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March 9, 2020

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

3M Comments on Proposed Designation of PFOS and Its Salts as Priority Chemicals under Maine Toxic Chemicals in Children's Products Act

Dear Ms. Malinowski:

The 3M Company (3M) is providing detailed comments to the Maine Department of Environmental Protection (Maine DEP or the Department) on the proposed priority designation for perfluorooctane sulfonic acid (PFOS) and its salts under the Toxic Chemicals in Children's Products Act (the Act). 38 M.R.S.A. § 1691, *et seq*. We support the policy objectives of the Act and implementing regulations and we appreciate the opportunity to participate in this important stakeholder dialogue with the Department.

As a preliminary matter, 3M wishes to remind the Department that the vast body of scientific evidence does not show that PFOS and its salts cause adverse health effects in humans at the low current, or even historic, exposure levels found in the blood. This has been recently acknowledged by the U.S. federal Agency for Toxic Substances and Disease Registry (ATSDR) and by an Expert Health Panel assembled to advise the Australian federal government. *See* Section III.c.i.

A full review of the literature demonstrates that PFOS and its salts do not meet the hazard criteria for a Chemical of High Concern under the Act. These chemicals are therefore ineligible for prioritization. Furthermore, extensive federal efforts are already underway that involve information gathering on current uses of these chemicals, as well as proposing additional regulation. The Department's proposal is duplicative of these efforts, and the state's resources would be better used prioritizing other substances listed as Chemicals of High Concern.

I. 3M's Voluntary Phase-out and Declining Industry Uses of PFOS and Its Salts

As a science-based company, 3M has substantial experience and expertise with the breadth of issues mentioned in the Department's regulatory record regarding PFOS and its salts. As recognized in the PFAS Task Force Final Report, the levels of PFOS in the blood of the general population in the U.S. have declined sharply, and are expected to continue to decline, in

the years after 3M and other manufacturers voluntarily phased out PFOS and PFOA. *See* PFAS Task Force Final Report, January 2020 at p. 5. The Department's regulatory record confirms this. *See* Section IV.b. This is important context for the Department as it considers how to prioritize its resources among the many Chemicals of High Concern that may be eligible for prioritization.

II. Legal Background

Only chemicals listed as Chemicals of High Concern are eligible for designation as Priority Chemicals. 38 M.R.S.A. § 1694. In order to add a chemical to the Chemical of High Concern list, the Department must determine, in concurrence with the Maine Center for Disease Control and Prevention ("Maine CDC"), that there is "strong credible scientific evidence that the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen." *Id*. § 1693-A(2) (emphasis added). The term "credible scientific evidence" is defined as:

> the results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal or publication of an authoritative federal or international governmental agency, including but not limited to the United States Department of Health and Human Services, National Toxicology Program, Food and Drug Administration and Centers for Disease Control and Prevention; the United States Environmental Protection Agency; the World Health Organization; and the European Union, European Chemicals Agency.

Id. § 1691. The term "strong credible scientific evidence" is not defined in the Act or regulations, but has been interpreted by the Department to mean "a top-tiered weight-of-evidence determination by an authoritative federal or international government agency, or the presence of multiple scientific studies published in peer-reviewed scientific literature with consistent findings." Letter from Bruce Bates, Director, Maine CDC to Paul Mercer, Commissioner, Maine DEP, February 23, 2018 ("Maine CDC Letter") (emphasis added).[1]

When considering a Chemical of High Concern for priority designation, the Department must re-evaluate the chemical's hazard traits. Supplemental Basis Statement, Re-opened 06-096 CMR Chapter 880 at 5 ("Any chemical that is a candidate for priority designation will undergo further evaluation by the Department.").[2] This includes a review of "the most current credible scientific evidence, peer reviewed study, and risk assessment information available." Supplemental Basis Statement, Chapter 880 at 8.[3] Thus, the Department must re-confirm, taking into account the best and most recent research, that the chemical meets the hazard criteria of a Chemical of High Concern. This is particularly critical where, as here, several years have passed between a chemical's designation as a Chemical of High Concern and its consideration for priority designation.

