July 18, 2022 *via* electronic submission

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17 State House Station
August, Maine 04333-0017

Subject: HCPA Comments on Concept Draft for the Maine PFAS in Products Program

Dear Ms. Farris,

The Household & Commercial Products Association[1] (HCPA) appreciates the opportunity to provide comments to the Maine Department of Environmental Protection (DEP) on the Concept Draft to implement Public Law c. 477, An Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution (LD 1503, 130th Legislature).[2]

HCPA is a voluntary, non-profit U.S. trade association representing approximately 240 companies engaged in the manufacture, formulation, distribution, and sale of products for the household, institutional, commercial, and industrial use. HCPA member companies manufacture and/or market products that may be impacted by this program.

HCPA supports the responsible production, use, and management of fluorinated substances, including regulatory requirements that are protective of human health and the environment for those substances which are persistent, bioaccumulative, and toxic (PBT). HCPA recognizes that DEP must implement the very broad definition of PFAS found within the law but believe that it is critically important to take into consideration the diversity of chemicals which meet this definition and their distinctive applications. A singular policy approach toward PFAS in products is not reflective of the current marketplace. Further, we advise the agency to closely monitor related activity by the U.S. Environmental Protection Agency (EPA) and other state regulators.

[1] The Household & Commercial Products Association (HCPA) is the premier trade association representing companies that manufacture and sell $180 billion annually of trusted and familiar products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments. HCPA member companies employ 200,000 people in the U.S. whose work helps consumers and workers to create cleaner, healthier and more productive lives.
[2] 38 M.R.S. § 1614

With respect to the PFAS in the Products Program described by DEP in its Concept Draft, HCPA would like to provide the following comments and requests for clarity.

I. HCPA Comments on the Definition of PFAS within the Concept Draft and Unavoidable Applications

There are substances that meet the definition of PFAS, such as perfluorooactanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) that have known and clear risks, thus taking action to limit their use and potential exposure is appropriate. HCPA is compelled to note that there are many substances captured within the broad definition of PFAS for which sufficient research has determined that they pose minimal potential risk and provide a societal benefit.

There is no scientific consensus on the definition of PFAS,[3] and many of the substances which fall under Maine's definition are utilized for their unique properties. Accordingly, it is essential that DEP have a clear process through which stakeholders can discuss specific applications for which a substance or substances can be used as they are necessary, and alternatives are not available. Removal of these substances without technologically and commercially feasible substitutes would result in sweeping changes for society, especially for consumers unaware of the contributions these substances provide to the improvement of their lives.

The law defines "currently unavoidable use" as a use of PFAS that the DEP has determined, by rule under this section, to be essential for health, safety, or the functioning of society and for which alternatives are not reasonably available. However, the Concept Draft does not appear to address the language from the authorizing statute which grants DEP the authority to allow applications of PFAS which are determined to be currently unavoidable. HCPA believes that the Concept Draft must provide a pathway for stakeholders to discuss substances which are currently unavoidable.

The active pharmaceutical ingredient (APIs) of several pharmaceuticals,[4] such as Cipro, Prozac, and Flonase, as well as the propellant in metered dose inhalers (MDIs), better known as asthma inhalers, are considered PFAS under Maine's statutory definition. Mobile vehicle air conditioning (MVAC) systems universally use fluorinated gases as refrigerants which meet Maine's definition of PFAS. Moreover, several pesticides[5] which protect humans and agriculture from a variety of insects and pests would disappear from Maine without any suitable replacements. These are just a few examples of the many that exist. As such, HCPA recommends DEP develop a process for which responsible parties may be able to present

[3] Williams, A.J. et al. Assembly and Curation of Lists of Per- and Polyfluoroalkyl Substances (PFAS) to Support Environmental Science Research. Front. Environ. Sci., 05 April 2022, Sec. Toxicology, Pollution and the Environment. https://doi.org/10.3389/fenvs.2022.850019

[4] Hammel, E. et al. Implications of PFAS definition using fluorinated pharmaceuticals. iScience. Volume 25, Issue 4, 15 April 2022. https://doi.org/10.1016/j.isci.2022.104020.

[5] The pesticide manual: a world compendium, J A Turner; British Crop Production Council, 2018

information on their products and the due diligence that they have undergone to show that there are not currently available alternatives.

