

November 4, 2019

Kerri Malinowski
Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333-0017

Re: Draft Chapter 890, Designation of PFOS as a Priority Chemical

Dear Ms. Malinowski:

On behalf of the Environmental Health Strategy Center (EHSC), the Conservation Law Foundation (CLF), Sierra Club Maine (Sierra), and Toxics Action Center (TAC), thank you for the opportunity to provide comment on DEP's revised proposal to designate perfluorooctane sulfonic acid (PFOS) a priority chemical in accordance with M.R.S. Title 38, Chapter 16-D. We all strongly support efforts that would help eliminate PFOS from all consumer products and believe this is a significant first step. For the benefit of the Board of Environmental Protection, we reiterate the comments EHSC made in reference to the April draft proposal on this topic and have included those as an attachment to this document. We appreciate and are generally supportive of DEP's revisions from the first draft posted in April of this year. However, as outlined in these comments, we believe the proposed rules must be strengthened and clarified by addressing the statutory language making it applicable to precursors and further clarifying it's applicability to products that may expose fetuses.

The Environmental Health Strategy Center is a Maine-based charitable nonprofit working to create a world where all people are healthy and thriving, with equal access to safe food and drinking water, and products that are toxic-free and climate-friendly. EHSC protects public health by fighting for safe food and drinking water, toxic-free products, and good green manufacturing jobs. EHSC led the fight for the enactment of the Toxic Chemicals in Children's Products Act, also referred to as the Kids Safe Products Act (KSPA) and has been actively monitoring its implementation in the subsequent years. This law provides critical authority to the State of Maine to protect our most vulnerable from unnecessary exposure to dangerous chemicals.

The Conservation Law Foundation protects New England's environment for the benefit of all people. Founded in 1966, CLF is a non-profit, member-supported organization with offices located in Maine, Massachusetts, Vermont, Rhode Island, and New Hampshire. CLF uses the law, science, and the market to create solutions that protect public health, preserve natural resources, and sustain a vibrant economy. CLF has been a leading advocate for healthy communities and safe drinking water in Maine and throughout New England, and is engaged in numerous efforts to address the threat of emerging contaminants, including PFAS, throughout New England.

Sierra Club Maine is an environmental and conservation advocacy organization with 18,000 members and supporters. It is one of 63 Chapters of Sierra Club nationwide with more than 3 million members, and we speak with one voice.

Toxics Action Center is an environmental health nonprofit that works side-by-side with communities to clean up and prevent pollution at the local level in Maine and across New England. Toxics Action Center has been working to close the loopholes in our toxics regulations, strengthen drinking water protections, and support community groups fighting for the right to clean drinking water and PFAS-free communities.

Inclusion of Precursor Chemicals

38 M.R.S. 1691(2) defines chemical as “a substance with a distinct molecular composition or a group of structurally related substances and includes the breakdown products of the substance or *substances that form through decomposition, degradation or metabolism.*” (emphasis added). In identifying PFOS as a priority chemical, under the plain language of this definition, DEP is also identifying those substances that form PFOS through decomposition, degradation or metabolism. For simplicity, we refer to substances which form PFOS through decomposition, degradation or metabolism as PFOS precursorsⁱ.

In addition to complying with the statutory definition, the inclusion of PFOS precursors is critical to address the threats posed by PFOS to the environment and to public health. Regulatory authorities nationally and internationally have recognized a number of PFOS precursors and the importance of addressing them in order to address PFOS itself. In discussing the contamination of water with PFOS or PFOA, US EPA has noted that, “PFOS and PFOA can also be formed by environmental degradation or by metabolism in larger organisms from a large group of related PFASs or precursor compounds.... Therefore, if precursors are not addressed during remediation, over time they may be transformed to PFAAs, such as PFOS and PFOA.”ⁱⁱ Health Canada has also documented that, “...the abiotic degradation of certain PFOS precursor molecules can lead to PFOS as the end stage metabolite product,” and further referenced studies of drinking water treatment facilities where, “...concentrations in the finished water were higher than in the raw water, likely due to the breakdown of precursor compounds to form PFOS during the treatment.”ⁱⁱⁱ

Building on efforts of toxicologists and chemists to identify pathways for the formation of PFOS from PFOS precursors, Gebbink, Berger, and Cousins modeled the contribution of PFOS precursors to the overall intake of PFOS by humans. In summary, they estimated that, “The precursor contributions to the individual perfluoroalkyl acid (PFAA) daily exposures are estimated to be 11–33% for PFOS ...”^{iv} Other researchers estimated that for sub-groups of the population with high exposure, precursor contributions could account for up to 80% of total PFOS dose.^v It is notable that as these studies are based on older data, and as the production of PFOS itself has been greatly reduced, it is likely that current PFOS exposure may be driven to an even greater extent by PFOS precursors.