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[1] Available at http://www.maine.gov/tools/whatsnew/attach.php?id=1587968&an=3.
[2] Available at https://www.maine.gov/dep/safechem/childrens-products/rules/ch880_suppl_basis_stmnt-Jun2012.pdf.
[3] Available at https://www.maine.gov/dep/safechem/childrens-products/rules/ch880_suppl_basis_stmnt-Feb2012.pdf.

The Department must consider other factors as well. According to the Department's regulations, it "shall consider," among other things, the need for additional information on existing uses of the chemical and whether designation is "necessary and appropriate in light of actions taken or underway with respect to the chemical in other states and jurisdictions." ME ADC 06-096 Ch. 880 § 4 (emphasis added). When promulgating the Act's framework regulations, the Department also pledged to consider as part of its priority determination, any "voluntary efforts" (i.e., phase-outs) regarding a chemical. Basis Statement, Chapter 880 at 28.[4]

It is readily apparent why these factors must be considered. First, the Department has limited resources that should not be used to duplicate efforts completed or underway in other jurisdictions. *Id*. ("It is not the intent of this rule to regulate chemicals that are already being adequately addressed at the federal or international level."). Second, priority designation imposes obligations on product manufacturers and distributors to confirm with supply chain partners that their products do not contain the designated chemical or, in the alternative, to file reports with the Department. These obligations should not be imposed when information about a chemical's use is already being collected or will be collected and published by other bodies. ME ADC 06-096 Ch. 880 § 4 (acknowledging the "burden of disclosure on product manufacturers and distributors" and discouraging the Department from requiring disclosure of information that "already is available or otherwise is not needed").

Finally, when considering a chemical for priority designation, Maine's Administrative Procedure Act requires the Department's findings to be presented in sufficient detail to allow meaningful public participation. 5 M.R.S.A. § 8052.

III. Comments on Proposed Priority Designation

a. There is No Indication the Department or Maine CDC Have Analyzed Peer-Reviewed Literature in More Than Five Years

The Department has not met its obligation to consider "the most current" peer-reviewed literature on PFOS and its salts when proposing them for priority designation. In the last five years, the potential hazard characteristics of these chemicals have been intensely reviewed by many teams of scientists. Yet the record is devoid of any indication that the Department (or Maine CDC) have reviewed any of the resulting peer-reviewed literature, let alone taken the literature into account, when proposing PFOS and its salts for priority designation.

The Department's record on hazard characteristics consists of little more than a list of studies compiled by Maine CDC. Maine CDC Letter Appendix 1 at 7-8. This list is identical to a list Maine CDC published five years ago. *Compare* CDC Letter Appendix 1 at 7-8 *with* Chemicals of High Concern, Triennial Update Documentation, July 21, 2015 ("CHC 2015 Update") Appendix 1 at 31-32.[5] The Department's record references no peer-reviewed human toxicity studies more recent than 2014 and no peer-reviewed animal toxicity studies more recent

[4] Available at https://www.maine.gov/dep/safechem/childrens-products/rules/ch880_basis_statement.pdf.
[5] Available at https://www1.maine.gov/dep/safechem/childrens-products/highconcern/index.html. The two Appendices to this document are also available for download at this address.

than 2009. The Maine CDC Letter confirms that Maine CDC's opinions regarding the scientific literature rely wholly on "previously identified" studies, i.e., studies listed in the CHC 2015 Update. Maine CDC Letter at 2; *see also* Maine CDC Letter Appendix 1 at 1.

This is a critical lapse. In the last five years, more than one hundred toxicology and epidemiology studies have been published. Some of these studies call into question the meaning of studies cited by Maine CDC. *See* Section III.c.i. Many of these studies are on primates and are therefore more meaningful than studies on rodents. *Id.* The more recent studies do not show health effects in humans or primates at perfluoroalkyl serum levels many times U.S. averages. *Id*. The Department, in conjunction with Maine CDC, should fulfill its obligation to review "the most current" scientific literature available.

b. The Department's Record Contains Insufficient Detail to Allow Meaningful Public Participation

The Department's recent public record contains no scientific analysis on the hazard characteristics of PFOS and its salts. The Maine CDC Letter, for example, merely contains legal conclusions supported only by a list of studies. The letter does not analyze, explain, or even identify what "strong credible scientific evidence" these studies might provide to support its legal conclusion. Because the Department failed to include a detailed discussion of hazard characteristics, 3M must limit its comments largely to general points, along with a few specific considerations.

