January 28, 2025

Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333

Re: Comments on the Concept Draft for PFAS in Products Program

Dear Board of Environmental Protection,

Thank you for the opportunity to provide comments on the draft rules for Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances. Below you will find the Natural Resources Defense Council's comments on the draft rule. We appreciate the work that the Department has done to draft this language. We do, however, have concerns with some of the language in the draft.

The idea of essential use was first introduced in the Montreal Protocol, which addresses environmental harms caused by ozone-depleting substances by setting a timetable for phasing them out, with time-limited exemptions for essential uses.[1]

Since then, the concept has been proposed for broader use and further developed by experts in chemical regulation and PFAS as a way to systematically, efficiently, and transparently reduce unnecessary uses of chemicals of concern, including PFAS - a task that is urgently needed in response to the PFAS crisis.[2] Most recently, Bălan et al., 2023, published a paper intended to

[1] Ozone Secretariat. "Handbook for the Montreal Protocol on Substances That Deplete the Ozone Layer." United Nations Environment Programme, May 1991. https://p2infohouse.org/ref/17/16875.pdf; D'Souza, Sheila. "The Montreal Protocol and Essential Use Exemptions." *Journal of Aerosol Medicine* 8, no. s1 (January 1995): S-13. https://doi.org/10.1089/jam.1995.8.Suppl_1.S-13.

[2] Cousins, Ian T., Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, Carla A. Ng, Sharyle Patton, et al. "The Concept of Essential Use for Determining When Uses of PFASs Can Be Phased Out." *Environmental Science: Processes & Impacts* 21, no. 11 (November 13, 2019): 1803–15. https://doi.org/10.1039/C9EM00163H; Glüge, Juliane, Rachel London, Ian T. Cousins, Jamie DeWitt, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, et al. "Information Requirements under the Essential-Use Concept: PFAS Case Studies." *Environmental Science & Technology* 56, no. 10 (May 17, 2022): 6232–42. https://doi.org/10.1021/acs.est.1c03732; Cousins, Ian T., Jamie C. De Witt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, et al. "Finding Essentiality Feasible: Common Questions and Misinterpretations Concerning the 'Essential-Use' Concept." *Environmental Science. Processes & Impacts* 23, no. 8 (August 1, 2021): 1079–87. https://doi.org/10.1039/d1em00180a.

describe the optimal implementation of this concept in the US and Canada.[3] We have summarized this in an issue brief that provides concrete examples of the essential use concept.[4]

Furthermore, in 2020, the European Union released its Chemicals Strategy for Sustainability, calling for phasing out use of the most harmful chemicals such as PFAS and endocrine disruptors, except for uses that are determined to be essential for society.[5] The EU Commission followed this call with the publication of "Guiding Criteria and Principles for the Essential Use Concept in EU Legislation Dealing with Chemicals" in 2024.[6] The main principles and criteria for implementing this concept generally align between all of the scientific papers, commentaries, and authoritative bodies in the EU. Unfortunately, these well-reasoned and peer reviewed principles and criteria are not reflected in Maine's draft regulations.

In practice the concept is straightforward, and is addressed by answering the following three questions when applied to PFAS use: 1) Are there no safer alternatives to PFAS that are reasonably available? (2) Is the function provided by PFAS in the product necessary for the product to work?[7] (3) Is the use of PFAS in the product critical for health, safety, or the functioning of society? The answer to all three questions must be yes in order to justify continued use of a class of chemicals as concerning as PFAS (receive a "currently unavoidable use" or CUU exemption).[8]

Maine's draft regulations, however, conflates several concepts, risks confusion as to what qualifies for a CUU exemption, and creates unnecessary burdens for both regulated entities and the agency. We recommend the following changes to address these issues:

1) The criteria for making a CUU determination should be clearly stated and align with current thinking on the essential use concept.

---

[3] Bălan, Simona A., David Q. Andrews, Arlene Blum, Miriam L. Diamond, Seth Rojello Fernández, Elizabeth Harriman, Andrew B. Lindstrom, et al. "Optimizing Chemicals Management in the United States and Canada through the Essential-Use Approach." *Environmental Science & Technology*, January 19, 2023. https://doi.org/10.1021/acs.est.2c05932.

[4] Reade, Anna. "The Essential-Use Approach: A Policy Tool for Reducing Exposures to Toxic Chemicals." NRDC, January 31, 2023. https://www.nrdc.org/resources/essential-use-approach-policy-tool-reducing-exposures-toxic-chemicals.