While we believe that by identifying PFOS as a priority chemical, by statutory definition, DEP is including PFOS precursors, for the sake of clarity and understanding by the regulatory community, DEP should better elucidate this fact in the proposed rule. At a minimum, DEP should, in defining the applicability in section 1 of the rule note that PFOS means perfluorooctane sulfonic acid, its salts^{vi}, and any substance which may form PFOS through decomposition, degradation or metabolism.

If DEP wishes to provide additional clarity, it can draw on the work of other governmental authorities. The US EPA has published two lists of PFOS precursors as part of “Significant New Use Rules” that require companies to notify the agency about certain uses of the included chemicals. These lists include commercialized chemicals, many with available CASRNs, as well as a number of chemicals submitted for review under the agency’s Pre-Manufacturing Notice program identified only a PMN number and

chemical name. The first list, now codified as Table 1 at 40 CFR 721.9582, includes, according to the agency: "...13 chemicals, including polymers, that are derived from perfluorooctanesulfonic acid (PFOSH) and its higher and lower homologues.... All of these chemical substances have the potential to degrade to PFOSH in the environment. Information also suggests that these chemical substances may be converted to PFOSH via incomplete oxidation during the incineration of PFOS-containing materials."^{vii}

The second list, now codified as Table 2 at 40 CFR 721.9582, includes an additional 75 substances. The agency notes that "Most of these PFAS chemical substances include the C8 chain length characteristic of PFOS and thus have the potential to degrade to PFOSH in the environment or to be converted to PFOSH via incomplete oxidation during the incineration of PFOS-containing materials."^{viii}

In including PFOS as a persistent organic pollutant under the Stockholm Convention, the parties specifically addressed the precursor issue, noting, "...there is a potential that any molecule containing the PFOS moiety could be a precursor to PFOS," and specifically citing European Union regulatory actions that had, "...addressed all molecules having the following molecular formula: C₈F₁₇SO₂X (X= OH, Metal salt (O-M+), halide, amide and other derivatives including polymers)."^{ix} In its nomination of PFOS to the convention, Sweden identified a list of 96 PFOS precursors that is also available for reference.^x

Canada has also put forward a specific definition of PFOS precursor, writing in its risk management plan for PFOS: "The expression 'PFOS precursors' refers to compounds that contain the C₈F₁₇SO₂, C₈F₁₇SO₃ or C₈F₁₇SO₂N group. These compounds were included in the ecological and human health screening assessments and in this Risk Management Strategy since these substances have similar use applications, have the potential to transform or degrade to PFOS in the environment and the final degradation product of these substances is PFOS."^{xi} This definition was ultimately adopted in Canadian regulation.^{xii} While making clear that the broader definition held and its list was not all-inclusive, Canada also published a list of 57 PFOS precursors that is available for download.^{xiii}

DEP should consider referencing all three lists to help the regulated community identify substances as PFOS precursors and subject to the chapter 890 requirements.

Application of Rule to Products Exposing Fetuses

As EHSC noted in its April comment, DEP is required to address Priority Chemicals found within "Children's Products." This term is defined at 38 M.R.S. 1691(7) to include, "...any consumer product containing a chemical of high concern that when used or disposed of will likely result in a child under 12 years of age or a fetus's being exposed to that chemical" (emphasis added). This definition also appears in Chapter 880 of the implementing rules. Further, a consumer product that will likely result in a fetus being exposed to a chemical is any consumer product whose use would likely result in a woman of child-bearing age being exposed to it. There is no feasible or logical approach to segregate products used by women who may be pregnant from women who are not. As the statutory framework is based on the potential for exposure and not on calculations of absorption or other risk-based factors, the only logical approach is for DEP to assume that any potential exposure to a woman is a potential exposure to a fetus and thus covered under the law.