Further, as technology changes and new chemistries come to market, HCPA also believes that timely reviews need to be a part of this process to verify whether or not an application remains unavoidable. With this in mind, HCPA recommends that parties with applications that are determined to be unavoidable should be permitted to either reapply for a new ruling every five years or notify DEP when a technologically and commercially feasible alternative becomes available. However, HCPA also believes that the responsible party should not be required to identify for DEP what alternative is being utilized unless it also meets the definition of PFAS in order to protect confidential business information (CBI).

Lastly, HCPA believes that companies should be encouraged to review each substance used within their product to determine whether or not it meets Maine's definition of PFAS. HCPA is concerned with DEP providing a link to the U.S. EPA's webpage of chemicals that have been identified as PFAS as this list will not encompass all substances that meet Maine's statutory definition. Providing this link may result in some companies only using the list generated by EPA rather than conducting reviews of all ingredients and we recommend the DEP provide clear information to companies.

II. HCPA Requests Clarification of the Responsible Party to Report to DEP

HCPA is concerned about the confusion that exists over exactly which companies are required to report applications of PFAS as defined by the law to DEP. HCPA's interpretation of the law is that the responsible party is the company which markets the product and whose name appears on the label. In instances where the marketing company does not exist within the United States, the importer is the responsible party. However, based on the current wording of the Notifications section of the Concept Draft, there are questions as to whether or not there are reporting obligations for the rest of the supply chain. The term "Product" is defined in the draft as "an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including its product components, that is sold or distributed for personal, residential, commercial, or industrial use, including for use in making other products." It is conceivable that a company might sell a component into Maine to a company that assembles the end-use product in Maine, who then sells the fully assembled product to consumers and other users in the state. In this instance, there is confusion as to whether the supplier of the component would be subject to reporting requirements. In other scenarios in which the component is sold to a company that assembles the final product outside the state of Maine, but then the end-use product is sold within the state, there are questions as to exactly who is responsible. As such, HCPA recommends DEP draft a definition for the term "responsible party" and utilize that term within the Notification section of the Concept Draft so that is clear to all stakeholders who are compelled to report.

III. HCPA Requests Clarification on Unintended PFAS Contamination

HCPA believes that the Concept Draft needs additional clarity for stakeholders on products that may contain unintentional PFAS. While the law is clear that "intentionally added PFAS" includes any degradation by-products of PFAS, and the term does not include PFAS that is used in or that comes in contact with a product during the manufacturing process but is not present in the final product. Unfortunately, the Concept Draft does not address situations where products are unintentionally contaminated with PFAS. For instance, many of the products HCPA represents are water-based products. As water testing has shown the presence of substances defined as PFAS in numerous water systems, it should be made clear within the Concept Draft that products found to contain PFAS which is the result of an impurity does not require reporting. Not including such a provision would discourage product manufacturers, marketers, and importers from monitoring their raw material supply chains so that they would be unaware of such contamination that could otherwise be addressed.

IV. HCPA Believes that "Significant Change" Requires Flexibility for Various Applications

The term "significant change" is going to have a different meaning for various applications. HCPA does not believe that there should be a "one fit size for all" approach when defining this term. Rather, HCPA believes that DEP should develop a process through which responsible parties can provide information detailing what they believe a significant change would mean for their application and have a conversation over what can reasonably be reduced. While the information stakeholders present to DEP will vary based on the application, if there are general topics DEP would wish to receive from stakeholders, guidance would be appreciated.

V. HCPA Recommends Exploring All Avenues for Shared Reporting Services with Other States and EPA

HCPA is concerned that the Concept Draft requires onerous reporting that may be duplicative. Subsection 3 of the law provides DEP the authority to waive all or part of the notification requirement under subsection 2 if DEP determines that substantially equivalent information is already publicly available. HCPA implores DEP to explore potential agreements with other states to reduce duplicative actions that will likely result from numerous state actions around PFAS. Further, as EPA is in a rulemaking process under the Toxic Substances Control Act (TSCA) Section 8 that will require those that manufacture and import any identified PFAS to report information regarding uses, disposal, exposures, hazards, and production volumes, HCPA believes that this is an opportunity for Maine and other states to reduce their reporting requirements and utilize the information gathered federally.