[5] Scholz, Stefan, Werner Brack, Beate I. Escher, Jörg Hackermüller, Matthias Liess, Martin von Bergen, Lukas Y. Wick, Ana C. Zenclussen, and Rolf Altenburger. "The EU Chemicals Strategy for Sustainability: An Opportunity to Develop New Approaches for Hazard and Risk Assessment." *Archives of Toxicology* 96, no. 8 (August 1, 2022): 2381–86. https://doi.org/10.1007/s00204-022-03313-2.

[6] EU Commission. "Guiding Criteria and Principles for the Essential Use Concept in EU Legislation Dealing with Chemicals," 2024. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52024XC02894.

[7] As the EU Commission points out, "Technical functions of most harmful substances that only impart properties relating to convenience, leisure, decoration or luxury to the user of the final product should normally not be deemed necessary for health or safety or critical for the functioning of society."

[8] In the EU guiding criteria and principles, the three questions they recommend considering are laid out in Figure 1 on page 9 (two of the questions are articulated in Step 1 and the other question is in Step 2) and accompanying discussion thereafter.

2) The information being requested in the draft rule should align with the criteria for CUU decision making and should not introduce extraneous considerations.
3) The definition of "reasonably available" undermines the essential use concept and should be changed to better reflect the statue.

1) CUU Criteria Should be Clearly Identified in One place

We recommend that the Department align its criteria for determining CUU with established scientific literature and the guidance prepared by the EU Commission. In short, the use of PFAS in a product category is a CUU only if all the following criteria are met: (1) There are no safer alternatives to PFAS that are reasonably available. (2) The function provided by PFAS in the product is necessary for the product to work. (3) The use of PFAS in the product is critical for health, safety, or the functioning of society.

Recommended change (in red strikeout and underline):

Insert a new Subsection 9.A with CUU criteria:

9. Currently Unavoidable Use.

A. A use of PFAS is a currently unavoidable use only if all of the following criteria are met: (1) There are no safer alternatives to PFAS that are reasonably available. (2) The function provided by PFAS in the product is necessary for the product to work. (3) The use of PFAS in the product is critical for health, safety, or the functioning of society.

~~A~~ B. Proposal for Currently Unavoidable Use Determinations.

2) Only Information Relevant to the CUU Criteria Should be Required from Manufacturers

It is troubling to see risk-based information and analysis requested from manufacturers in the Department's draft rules. As is implied by the name, the essential-use approach is designed to aid policymakers in discontinuing any non-essential uses of chemicals of concern in products or processes where they are not critical for health, safety, or the function of society. The idea of the essential-use approach is not to perform analysis of levels of exposure or risk from particular uses of a chemical or chemicals of concern. Instead, it proposes that chemicals whose use poses a hazard to human health and the environment should only be used when absolutely necessary. The Maine legislature has already determined that any use of PFAS, especially when considering their lifecycle, is of serious concern and should be avoided whenever possible. Thus the essential use concept - using the clear, established criteria we outline above - is the only relevant approach here. The essential use concept should not be tied to risk-based

decision making or tack on additional analysis of exposures, which would only serve to undermine the concept and create unnecessary reporting, analysis and review.

Recommended changes:
Delete all risk and exposure information required and anything else not related to the CUU criteria and align information request to CUU criteria.

B.~~A~~ Proposal for Currently Unavoidable Use Determinations.

Proposals for currently unavoidable use ("CUU") determinations may be submitted by manufacturers individually or collectively. A separate proposal must be submitted for each individual combination of product category and the associated industrial sector. The Department requests that manufacturers submit their proposals to PFASProducts@maine.gov with a subject line of "CUU Proposal for [GPC/HTC] in [NAICS] sector by [Proposal Submitter's Name or Organization]".

For initial currently unavoidable use proposals, the requester shall submit the information in this section no later than 18 months prior to the applicable sales prohibition. The Department will not consider any proposals for an initial currently unavoidable use determination prior to 36 months in advance of the applicable sales prohibition; any proposals received prior to this date will need to be updated and resubmitted between 36 and 18 months before the effective date of the applicable sales prohibition (with the exception of CUU proposals for sales prohibitions taking effect 2026, which must be submitted no later than June 1, 2025). Proposals received after the 18 months prior to the sales prohibition effective date may be evaluated for inclusion in a subsequent rulemaking. Proposals received after the sales prohibition is in effect will be evaluated for inclusion in a subsequent Department CUU rulemaking.