While we were pleased to see DEP expand the language in section 1, applicability, to incorporate various indoor consumer products and remove many of the references to "children's" in the definitions and section 4 categories, we remain concerned that the "applicability" section is still somewhat unclear as to the scope of products that are included on quick read. Removing replacing "children's" with "consumer"

in the first sentence would make it easier to appreciate the scope. Additionally, the definition of “Cosmetics and personal care products” in section 2(g) includes a reference to “...applied to a child’s body for hygienic care or treatment...” that, while arguably not restricting the entire definition to products focused on children, adds unnecessary confusion to the definition. Replacing the words, “a child’s” with “the” in the definition would make it both more understandable and in line with the statutory requirements to address potential exposures to a fetus.

We look forward to working with DEP to continue to address the challenges posed by PFOS and other PFAS chemicals. If you have any questions about our comments, please contact Patrick MacRoy of the Environmental Health Strategy Center at 207-699-5796 or PMacRoy@preventharm.org

Sincerely,

Patrick MacRoy
Deputy Director
Environmental Health Strategy Center

Phelps Turner
Staff Attorney
Conservation Law Foundation

Alice D. Elliott
Director
Sierra Club Maine

Dana Colihan
Maine Community Organizer
Toxics Action Center

ⁱ For an overview of the chemistry in the formation of PFOS from PFOS precursors see: Martin, JW., et al. “PFOS or PreFOS? Are perfluorooctane sulfonate precursors (PreFOS) important determinants of human and environmental perfluorooctane sulfonate (PFOS) exposure?” *J Environ Monit.* 2010 Nov; 12(11):1979-2004. doi: 10.1039/c0em00295j.

ⁱⁱ US EPA. “Technical Fact Sheet – Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA).” November 2017. Available at https://www.epa.gov/sites/production/files/2017-12/documents/ffrrofactsheet_contaminants_pfos_pfoa_11-20-17_508_0.pdf

ⁱⁱⁱ Health Canada. “Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Perfluorooctane Sulfonate (PFOS).” December 2018. Available at <https://www.canada.ca/content/dam/canada/health-canada/migration/healthy-canadians/publications/healthy-living-vie-saine/guidelines-canadian-drinking-water-quality-guideline-technical-document-perfluorooctane-sulfonate/PFOS%202018-1130%20ENG.pdf>

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- ^{iv} Gebbink, Wouter A., Urs Berger, Ian T. Cousins. "Estimating human exposure to PFOS isomers and PFCA homologues: The relative importance of direct and indirect (precursor) exposure." *Environment International* 74 (2015) 160-169. (See also their reference list for studies documenting the production of PFOS from PFOS precursors).
- ^v Vestergren, Robin, et al. "Estimating the contribution of precursor compounds in consumer exposure to PFOS and PFOA." *Chemosphere* 75 (2008) 1617-1624. <https://www.ncbi.nlm.nih.gov/pubmed/18834614>
- ^{vi} DEP already has a clarity problem in that the rule only references "perfluorooctane sulfonic acid", while the letter of concurrence from DHHS references "PFOS and its salts." There are different CASRNs at least for the acid, its potassium and its ammonium salt. As these salts all dissociate readily, they are in effect precursors to the molecule that is actually of concern.
- ^{vii} 67 FR 11008-9. Available at <https://www.govinfo.gov/content/pkg/FR-2002-03-11/pdf/02-5746.pdf>
- ^{viii} 67 FR 72858. Available at <https://www.govinfo.gov/content/pkg/FR-2002-12-09/pdf/02-31011.pdf>
- ^{ix} UNEP. "Report of the Persistent Organic Pollutants Review Committee on the work of its third meeting. Addendum: Risk management evaluation on perfluorooctane sulfonate." 4 Dec 2007. UNEP/POPS/POPRC.3/20/Add.5
- ^x See Annex 1 of: Swedish Chemicals Inspectorate (KemI) and the Swedish EPA. "PERFLUOROOCTANE SULFONATE (PFOS): Dossier prepared in support for a nomination of PFOS to the UN-ECE LRTAP Protocol and the Stockholm Convention." August 2004. Available at http://www.unece.org/fileadmin/DAM/env/lrtap/TaskForce/popsxg/2004/Sweden_PFOS_dossier_Aug_2004.pdf
- ^{xi} Government of Canada. "Risk management strategy for perfluorooctane sulfonate and its salts and precursors." June 2006. Available at <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/risk-management-strategy-perfluorooctane-sulfonate.html>
- ^{xii} Canada Gazette Part II, Vol. 142, No. 12. "Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations." <http://publications.gc.ca/gazette/archives/p2/2008/2008-06-11/pdf/g2-14212.pdf>
- ^{xiii} <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/risk-management-strategy-perfluorooctane-sulfonate/appendix-1.html>