Documents previously released by the Department or Maine CDC also contain little or no analysis. In 2015, Maine CDC released a set of documents purporting to establish that PFOS and its salts (among other chemicals) possessed the hazard criteria necessary for listing as Chemicals of High Concern. CHC 2015 Update. Yet these documents also contain a legal conclusion supported solely by a list of studies, with no analysis. CHC 2015 Update at 9 (legal conclusion: "PFOS meets the toxicity criteria . . . with strong credible evidence to be appropriately listed as a CHC"); CHC 2015 Update Appendix I at 31-32 (list of studies as sole support of legal conclusion).

A 2012 Maine CDC document cites a single peer-reviewed paper studying the potential effects of PFOS in humans. Deriving Chemicals of High Concern, Process Documentation, June 27, 2012 at 12, *citing* Shankar, et al. (2011).[6] This document briefly explains why the study made Maine CDC believe, at the time, that PFOS could affect human kidney function. However, Maine CDC does not acknowledge other more recent peer-reviewed studies, which noted an absence of PFOS-related effects on renal functions in primates. *See*, *e.g.*, Chang, et al. 2017.[7] This was true even when serum PFOS concentration reached as high as 175,000 parts per billion (ppb). For reference, per a study cited in the Maine CDC Letter, mean PFOS serum levels in the

[6] Shankar, A.; Xiao, J., and Ducatman, A. (2011). Perfluoroalkyl Chemicals and Chronic Kidney Disease in US Adults. *American Journal of Epidemiology* 174 (8): 893–900.

[7] Chang, S., Allen, B.C., Andres, K.L., Ehresman, D.J., Falvo, R., Provencher, A., Olsen, G.W., and Butenhoff, J.L. (2017). Evaluation of serum lipid, thyroid, and hepatic clinical chemistries in association with serum perfluorooctanesulfonate (pfos) in cynomolgus monkeys after oral dosing with potassium pfos. *Toxicol Sci* 156, 387-401.

U.S. were about 5 ppb in 2013-14, and were trending downward. Maine CDC Letter, Appendix 1 at 5.

Additionally, ATSDR concluded recently that studies analyzing the effects of perfluoroalkyls on renal functions "are not consistent across study populations." ATSDR Toxicological Profile for Perfluoroalkyls, Draft for Public Comment, June 2018 (ATSDR 2018 Analysis) at 210.[8] Even for those few studies that correlated perfluoroalkyl levels and renal function, ATSDR noted that "these alterations may be due to reverse causality." *Id.* In sum, studies do not consistently show effects on renal function in either humans or primates, and no causal link has been established. Therefore there is no "strong credible scientific evidence" (i.e., "multiple scientific studies . . . with consistent findings") to support a continued designation as a Chemical of High Concern.

Regarding each of the other peer-reviewed studies cited in the Department's record (none more recent than 2014), neither the Department nor Maine CDC provide any analysis. No explanation is provided, for example, why only 21 hazard studies were cited in the 2018 Maine CDC Letter, but more than one hundred other available studies were not considered. This is particularly critical because the "strong credible scientific evidence" standard means that the peer-reviewed studies should have "consistent findings." As discussed below, when considering all of the available peer-reviewed literature, both ATSDR and the Australian Expert Health Panel recently concluded that the vast body of scientific evidence does not show that PFAS causes adverse health effects in humans at current exposure levels. The Department's lack of analysis precludes a meaningful dialogue with stakeholders on this critical issue.

c. PFOS and its Salts Do Not Meet Chemical of High Concern Hazard Criteria

Considering all available evidence, PFOS and its salts do not qualify as Chemicals of High Concern under the Act. There is no "strong credible scientific evidence" that these chemicals meet the toxicity criteria, i.e., that they are reproductive or developmental toxicants, endocrine disruptors, or human carcinogens. 38 M.R.S.A. § 1693-A(2). The Department was required to, but did not, meaningfully reconsider this issue when it proposed these chemicals for priority designation. Since these chemicals do not qualify as Chemicals of High Concern, they are ineligible for priority designation. *Id.* § 1694.

