environmental challenges than the existing product. Given the high societal value of fluoropolymer products in critical electronics, medical devices, protective clothing for health care workers and first responders, firefighters, police and the military (etc.), performance and durability must continue to be key considerations in use decisions.

While it is technically possible to recycle some fluoropolymers^{9,10} fluoropolymer recycling has not yet been implemented on a commercial scale. Work should continue to develop commercial recycling of fluoropolymers to bring them in line with Circular Economy goals. In the meantime, the durability of fluoropolymers will extend the useful life of the products that depend on them, which is a key aim of the Circular Economy.

Persistence may be one of several appropriate screening criteria for identifying potentially hazardous substances, but persistence alone merely indicates the substance will be present in a given medium for an extended period of time. It cannot predict the potential for degradation, bioavailability, toxicity, exposure, mobility, water solubility, health or environmental hazard or overall risk.

⁸ Int J Mol Sci. 2012; 13(12): 16812–16821.

 ⁹Schlipf M, Schwalm T. 2014. Closing the recyling loop. Kunststoffe Intl 2014/06. [cited 2017 July 12]. https://www.kunststoffe.de/en/journal/archive/article/up-cycling-of-end-of-life-fluoroplastics-841786.html
¹⁰Invertec. 2017. Pilot project: Recycling of fluoropolymers (PTFE). [Cited 2017 July 12]. https://www.invertec-ev.de/en/projects/environmental-care/ptfe-recycling/

Position on Essential Use

There seems to be no consensus regarding the meaning of "essential use" and Gore has many questions regarding how the proposal to restrict PFAS to essential uses could be implemented as a practical matter. Based on what we do know, however, Gore does not believe that applying an essential use concept to restrict all PFAS is an effective or appropriate way to address the important health and environmental concerns being considered.

Context

Essential use has been applied in the past through essential use analyses like the Montreal Protocol, where there was:

- A clear, unacceptable risk to human health or the environment
- A demonstrated causal link between a specific set of substances and the risk
- A consensus that production phase out was the only solution to address the risk
- A process to prioritize substances for elimination based on the potential of the substance to cause that unacceptable risk and to identify essential uses that should be exempted from the phase out
- Methods to assure that the alternatives to the substances being phased out represented an improvement

Applying essential use to PFAS is inappropriate because:

Not all PFAS are the same;

- Substances within the broad PFAS group have very different physical, chemical, and toxicological properties. Based on their properties, some individual PFAS are relevant to a specific health and environmental topic (e.g., water quality) and others are not (e.g., non-water soluble PFAS).
- For example, fluoropolymers meeting the OECD Polymer of Low Concern criteria have very low health and environmental risk.

When considering the wide range of uses of PFAS and the diversity of stakeholders, we see no practical way to develop consensus on objective criteria for what is an essential product; we advocate instead for use of sound risk management principles.

- Risk-benefit analyses start with identification of an unmitigated residual risk compared to the societal benefits the substance or product provides. What is the risk (i.e., hazard x exposure) being addressed through essential use analyses?
- PFAS (and other chemical substances) are used in critical components of complex products that simultaneously serve end uses that range from life critical to discretionary.
- Even if broad consensus on essentiality is achieved for a given PFAS with residual unmitigated risk, the challenges facing society and the corresponding views on essentiality can both change quite rapidly.

There would be significant negative impacts to individuals and society by broadly restricting all PFAS without considering the specific potential impacts and options available.

- An essential use framework that broadly bans high performance materials would limit current solutions as well as innovation that promises to address many societal challenges in areas such as climate change, energy, transportation, communications, and health care.
- Non-specific essentiality criteria are even more problematic when they may restrict some substances known to have very low potential harm, but which enable products of high value to society.

Gore supports science-based proportional regulation of all chemical substances, including PFAS.