May 6, 2019

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Re: Draft Chapter 890, Designation of PFOS as a Priority Chemical

Dear Ms. Malinowski:

Thank you for the opportunity to provide comment on DEP's proposal to designate perfluorooctane sulfonic acid (PFOS) a priority chemical in accordance with M.R.S. Title 38, Chapter 16-D. The Environmental Health Strategy Center strongly supports efforts that would help eliminate PFOS from all consumer products and believes this is a significant first step. However, as outlined in these comments, we are also concerned that DEP's proposal is not as inclusive as required by statute, and also urge the Department to move expeditiously in working towards naming the entire class of per- and polyfluoroalkyl substances (PFAS) as a priority chemical.

The Environmental Health Strategy Center is a Maine-based charitable nonprofit working for a world where all people are healthy and thriving in a fair and healthy economy. We protect public health by fighting for safe food and drinking water, toxic-free products, and good green manufacturing jobs. Our organization led the fight for the enactment of the Toxic Chemicals in Children's Products Act, also referred to as the Kids Safe Products Act (KSPA). We have been actively monitoring its implementation in the subsequent years. This law provides critical authority to the State of Maine to protect our most vulnerable from unnecessary exposure to dangerous chemicals. It is incredibly unfortunate that DEP under the prior administration did so little to utilize it and the Department is only now designating PFOS a priority.

There is no doubt that PFOS qualifies as a Priority Chemical as it is already listed as a chemical of high concernⁱ and meets all three of the criteria (while only one is required) at 38 M.R.S. § 1694 of having been found in biomonitoring samples, found in dust or drinking water, and being used in consumer products.ⁱⁱ

Some may claim that since US chemical producers stopped manufacturing PFOS, there is little to gain in adding it a priority chemical. We disagree. A December 2017 report from the Commission for Environmental Cooperation which tested clothing, apparel, and Children's items from the US, Canada, and Mexico for PFAS, found PFOS specifically in 16% of the items tested.ⁱⁱⁱ Whether as a

degradation product or from a foreign manufacturer, there is good reason to believe there is still PFOS in products relevant to KSPA. The use of PFOS in a variety of other household products has also been well documented by other authorities, including the Swedish Chemicals Agency.^{iv}

We are deeply concerned, however, that DEP's proposed Chapter 890 is not adequately expansive to fulfil the Department's statutory duty to address exposures to pregnant women and fetuses.

DEP is required to address Priority Chemicals found within "Children's Products." This term is defined at 38 M.R.S. 1691(7) to include, "...any consumer product containing a chemical of high concern that when used or disposed of will likely result in a child under 12 years of age *or a fetus's* being exposed to that chemical" (emphasis added). This definition also appears in Chapter 880 of the implementing rules. This legislative directive is grounded in the fact that exposure *in utero* to various chemicals has been associated with both adverse birth outcomes as well as increased risk of deleterious health conditions in childhood and throughout life.^v Specifically to PFOS, animal studies have shown impacts to offspring from maternal exposures, and some epidemiological studies in humans found maternal PFOS levels to be associated with alterations in cord blood hormone levels that may present future risks to the child as well as increased risks of global executive functioning and metacognition problems in children.^{vi}

A consumer product that will likely result in a fetus being exposed to a chemical is any consumer product whose use would likely result in a woman of child-bearing age being exposed to it. There is no feasible or logical approach to segregate products used by women who may be pregnant from women who are not. As the statutory framework is based on the potential for exposure and not on calculations of absorption or other risk-based factors, the only logical approach is for DEP to assume that any potential exposure to a pregnant woman is a potential exposure to a fetus and thus covered under the law.^{vii}

We therefore believe that DEP must expand the definition of products within section 2 of the proposed Chapter 890 to also include consumer products that are utilized by women of a child-bearing age. This can be accomplished by changing "child under the age of 12 years" to "child under the age of 12 years or woman of a child-bearing age" where it appears in subsections B, C, D, E, G, H, and I of section 2. We recognize that this substantially increases the universe of products the regulation applies to, but this is what is required in order to meet the clear statutory language and intent of Maine's law.