The Maine CDC Letter cites two factors in concluding that PFOS "continues to meet the toxicity criteria for listing as a chemical of high concern." Maine CDC Letter Appendix 1 at 4. First, Maine CDC cites its 2015 literature review which, as discussed above, is both out of date and wholly lacking in analysis. Second, Maine CDC cites Japan's 2017 listing for PFOS in its Globally Harmonized System of Classification and Labelling of Chemicals (GHS) database. However, the letter fails to mention contrary conclusions by ATSDR and the Australian Expert Health Panel, and fails to account for the dozens of other countries that have implemented GHS but have not implemented a top-tier listing for PFOS.

[8] Available at https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.

i. Peer-Reviewed Literature Does Not Provide "Strong Credible Scientific Evidence" that PFOS and its Salts Meet the Chemical of High Concern Hazard Criteria

The vast body of scientific evidence does not show that PFOS and its salts cause adverse health effects in humans. This is true both at historical exposure levels and at current exposure levels, which are much lower after voluntary phase-outs and regulation on the use of these chemicals.

Lack of observed effects in humans. Two authoritative bodies have recently reviewed current research and concurred about the lack of health effects in humans. ATSDR recently concluded regarding perfluoroalkyls: "The available human studies have identified some potential targets of toxicity; however, cause and effect relationships have not been established for any of the effects, and the effects have not been consistently found in all studies." ATSDR 2018 Analysis at 635-36 (emphasis added).[9]

The Australian Expert Health Panel concluded in March 2018 that "there is mostly limited or no evidence for any link with human disease from these observed differences. Importantly, there is no current evidence that supports a large impact on a person's health as a result of high levels of PFAS exposure." Expert Health Panel for PFAS: Summary at 2 (emphasis added).[10] The report further stated: "After considering all of the evidence, the Panel's advice . . . is that the evidence does not support any specific health or disease screening or other health interventions for highly exposed groups in Australia, except for research purposes." *Id.* (emphasis added). Like ATSDR, the Australian Expert Health Panel analyzed hundreds of studies when reaching this conclusion. Expert Health Panel for Per- and Poly-Fluoroalkyl Substances (PFAS), March 2018 at 382-403.[11]

Additionally, in its brief list of human studies considered, Maine CDC fails to include key studies that limit the significance of studies it did cite. Maine CDC cites Fei et al. (2009),[12] but the conclusions of this paper were called into question by Olsen et al. (2009),[13] which cited several "troubling issue[s]" in the Fei study. Fei et al. acknowledged in 2012 that the potential causal connections between perfluoroalkyls and fertility they alleged in 2009 could also be explained by reverse causality. Fei et al. (2012).[14] The latter Fei et al. paper is not included in Maine CDC's bibliography. Maine CDC also failed to cite a Whitworth et al. paper on the same topic, which concludes "we found no evidence of an adverse effect on subfecundity at the

[9] Available at https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.
[10] Available at https://www1.health.gov.au/internet/main/publishing.nsf/Content/C9734ED6BE238EC0CA2581BD00052C03/$File/summary-panels-findings.pdf.
[11] Available at https://www1.health.gov.au/internet/main/publishing.nsf/Content/C9734ED6BE238EC0CA2581BD00052C03/$File/expert-panel-report.pdf.
[12] Fei, C. McLaughlin, J.K., Lipworth, L. Olsen, J., 2009. Maternal levels of perfluorinated chemicals and subfecundity. *Human Reproduction*, 24, 1200-1205.
[13] Olsen, G.W., Butenhoff, J.L., Zobel, L.R., 2009. Perfluoroalkyl chemicals and human fetal development: an epidemiologic review with clinical and toxicological perspectives. *Reprod Toxicol*, 27, 212-230.
[14] Fei, C., Weinberg, C.R., Olsen, J., 2012. Commentary: perfluorinated chemicals and time to pregnancy: a link based on reverse causation? *Epidemiology*, 23, 264-266.

[perfluorinated chemicals] levels in our population." Whitworth et al. (2012).[15] Also not cited is a Bach et al. paper assessing human epidemiologic studies regarding PFAS and fertility and concluding that available evidence "failed to support a causal relationship between PFAS exposure and fertility in women." [16] In sum, there is no "strong credible scientific evidence" (i.e., "multiple scientific studies … with consistent findings") that PFOS causes health effects in humans.