- We are convinced that there are ways to address the health and environmental harms posed by some PFAS while preserving for society the benefits of the PFAS group.
- To achieve this, we urge the development of frameworks that:

- 1. Define the health and environmental hazard posed by the PFAS based on its chemical, physical and biological properties.
- 2. Identifies the uses of the PFAS.
- 3. Identifies the efficacy and availability of potential control measures (e.g. environmental controls, product end of life requirements), that can be employed in the context of the uses to adequately address the specific harm posed by each use of the PFAS.
- 4. If the residual risk cannot be sufficiently minimized, then consider further PFAS regulation or restriction.
- Multiple PFAS with the same hazard, uses and control measures could be grouped for further regulation/restriction.
- If the conclusion of such an analysis is that eliminating the use of all PFAS or some collection of PFAS in some products is the only practical solution to address the harm, then there should be a mechanism to balance the societal harm of losing the product use against the societal harm of continuing the use.
- If alternatives for the PFAS causing harm are proposed, then to avoid regrettable substitutions, the alternatives should be evaluated by the same process to determine if they represent an improvement compared to the incumbent material.

CARB and OEHHA Must Exercise Caution in Adopting or Adapting Health **Reference Values from Other Jurisdictions**

August 12, 2020

The following table from Fiedler, Kennedy and Henry, 2020 (submitted to IEAM 6/2020) compares drinking water HBVs for five perfluoroalkyl acids (PFBA, PFHxA, PFOA PFBS PFOS) and HFPO NH4⁺ values across US state, US federal and other countries. Note the wide differences in HBVs across these jurisdictions for the same PFAA: 300x PFBA; 11x PFHxA; 17,647x PFOA; 6,670x PFBS; 1,698x PFOS; 5X HFPO NH4⁺.

Table 4: Standards and Guidance Values for PFAS in Drinking Water; PFAS Analyte Concentration (µg/L) (Modified from ITRC, Table 4-1, accessed 2020-06-24.)

Location	Agency / Dept	Standard / Guidance	Туре	PFBA	PFHxA	PFOA	PFBS	PFOS	HFPO NH ₄ *	Min to Max (µg/L)
CAS Number				375-22-4	307-24-4	335-67-1	375-73-5	1763-23-1	3252-13-6	PFBA 0.1 to 30
U.S. Environmental Protection Agency										PFHxA 0.09 to 1
USEPA	Office of Water	HA	DW			0.070		0.070		PFOA 0.0051 to 90
U.S. States										PFBS 0.1 to 667
Alaska (AK)	DEC	Action Level	DW/GW/SW			0.070		0.070		PFOS 0.0053 to 9
California (CA)	SWRCB	NL	DW			0.0051		0.0065		HFPO NH4 0.140 to 0.7
	SWRCB	RL (CA)	DW			0.0100		0.0400		
Connecticut (CT)	DPH	AL	DW/GW			0.070		0.070]
Massachusetts (MA)	DEP	Drinking Water Values	DW			0.020		0.020		1
Michigan (MI)	DEQ.	GCC	DW/GW			0.070		0.070		1
	DHHS	Screening Levels	DW			0.009	1	0.008		1
	MDH	HRL- subchronic	DW/GW	7		0.035	9			1
	MDH	HRL - chronic	DW/GW	7		0.035	7	0.300		1
Minnesota (MN)	MDH	HBV - subchronic	DW/GW				3	0.015		1
	MDH	HBV - chronic	DW/GW				2	0.015		1
Nevada (NV)	DEP	BCL	DW			0.667	667	0.667		1
	DEP	MCL	DW							1
New Jersey (NJ)	DWOI	MCL	DW			0.014				1
	DWOI	MCL	DW					0.013		1
North Carolina (NC)	DHHS	Health Goal	DW						0.140	1
Ohio (OH)	ODH	Action Level	DW			0.070	140	0.070	0.700	1
Rhode Island	DEM	GWQS	DW/GW			0.070		0.070		1
	DEC/DOH	MCL	DW/GW			0.020		0.020		1
Vermont (VT)	DEC/DOH	на	DW/GW			0.020		0.020		1
International										1
Australia	DOH	health-based	DW			0.560		0.070		1
British Columbia, Canada		water standard	DW/GW			0.200	80	0.300		1
Canada	нс	DWSV	DW	30	0.200	0.200	15	0.600		1
	HC	DWSV	DW							
	HC	MAC	DW			0.200		0.600		
Denmark	EPA	health-based	DW/GW	0.100	0.100	0.100	0.100	0.100		1
Germany	GMH	health-based	DW			0.300		0.300		1
		administrative	DW			0.100		0.100		
Italy	,	health-based	DW	7	1	0.500	3	0.030		1
Netherlands	EPA	health-based	DW					0.530		1
		administrative	DW					0.0053		1
Sweden		health-based	DW					0.090		1
		administrative	DW		0.090	0.090	0.090	0.090		
	DWI	health-based	DW			10		0.300		1
UK		admin. Level 1	DW			0.300		0.300		1
		admin. Level 2	DW			10		1		1
		admin. Level 3	DW			90		9		1

