January 28, 2025

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 Defend Our Health's detailed comments on the draft rule. Please don't hesitate to contact us if you have any follow up questions or would like clarifications of these comments.

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. None of the amendments and updated language we suggest require legislative update of the statutory language.

Specific Comments on Draft Rule by Section

<u>Definitions</u>

1. The draft rule defines "chemically formulated" as "*a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources*": This does not take into account where PFAS doesn't chemically "change" the natural substance but is still added to the substance. For example, PFAS added to the surface of cotton fabric to make it stain resistant does not necessarily change the chemical composition of the cotton. Additionally, the term "naturally occurring biological processes" is concerningly vague. Does that include biological processes artificially induced in a lab? What about the use of chemical substances that facilitate or speed up a naturally occurring biological process? This should be amended to more clearly read "...a process that chemically changes *the properties of* a substance extracted from naturally occurring plant, animal, or mineral sources *except that such term does not apply to substances created by living organisms through normal metabolic processes*".

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2. Under the definition for "commercially available analytical method" the Department states that "*commercially available analytical methods do not need to be performed at a third-party laboratory*". We disagree with this. Industry must not be allowed to test their own materials; history has shown us that industry has not been trustworthy when it comes to the health impacts of PFAS[1] or the use of PFAS in certain products. They absolutely should be required to use a third-party laboratory to test to prove that the information is correct, valid, and unbiased. Products must be tested in independent third-party laboratories, and reporting on both the methods used and the results should be required to be reported in full. We have related concerns with the statement that "*method must remain unmodified when not performed by a third-party laboratory*" - the question is "unmodified" from what? Third-party labs may have slight variations in their protocols; it's possible there won't necessarily be an exact standard accepted protocol. There should be full transparency in reporting the methods for every test done, and all tests must be conducted by third-party labs to avoid the inherent and well-documented reliability issues that come from lab testing conducted internally by industry, where conflicts of interest between scientific accuracy and business priorities unavoidably skew results[2–6].

3. Cosolvent is defined as "*substances added to a primary solvent in small amounts to increase the solubility of a poorly soluble compound*". Cosolvents can be used in a wide range of concentrations so the "small amounts" should be removed from the definition. Also, the "poorly soluble" is unnecessarily restrictive. We recommend the more concise and easily applicable definition of: *"Cosolvent" means substances added to a primary solvent to increase the solubility of a compound*.

4. Under the definition of "cookware," the draft states "*NOTE: The definition of cookware is limited to houseware. Cookware does not encompass items intended for use in and market exclusively for use in commercial, industrial, or institutional settings*." However, LD 1537 in section A-10 states that the definition of cookware "Cookware product" means a *durable houseware product intended to be used to prepare, dispense or store food, foodstuffs or beverages, including, but not limited to, a pot, pan, skillet, grill, baking sheet, baking mold, tray, bowl and cooking utensil*." There is no exemption for industrial or commercial cookware. To do so goes against the clear intent of the legislature and the specific wording of the law; this commercial/industrial/institutional exemption must be removed from the draft rules.

5. Regarding fluorinated containers, the draft defines a fluorinated container as "*any container which has been treated with fluorine atoms to create a permanent barrier*." The statute makes no exceptions for the purpose for which containers are fluorinated. To restrict the scope of the term based on purpose is therefore contrary to statute. Fluorinated containers should be covered regardless of whether they are fluorinated to create a permanent barrier, to prevent odor, to prevent distortion, or for any other purpose. The agency does not have the authority to narrow the definition of a statutory term. Therefore, the definition should simply read "*any container which has been treated with fluorine atoms*".

6. For the definition of semiconductor, part of the definition states "*intended to perform electronic and other related functions*". This definition is incredibly broad and would potentially expose Mainers to significant unnecessary PFAS exposure well beyond the intent of the legislature and the statute. Given that this will be an exemption from the law, this definition needs to be extremely clear and limited to only the exemption intended by the law. To be eligible for exemption, only semiconductor devices "*whose primary purpose is to control the flow of electric current, amplify signals, act as a switch, or perform energy conversions*" should be considered exempt[7,8].

7. The concept draft definition proposes that "significant change" would include a specific percentage change in the amount of PFAS included in the product. Defining "significant change" by means of a percentage change creates challenges for compliance and fails to provide useful information to the public. For example, a 10% change in a product with 1 ppt, may be difficult to measure or predict from inputs opposed to a 10% change in a product with 1000 ppm. Instead, we urge that a significant change of quantity of PFAS be defined as a change that would result in moving between the Department's defined reporting ranges. This standard is much easier for industry to comply with, for Department staff to regulate and review, and for the public to understand.