A proposal must, at a minimum, contain:
(1) A brief description of the type of product to which PFAS is intentionally added including:

(a) A brief narrative of the product; its physical structure and appearance; how it functions; and if applicable its place in larger items, systems, or processes;
(b) If applicable, the Global Product Classification (GPC) brick category and code, or if GPC is not applicable then the Harmonized Tariff System (HTS) code; and
(c) The North American Industry Classification System (NAICS) code for the sector
or sectors in which the products containing intentionally added PFAS will be utilized.

(2) An explanation of why the ~~availability~~ use of PFAS in the specific product identified in subsection 1 is essential for health, safety or the functioning of society. This may include or take the form of a description of the negative impact that would be caused by the unavailability of PFAS for use in the product and the subsequent unavailability

~~or unsatisfactory performance~~ of the product; [Note: The recommended deletion of "unsatisfactory performance" is related to the comments provided further below that criteria such as this insert extra-statutory considerations into the analysis of reasonable availability of alternatives. In addition, for consistency with subsection (3) below and with the recommended criteria above, we recommend modifying the language to reference "use of PFAS" instead of availability.]

(3) A description of how the specific use of PFAS in the product is essential to the function of the product. Including:

(a) If this use of PFAS is required by federal or state law or regulation, provide citations to that requirement. For the purposes of this subsection, "required" means the applicable statute or regulation specifically states that PFAS or a specific PFAS is required to be present in the product, not that the proposer's understanding or experience of PFAS is necessary to meet a performance standard; such performance standards may be addressed in subsection b, below;

and

NOTE: Products required to meet certain federal standards or regulated under certain federal programs are exempt from this Chapter. See section 4 for more information.

(b) ~~The required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals.~~ The function provided by PFAS in the product and why it is necessary for the product to work, i.e., required for the product to perform its primary function.

(4) Evidence that demonstrates that there no safer alternatives to the use of PFAS that are reasonably available, inclusive of materials, processes, designs, products, or chemicals, and that are sufficient for achieving the primary function provided by the product. ~~*A description of whether there are alternatives for this specific use of PFAS which are*~~

~~reasonably available including:~~

~~(a) Identification of specific compounds, classes of materials, or combinations of materials identified as potential alternatives including the removal of PFAS without substitution;~~

~~(b) An assessment of how the materials in subsection a, above, meet or fail to meet the criteria identified in 3(b);~~

~~(c) An assessment if materials identified in subsection a, above, are anticipated to be available in sufficient quantities to meet production needs without regard to cost;~~

~~(d) An assessment of the anticipated cost difference between obtaining PFAS for use in a product and obtaining the material identified in (a), for the same purpose;~~

~~(e) A comparison of the known risks to human health and the environment between PFAS and the materials identified in (a); and~~

~~(f) An assessment of whether there are feasible changes to the manufacturing process of the product that would eliminate the need for PFAS.~~

(5) A list of federal regulations, other State of Maine rules, and regulations of other states which the product described in subsection 1 is subject to by reason of containing

intentionally added PFAS, including;

(a) Details of any sales prohibition the product is subject to because of containing intentionally added PFAS including;

(i) Whether that sales prohibition is absolute or if there is a process similar to the State of Maine's currently unavoidable use determination.

(ii) If there is a similar process available, whether the requester has filed a proposal under the relevant state or federal program, and its status.

(6) If, in another jurisdiction the product is subject to an absolute prohibition or no currently unavoidable use determination or similar has been made, a list of comparable products that the proposer is aware of remaining available for sale, offered for sale, or distributed for sale within that jurisdiction;

(7) If a similar program's sales prohibition is identified as applicable in subsection 5 and similar products are available for sale, offered for sale, or distributed for sale;

(a) A justification explaining how products available in compliance with other similar sales prohibitions are not reasonably available alternatives for the product subject to the proposed CUU in the State of Maine. This may include demonstrating that additional sales in the State of Maine would result in such an increased demand for the PFAS alternative that it would no longer be available in sufficient quantities, such a demonstration must include an assessment that an increase in production of the PFAS alternative is not possible; or

(b) Documentation demonstrating that products containing PFAS alternatives in other jurisdictions would not perform as intended in the State of Maine due to differing physical or climate conditions in the State of Maine;