Lack of observed effects in primates. Maine CDC's bibliography of animal studies is also overly reliant on rodent studies. Ten out of the eleven animal studies cited by Maine CDC focus on rodents, and only one focuses on primates. Peer-reviewed research has confirmed that rodents may not be the most appropriate species for human hazard assessments of PFOS due to differences in mode of action in rodents relative to humans. Klaunig et al., 2012.[17] In particular, the significance of one of the studies cited by Maine CDC (Luebker et al., 2005) has been called into question because in toxicology studies with PFOS, the inactivation of nuclear receptor PPARα in mice can attenuate or completely minimize the developmental toxicity seen in pups, along with other toxicity endpoints. Abbot et al., 2009;[18] Abbott et al., 2007;[19] Albrecht et al., 2013.[20] The relevance of the Luebker study cited by Maine CDC and its relevance to humans is questionable given the lower prevalence of PPARα in humans. Whereas agencies in the past have applied uncertainty factors based on the conservative assumption that humans are more sensitive than rodents to perfluoroalkyls, published data support the opposite conclusion. *Id*.

Maine CDC and the Department should therefore more thoroughly review primate studies. Primates have always been valued as the most scientifically appropriate species for human risk assessment because it is the second-highest order species next to humans. The single primate study cited by Maine CDC, Seacat et al., 2002, was reevaluated more recently based on questions raised by the interpretation of the data. Chang et al., 2017. The reevaluation showed a consistent absence of the effects from PFOS in thyroid functions, liver functions, renal functions, electrolytes, and coagulations both prior to and after PFOS treatments in monkeys, where serum PFOS concentration reached as high as 175,000 ppb. This is orders of magnitude larger than mean PFOS serum concentration in the U.S. population (5 ppb) according to sources cited by Maine CDC. *See* Maine CDC Letter, Appendix 1 at 5.

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[15] Whitworth, K.W., Haug, L.S. Baird, D.D., Becher, G., Hoppin, J.A., Skjaerven, R., Thomsen, C., Eggesbo, M., Travlos, G., Wilson, R., Cupul-Uicab, L.A., Brantsaeter, A.L., Longnecker, M.P., (2012). Perfluorinated compounds in relation to birth weight in the Norwegian mother and child cohort study. *Am J Epidemiol*, 175, 1209-1216.

[16] Bach, C.C., Vested, A., Jorgensen, L.T., Bonde, J.P.E., Henriksen, T.B., and Toft, F. (2016) Perfluoroalkyl and polyfluoroalkyl substances and measures of human fertility: a systematic review. *Crit. Rev. Toxicol.* 46:735-55.

[17] Klaunig, J.E., Hocevar, B.A., and Kamendulis, L.M. (2012). Mode of Action analysis of perfluorooctanoic acid (PFOA) tumorigenicity and Human Relevance. *Reprod Toxicol*. 33, 410-8.

[18] Abbott, B.D., Wolf, C.J., Das, K., Zehr, R.D., Schmid, J.E., Lindstron, A.B., Strynar, M.J., and Lau, C. (2009). Developmental Toxicity of Perluorooctane Sulfonate (PFOS) is not dependent on expression of Peroxisome Prooliferator activated Receptor-alpha (PPARa) in the mouse. *Reproductive Toxicology*. 27, 258-265.

[19] Abbott, B.D., Wolf, C.J., Schmid, J.E., Das, K.P., Zehr, R.D., Helfant, L., Nakayama, S., Lindstrom, A.B., Strynar, M.J., and Lau, C. (2007). Perluorooctanoic acid induced developmental toxicity in the mouse is dependent on expression of peroxisome proliferator activated receptor-alpha. *Toxicol. Sci.* 98(2), 571-81.

[20] Albrecht, P.P., Torsell, N.E., Krishnan, P., Ehresman, D.J., Frame, S.R., Chang, S.C., Butenhoff, J.L., Kennedy, G.L., Gonzalez, F.J., and Peters, J.M. (2013). A species difference in the peroxisome proliferator-activated receptor alpha-dependent response to the developmental effects of perfluorooctanoic acid. *Toxicol Sci.* 131, 568-82.