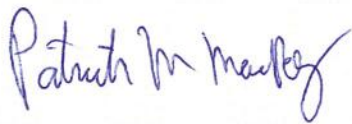
With this addition, we support DEP's broad inclusion of the universe of products covered under KSPA for reporting under the proposed chapter 890.

Although we were pleased to see DEP take this action on PFOS and believe it is an important step to help protect Mainers, it is important to recognize that PFOS is only one of many PFAS in consumer products posing a risk to our children. Rather than identify class members one by one, which would take an exorbitant amount of time and effort from the agency, as well as from manufacturers that would have to report their use, we strongly encourage DEP to address PFAS as a group. The legislature granted DEP the authority to add classes of chemicals to the lists of chemicals of concern, chemicals of high concern, and to designate a class as a Priority Chemical.^{viii} Given the structural similarities, the universal characteristic that PFAS are very persistent given their carbon-fluorine bonds,^{ix} and the consensus amongst independent scientists that we must take a class-based regulatory approach to avoid the

separate evaluation of 5,000 different members of the PFAS class,^x we urge DEP to expeditiously name PFAS as a class to the list of chemicals of concern, then the list of chemicals of high concern, and ultimately name the class as a priority chemical. This will allow the Department to collect information from manufacturers about their use all in one action and begin to explore the options for safer alternatives as expeditiously as possible.

We look forward to working with DEP to continue to address the challenges posed by PFOS and other PFAS chemicals. If you have any questions about our comments, please contact Patrick MacRoy at 207-699-5796 or PMacRoy@preventharm.org

Sincerely,



Patrick MacRoy
Deputy Director

ⁱ <https://www.maine.gov/dep/safechem/highconcern/index.html>

ⁱⁱ Information on all three topics are widely available, but are also summarized in Agency for Toxic Substances and Disease Registry (ATSDR). 2018. "Toxicological profile for Perfluoroalkyls. (Draft for Public Comment)." Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. Available at: <https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237>

ⁱⁱⁱ CEC. 2017. "Furthering the Understanding of the Migration of Chemicals from Consumer Products –A Study of Per- and Polyfluoroalkyl Substances (PFASs) in Clothing, Apparel, and Children's Items." Montreal, Canada: Commission for Environmental Cooperation. Available at: <http://www3.cec.org/islandora/en/item/11777-furthering-understanding-migration-chemicals-from-consumer-products-en.pdf>

^{iv} KEMI. 2015. "Occurrence and use of highly fluorinated substances and alternatives." Stockholm: Swedish Chemicals Agency.

^v American College of Obstetricians and Gynecologists. 2013 (Reaffirmed 2018). "Committee Opinion: Exposure to Toxic Environmental Agents." Available at: <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Exposure-to-Toxic-Environmental-Agents>

^{vi} Agency for Toxic Substances and Disease Registry (ATSDR). 2018. "Toxicological profile for Perfluoroalkyls. (Draft for Public Comment)." Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. Available at: <https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237>

^{vii} Although as a matter of law and policy, it should not be relevant, there is ample evidence that perfluoroalkyls, including PFOS, can be transferred to the fetus during pregnancy. See ATSDR Profile referenced above.

^{viii} 38 M.R.S. § 1694(2) – "'Chemical' means a substance with a distinct molecular composition or a group of structurally related substances and includes the breakdown products of the substance or substances that form through decomposition, degradation or metabolism." (Emphasis added).

^{ix} Brendel, et al. "Short-chain perfluoroalkyl acids: environmental concerns and a regulatory strategy under REACH." *Environ Sci Eur.* 2018; 30(1): 9. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5834591/>

^x Blum, et al. "The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)." *Environ. Health Perspect.* 123.5 (2015): A107-A111. Available at: <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1509934>