(8) Contact information for the submitter of the proposal. The contact person or persons should be familiar with the contents of the proposal and, if necessary, be able to answer Department questions or provide additional requested information.~~; and~~

~~(9) Any information known or reasonably ascertainable by the manufacturer regarding the impacts on human health or the environment of PFAS in the product. At a minimum this should include the following items, if available;~~

~~(a) Any information documenting impacts on human health as a result of the specific use of PFAS in the product;~~

~~(b) A description of the likely pathways of human exposure for the specific use of PFAS in the product;~~

~~(c) Any information documenting environmental impacts as a result of the specific use of PFAS in the product;~~

~~(d) A description of any likely pathways for environmental release of PFAS as a result of the specific use of PFAS in the product; and~~

~~(e) A description of the product's fate at the end of its lifecycle. This should include;~~

~~(i) Documentation of any product stewardship programs or other government imposed processes at the end of a product's lifecycle,~~

~~(ii) How the product is intended to be disposed of, such as landfilling or via a~~

~~sewage or septage system, and~~
~~(iii)The recycling rate of the product.~~

Information submitted to the Department must contain sufficient detail or supporting documentation to satisfy the requirements of the currently unavoidable use as essential for health, safety or the functioning of society for which alternatives are not reasonably available.

If any of the information above is omitted from the proposal, the requestor must explain why this information is omitted.

3) The definition of "reasonably available" should be changed to better reflect the statute

In the draft rules, the Department proposed to define "reasonably available" with respect to alternatives as:

> *"Reasonably available" means a PFAS alternative which is readily available in sufficient quantity and at a comparable cost to the PFAS, to include changes to the manufacturing process, it is intended to replace and performs as well as or better than PFAS in a specific application of PFAS in a product or product component*

The definition includes two problematic components.

First, the criterion of "performs as well or better than PFAS in a specific application of PFAS" has no connection to the concept of a "reasonably available" alternative since it does not relate to availability. It's not clear why this criterion is being added to the consideration of the reasonable availability of alternatives. Performing as well or better than PFAS is not necessary for an alternative to work and could unintentionally eliminate the ability to consider alternative materials, designs or processes (leaving only chemical drop-in replacements for consideration). For example, a safer alternative to stain resistant sprays for avoiding stains on upholstery could be the use of detergents or the use of fibers that are inherently stain resistant. These are completely different alternatives or approaches to the product and not just an alternative to the specific application of PFAS.

Furthermore, the Maine statute includes a broad definition of alternative that is focused on the functional equivalence of the *product (not just PFAS)*, and that is inclusive of other materials, designs, or processes. The definition expressly contemplates the removal of PFAS as an alternative, i.e., even if the alternative (no PFAS) does not perform as well or better than PFAS, as long, as the *product* still serves an equivalent function:

> *"Alternative" means a substance or chemical that, if used in place of a PFAS in a product, would result in a functionally equivalent product and would reduce the potential for harm to human health or the environment or that has not been shown to pose the*

same or greater potential harm to human health or the environment as the PFAS. "Alternative" includes: (1) A reformulated version of a product in which the intentionally added PFAS in the product has been removed; and (2) Changes to a product's manufacturing process that result in the removal of the PFAS from the product. (emphasis added)

The functionally sufficiency of an alternative is more appropriate to consider, especially in the context of implementing the essential use concept. "Functional substitution" is a method for identifying and evaluating alternatives to a substance that focuses on the function of the product and encourages a broader consideration of how this function can be achieved. For example, if focusing on the end use function of shopping receipts, harmful bisphenols in thermal paper could be eliminated by redesigning the paper itself or providing electronic receipts. Multiple papers and reports have described this important concept, including the European Chemicals Agency in its "Strategy to promote substitution to safer chemicals through innovation."[9] Additionally, in the EU's guiding criteria and principles for the essential use concept it states that,

"*Acceptable alternatives must be capable to provide the function and the level of performance that society can accept as sufficiently delivering the expected service and be safer … the assessment should not only consider possible alternatives with the same level of performance but also any alternative with a function and a level of performance that society can accept as sufficiently delivering the expected service. Therefore, the possible alternatives that need to be considered are:*
— products in the market in the same product category that do not use the most harmful substance;
— the alternatives that have a lower performance, provided it is acceptable from the societal point of view (10);
— those alternatives that provide a similar technical function and a similar level of performance to those provided by or with the most harmful substance"