Lack of endocrine disruption. There is also an absence of data in the literature suggesting PFOS is an endocrine disruptor. If it were, one would expect to observe: (1) disruption of reproduction in second generation studies; and (2) an indication that PFOS can act directly with endocrine receptors, such as estrogen receptors and thyroid receptors. In fact, neither effect has been observed. Data from large scale 2-generation reproductive and developmental studies (which are considered the most comprehensive test by various agencies for evaluating potential endocrine disruption), show that PFOS does not affect reproductive functions or performances in either males or females across multiple generations. Additionally, Ishibashi et al. (2007) reported that PFOS cannot directly activate human estrogen receptor α or β.[21] In a collaboration between 3M and the Mayo Clinic, no activation of human thyroid receptor α was observed when exposed to PFOS. Ehresman et al., 2014.[22]

ii. The Japanese GHS Listing for PFOS is Not "Strong Credible Scientific Evidence" that PFOS and its Salts Meet the Chemical of High Concern Hazard Criteria

The Maine CDC Letter also relies on a single top-tier listing for PFOS by the Japanese government in their GHS database. But the letter fails to mention that subsequent to this 2017 Japanese listing, two other bodies – ATSDR and the Australian Expert Panel – questioned the link between PFOS and human health effects. The Japanese listing alone therefore does not provide "strong credible scientific evidence" that PFOS and its salts meet the Chemical of High Concern hazard criteria.

IV. PFOS and Its Salts Should Not Be Designated as Priority Chemicals

PFOS and its salts do not meet any of the criteria that would make designation as priority chemicals appropriate.

a. PFOS and Its Salts Do Not Meet the Hazard Criteria of a Chemical of High Concern

As described in detail in Section III.c above, there is no "strong credible scientific evidence" that PFOS and its salts meet the hazard criteria for a Chemical of High Concern. This precludes listing PFOS and its salts as Priority Chemicals.

b. PFOS Are Being Phased Out and Are Declining in Serum

PFOS serum levels have consistently decreased in the U.S. population for at least 15 years. The Maine CDC Letter acknowledges these "steadily decreasing" levels and notes that they "likely reflec[t] the phaseout of PFOS manufacturing, and import and use reductions in the U.S. over this period." Maine CDC Letter Appendix 1 at 4. 3M agrees. As the Maine CDC

[21] Ishibashi, H., Ishida, H., Matsuoka, M., Tominaga, N., and Arizono, K. (2007). Estrogenic effects of fluorotelomer alcohols for human estrogen receptor isoforms alpha and beta in vitro. *Biol Pharm Bull*. 30, 1358-9.
[22] Ehresman, D.J., Webb, P., Ayers, S., Vanden Heuvel, J., Olsen, G.W., Chang, S.C., and Butenhoff, J.L. (2014). Effects of perfluoroalkyls on the activation of human CAR3, PXR, TRα, and TRβ in vitro (abstract 1135). *The Toxicologist*. 138, 302.

Letter acknowledges, PFOS serum levels decreased by approximately a factor of six between 1999-2000 and the most recent years for which data is available (2013-14). *Id*. at 5. *See also* PFAS Task Force Final Report, dated January 2020, at p. 5 ("since 1999 the measured levels of PFOS and PFOA in the blood serum of NHANES participants have decreased by about 80 percent."). In addition, 3M proactively started a perfluoroalkyl biomonitoring program with the American Red Cross adult blood donors. The most recent publication, which examined samples collected in 2015, also reported declining trends. Olsen et al. 2017.[23]

3M expects this trend to continue. This is due to the precise type of "voluntary efforts" that the Department pledged to consider as part of prioritization decisions. *See* Section II. As PFOS uses continue to decrease along with human serum levels, the need for the Department to begin gathering information and potentially consider restrictions also decreases. This weighs strongly towards prioritizing action on other chemicals.

c. The Proposed Designation is Duplicative of Federal Actions

Various federal initiatives are collectively evaluating the current uses of PFAS and how to address them. Those initiatives will generate a trove of public information that will be largely duplicative of the information the Department seeks to collect by designating PFAS as a Priority Chemical. Under the Department's own regulations, this weighs against prioritizing PFAS. ME ADC 06-096 Ch. 880 § 4 (stating that the Department "shall consider" the need for additional information "in light of actions taken or underway with respect to the chemical in other states and jurisdictions") (emphasis added). For these reasons, it would be a better use of Maine's resources to prioritize the study of other chemicals.