8. The draft definition states that a PFAS alternative is "reasonably available" if "*readily available in sufficient quantity and at a comparable cost to PFAS*." We do not think cost should be the focus of this definition and find the concept of a "comparable" cost too vague, given that the cost implications can vary dramatically from product to product. For instance, an alternative may initially be more expensive than PFAS but as demand increases, the cost may fall. Indeed, a ban on the use of PFAS may drive an increase in demand for an alternative and so it is important that cost is not considered with regards to "reasonably available". The definition also includes "*intended to replace and perform as well as or better than PFAS in a specific application of PFAS in a product or product component*". This part of the definition regarding performance is irrelevant to the concept of "reasonably available" - it and the "*at a comparable cost to PFAS*" clauses of this definition should be removed. We recommend the following definition: "Reasonably available" means an 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 quantity in the relevant timeframe"

Currently Unavoidable Use

1. The draft does not make clear the criteria that the agency will use to determine CUU and how the requested information will relate to that decision. We would recommend that the state establish clear criteria for how they will make CUU decisions and then have the information that they are asking for directly connect to each of the criteria and state how it will inform the decision. Any other information requests should be removed as to not increase work for both sides and to not create confusion as to what information is going to be used to make a decision. It is very important that the criteria align with international scientific work on this, which is also reflected in the EU guiding principles and criteria for the essential use concept[9].

    a. For example, under section A(9), the draft asks industry to provide information regarding "the impacts on human health or the environment of PFAS in the product". Given that the CUU determination as legislatively defined is to be based only on whether the use of PFAS in the product is necessary for the health, safety, or functioning of society, any data on the impacts of PFAS itself on health and the environment would be unnecessary (PFAS are harmful to human health and the environment, which is why the statute only permits ongoing use under the CUU criteria). We recommend removing A(9) and any other requirements of risk-based or exposure-related information (see below) to prevent industry applications that waste state resources and staff time reviewing irrelevant attempted industry justification for the use of PFAS in a product that has not met the actual CUU definition.

b. We recommend simplifying section A(4) to exclusively focus on requiring evidence to demonstrate that there are no safer alternatives to PFAS, inclusive to alternative designs or products that achieve the same primary function. Most importantly, we recommend removing A(4)(d) and A(4)(e).

Section A(4)(d) references a cost-based assessment, which we do not believe is appropriate given cost implications can vary dramatically from product to product (see comments above relating to the definition of "reasonably available").

Section A(4)(e) states "A comparison of the known risks to human health and the environment between PFAS and the materials identified in Subsection a". It makes no sense to require risk based criteria to get a currently unavoidable use designation. When the law was passed, it was passed because there is agreement that the use of any PFAS is a serious concern and that we need to stop all uses that we can. This is the essential use concept. This law was not intended to set up a risk-based framework. By setting up this process, it opens up the law to allow for unnecessary CUU designations and harms public health. This goes against the clear intent of the law that any ongoing use of PFAS must be permitted only when necessary for the "health, safety, and functioning of society".

While we believe that this section sets up a risk-based criteria that is not the purpose or intent of this law, if you decide to move forward with it, there must be criteria in place. For this section and for some of the other assessments in this section – what is the criteria for completing such a comparison/assessment? There needs to be clear criteria laid out so that industry cannot cherry pick studies that show what they want. Further, rather than ask for an open-ended comparison of risks, industry should be required to demonstrate that each of the alternatives listed in 4(a) have higher risks to human health and the environment than PFAS, in order to justify the use of PFAS.

2. In the currently unavoidable use section A(3)(b) the draft states "The required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals." They should have to provide additional information as to why this characteristic(s) is necessary for the products' function in health, safety, or the functioning of society. Or said more clearly: Why the absence of this characteristic(s) will negatively affect the function of the product and the resulting effect on the health, safety, functioning of society. A justification for the need for PFAS for the function of the product alone should not be sufficient for a currently unavoidable use (CUU) exemption.

3. The draft states on page 20 that "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." There should be very specific criteria for supporting documentation: such as primary literature citation, copy of any cited studies, results and methodology of a systematic literature review, data analysis, and other scientific methodology.

Thank you once again for the opportunity to provide these comments. We look forward to continuing discussions with the Department on its implementation of this critical law. Please feel free to contact me at SWoodbury@DefendOurHealth.org if we can provide additional information.

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Solutions for a Toxic-Free Tomorrow

Sincerely,

Sarah Woodbury
Vice President of Policy and Advocacy
Defend Our Health

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