Regulatory Agency

- DEC = Dept. of Environmental Conservation
- DEM = Dept. of Environmental Management
- DEP = Dept. of Environmental Protection
- DEQ = Dept. of Environmental Quality DHHS = Dept. of Health and Human Services
- DOH = Dept. of Health
- DPH = Division or Department of Public Health DWI = Drinking Water Inspectorate
- DWQI = NJ Drinking Water Quality Institute
- EPA = Environmental Protection Agency
- GMH = German Ministry of Health HC = Health Canada
- MDH = Minnesota Department of Health
- ODH Ohio Dept. of Health

SWRCB = California State Water Resources Control Board

Standard or Guidance AL = private well action level

- BCL = basic comparison level
- DWSV = Drinking Water Screening Value
- GCC = Generic Cleanup Criteria GWQS = Groundwater Water Quality Standard
- HA = lifetime health advisory
- HBV = health-based value
- HRL = health risk limit
- MAC = maximum acceptable/allowable
- concentration
- MCL = maximum contaminant level
- NL = Notification Level
- RL = reporting level
- RL (CA) = Response Level (California only)

Per- and polyfluoroalkyl substances

PFAS = per- and polyfluoroalkyl substances PFOA = perfluorooctanoic acid (C8) PFOS = perfluorooctane sulfonic acid (C8) PFBA = perfluorobutyric acid (C4) PFBS = perfluorobutane sulfonic acid (C4) PFHxA = perfluorohexanoic acid (C6) HFPO NH₄^{*} = hexafluoropropylene oxide dimer acid, ammonium salt

Type of Medium

DW = drinking water GW = groundwater

The Interstate Technology and Regulatory Council (ITRC) has published information on their website (<u>http://pfas-1.itrcweb.org</u>) about the differences between state and federal health based values. The following excerpt (emphasis added) highlights the need for exercising caution when adopting an HRV from another jurisdiction. Although this text refers only to differences among US state and federal agencies, these same differences exist among other countries as well.

"As of September 2019, regulatory human health–based guidance values and/or standards have been derived for 16 PFAAs, two polyfluoroalkyl precursors, and one fluorinated ether carboxylate (FECA) by state and/or federal agencies in the United States. The values for these nonpolymeric PFAS vary across programs, with *differences due to the selection and interpretation of different key toxicity studies, choice of uncertainty factors, and approaches used for animal-to-human extrapolation. The choice of exposure assumptions, including the life stage and the percentage of exposure assumed to come from non-drinking water sources, also differs...*These same key decision points also underlie the differences that exist in the other perfluoroalkyl substance regulatory values...".

Another contemporary reference expressing the same concern is Cordner et al., 2019 (pdf of the publication provided with this document). That publication compares PFOA drinking water health based values, uncertainty factors, exposure parameters etc. in different jurisdictions within the US.

Therefore, we believe it is critical that the California Air Resources Board and the Office of Environmental Health Hazard Assessment be aware of these methodological differences in adopting or adapting health reference values developed by other government agencies or authoritative bodies for California. To the extent CARB and OEHHA identify such values for potential use in the Air Toxics Hot Spots program, or for any other purpose, we ask that OEHHA adjust these values as necessary to reflect California risk assessment methodologies and policies. This approach will ensure consistency in application of uncertainty factors, route-to-route extrapolation approaches, sensitive target populations, etc, and will result in more scientifically rigorous HRVs to support future screening and regulatory decisions.