With the launch of EPA's PFAS Action Plan in 2019, EPA is taking a proactive, cross-agency approach to evaluating uses of PFAS (including PFOS and its salts) and potential restrictions on these uses. EPA has already taken steps towards establishing a federal maximum contaminant level for PFAS under the Safe Drinking Water Act and has already finalized guidance on soil and groundwater remediation standards for PFOS.

On December 20, 2019, the National Defense Authorization Act (NDAA) was signed into law, which includes several provisions that increase research, reporting, and monitoring obligations related to PFAS and accelerate the pace of certain initiatives already underway pursuant to EPA's PFAS Action Plan. Specifically, the NDAA:

- Provided money for research on PFAS;

- Will require manufacturers of PFAS to report detailed information about the PFAS substances they manufacture under a Significant New Use Rule to be issued under the Toxic Substances Control Act;

[23] Olsen, G.W., Mair, D.C., Lange, C.C., Harrington, L.M., Church, T.R., Goldberg, C.L., Herron, R.M., Hanna, H., Nobiletti, J.B., Rios, J.A., Reagen, W.K., and Ley, C.A. (2017). Per- and polyfluoalkyl substances (PFAS) in American Red Cross adult blood donors, 2000-2015. *Environ Res.* 157, 87-95.

- Added more than 600 PFAS substances to the Toxics Release Inventory effective January 1, 2020;

- Requires EPA to issue interim guidance within one year on the destruction and disposal of PFAS and materials containing PFAS, including aqueous film-forming foam; soil and biosolids; textiles (other than consumer goods) treated with PFAS; spent filters, membranes, resins, granular carbon, and other waste from water treatment; landfill leachate containing PFAS; and solid, liquid, or gas waste streams containing PFAS from facilities manufacturing or using PFAS; and

- Requires EPA to include any PFAS for which a method to measure the level of drinking water has been validated by EPA and is not already subject to a national primary drinking water standard in the fifth publication of the list of unregulated contaminants to be monitored.

Further information gathering by the Department under the Act would be duplicative, and would therefore be an inefficient use of public resources and an unnecessary burden to the regulated community. Additionally, the expected continued decline in PFOS use would make any future Maine restrictions on the use of PFOS and its salts in consumer products unnecessary.

3M appreciates the opportunity to provide these comments. Thank you for your consideration.

Regards,

Oyebode A. Taiwo, MD, MPH

Burke, Ruth A

From: Grace & Craig Cain <thecains@roadrunner.com>
Sent: Thursday, February 06, 2020 10:19 AM
To: DEP Rule Comments
Subject: Designation of PFOS as a priority chemical

I am writing to support this regulation. This is a good first step, I am glad that there will be reporting but ideally product labelling is essential to help consumers make informed choices.
Thank you,
Grace Cain
Kennebunk

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 precursors[i].

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 $C_8F_{17}SO_2$, $C_8F_{17}SO_3$ or $C_8F_{17}SO_2N$ 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

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[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

[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

ENVIRONMENTAL HEALTH STRATEGY CENTER

Healthy families, thriving in a healthy economy

May 6, 2019

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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:

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 concern[i] 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.

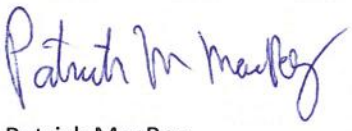
With this addition, we support DEP's broad inclusion of the universe of products covered under KSPA for reporting under the proposed chapter 890.

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

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[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

TWIN RIVERS
PAPER COMPANY

May 6, 2019

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

Re: Comments on proposed Chapter 890

Dear Ms. Malinowski:

Thank you for the opportunity to comment on the proposed Chapter in which would designate perfluorooctane sulfonic acid (PFOS) as a priority chemical.

Simply put, based on the available information, Twin Rivers Paper Company supports the rule as drafted for the public hearing held on April 23, 2019.

Please let me know if you have any questions.

Sincerely,

Mick

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