A product without PFAS need not perform as well or better than a PFAS-laden product in order to achieve the required function. For instance, Maine has previously phased out PFAS-containing firefighting foams for liquid fires even though those foams may act marginally more

[9] Tickner, Joel A., Jessica N. Schifano, Ann Blake, Catherine Rudisill, and Martin J. Mulvihill. "Advancing Safer Alternatives Through Functional Substitution." *Environmental Science & Technology* 49, no. 2 (January 20, 2015): 742–49. https://doi.org/10.1021/es503328m.
Roy, Monika A., Ian Cousins, Elizabeth Harriman, Martin Scheringer, Joel A. Tickner, and Zhanyun Wang. "Combined Application of the Essential-Use and Functional Substitution Concepts: Accelerating Safer Alternatives." *Environmental Science & Technology* 56, no. 14 (July 19, 2022): 9842–46. https://doi.org/10.1021/acs.est.2c03819.
Cousins, Ian T., Jamie C. De Witt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, et al. "Finding Essentiality Feasible: Common Questions and Misinterpretations Concerning the 'Essential-Use' Concept." *Environmental Science: Processes & Impacts* 23, no. 8 (2021): 1079–87. https://doi.org/10.1039/D1EM00180A.
European Chemicals Agency. *Strategy to Promote Substitution to Safer Chemicals through Innovation: January 2018.* LU: Publications Office, 2018. https://data.europa.eu/doi/10.2823/99862.

quickly to put out fires than PFAS-free alternative foams; however, the alternatives are just as successful at putting out fires, and that is the key function.

Second, a cost threshold is not appropriate in this context, because the cost implications can vary dramatically from product to product. Rather the focus should be on assessing what is "reasonably available." We believe that inquiry could involve considerations of adequate supply of the alternatives and potentially the cost to the public. Costs to manufacturers are variable and subject to market pressures, including the Department's actions. An alternative may initially start out significantly more expensive than the PFAS it is intended to replace, but as demand increases, the cost can fall rapidly, and a mandated switch away from PFAS could be the catalyst for demand for the alternative to increase. This is why it is important for cost considerations to not be determinative (and to have determinations of "currently unavoidable use" be time bound, as the availability of alternatives can change over time).

The need for any consideration of costs to be more focused on the impact to the public rather than the manufacturer is reinforced by the nature of alternatives that should be covered. As we propose above, the Department should adopt definitions that make clear that alternatives can include materials, processes, designs, products, or chemicals that achieve the desired result. In the example above where detergents are a viable alternative to PFAS treated upholstery, there would be little to no direct costs to the public, but there might be economic impacts for the manufacturer of the PFAS treated upholstery. Thus, the cost to the manufacturer should not be the relevant cost for the Department's analysis.

Furthermore, while there should be some consideration of the significance of additional cost to the public, minor costs should not influence the analysis. Even when considering costs to the public, a set threshold in absolute dollars should not be used as product categories may vary significantly in scale of cost. Nor is a percentage-based threshold appropriate because the significance of a certain percentage cost difference depends on the context–a high percentage could still amount to mere cents. In addition, any cost should be considered alongside societal costs of PFAS exposure and clean up.

We note that the statute makes no mention of cost.

Recommended changes:

Modify the definition of "reasonably available" to remove extraneous and extra-statutory considerations.

"Reasonably available" means an ~~PFAS~~ alternative to the use of PFAS or to the product containing PFAS which is readily available in sufficient quantity or can become readily available in sufficient quantify in the relevant timeframe. ~~and at a comparable cost to the PFAS, to include changes to the manufacturing process, it is intended to replace and performs as well as or better than PFAS in a specific application of PFAS in a product or product component~~

Please refer to our comments to the Minnesota Pollution Control Agency that detail our recommendations on how to develop regulations on the CUU concept that are in line with the many years of science and policy work spent developing this concept by experts in the field.[10]

Sincerely,

Anna Reade, PhD
Senior Scientist & Director PFAS Advocacy

Avi Kar
Senior Attorney & Senior Director, Toxics

Katie Pelch, PhD
Senior Scientist

[10] Kar, Avi, Anna Reade, and Katherine E Pelch. "Re: Request for Comments: Planned New Rules Governing Currently Unavoidable Use Determinations about Products Containing Per-and Polyfluoroalkyl Substances (PFAS), Revisor's ID Number R-4837," February 29, 2024. https://www.nrdc.org/sites/default/files/2024-03/currently-unavoidable-use-determinations-20240209.pdf.