HCPA also believes that there may be opportunities for DEP to reduce reporting obligations for companies already reporting product information to other departments within the state of Maine. For instance, companies must register their pesticide products with the Maine

Department of Agriculture, Conservation & Forestry before they are allowed to sell their products within the state, and Maine's Board of Pesticide Control recently adopted[6] a condition of registration which requires registrants to submit an affidavit whether the product contains PFAS. Pesticide product registrations must be renewed each year, so this is an opportunity for DEP to reduce their requirements so long as CBI can be protected.

It is also important for DEP to work with stakeholders when the requirements of LD 1503 conflict with other recent legislation in Maine that encourages the use of substances that are captured under the statutory definition to meet various state goals, such as combatting climate change. HCPA recommends that DEP conduct stakeholder outreach to discuss these occurrences; otherwise, the regulated community will be unsure of how to proceed forward within Maine.

VI. Consideration must be given to Confidential Business Information

DEP should take into consideration that under the Concept Draft, many entities will be requesting information that their suppliers will consider to be a "trade secret" or CBI. Moreover, reporting will be required for numerous products and sites and reflect potential CBI claims in several instances. For example, the very presence of a specific byproduct and impurity within a formulation can be considered CBI if it might divulge proprietary processes or formulation related information. So that suppliers aren't required to reveal commercial trade secret information to their downstream customers, the final rule should simplify electronic reporting in a manner that enables "joint submissions" when necessary. DEP should acknowledge in the Concept Draft that companies are able to assert claims of CBI for any PFAS for which a claim has already been approved by EPA for inclusion on the TSCA Confidential Inventory or for which a claim of protection exists under the Uniform Trade Secrets Act. The final rule should also make clear what information elements can be claimed as CBI, and allow for simplified substantiation procedures for CBI claims, so that each individual CBI claim does not require the submitter to complete the Department's substantiation questions on a chemical-by-chemical basis. Furthermore, HCPA has concerns with DEP's potential use of the Interstate Chemicals Clearinghouse (ICC) Platform. It is unclear to HCPA if companies report to the ICC Platform or if states share this information, how their CBI would be protected. Disclosures to DEP need to be balanced with the need to protect CBI so that innovation within the marketplace can continue.

VII. HCPA Comments on Commercially Available Analytical Methods

As written within the Concept Draft, the definition of "commercially available analytical method" could prevent companies and third-party laboratories from using the most accurate and up to date testing methods on their respective products due to the specification that the analytical method remains unchanged. Very few analytical test methods currently exist that are robust enough to accurately test the numerous complex mixtures that PFAS could be within

[6] https://www.maine.gov/dacf/php/pesticides/documents2/bd_mtgs/May22/2-Apr22min-draft.pdf

scope of the regulation. HCPA recommends that companies and third-party laboratories have flexibility to modify existing methods or develop new validated methods.

With that said, HCPA believes it is critical to note that Total Organic Fluorine (TOF) analysis measures all fluorine materials associated with organic fluorine and does not identify individual PFAS substances. Further, EPA has noted[7] that TOF testing can often contain inorganic fluorine. There are more specified methods currently under development, such as the EPA Draft Method 1621: Screening Method for the Determination of Adsorbable Organic Fluorine (AOF) in Aqueous Matrices by Combustion Ion Chromatography (CIC) released in April of this year and the Total Oxidizable Precursor (TOP) assay. Tests like these can predict the accelerated degradation and release of many polymeric PFAS but can still have limitations in their ability to reflect a product's life cycle and small changes in laboratory protocol may result in large differences in measured PFAS.

Considering that not all PFAS can be measured accurately or precisely by the same commercially available analytical methods, reporting PFAS as falling within a specific range could create issues. It is important to keep the complexity and evolving nature of PFAS analysis in mind when designing the notification process outline in Section 3.A(2)c because creating a range that is not based on the specific chemical and product life cycle could prevent products with reduced adverse impacts to human health and the environment from existing in the marketplace. HCPA requests that DEP add clarity to this section as to what "falling within a range approved by the Department" means.

HCPA also recommends that for the purposes of the notification that companies be allowed to use theoretical calculations for known amounts of intentionally added ingredients rather than requiring analytical testing. Instrumentation for this type of analytical testing is cost intensive and not widely available. Additionally, the time and staffing resources required to carry out these tests can put a strain on companies with limited capacity to comply with the requirements and there are not enough third-party laboratories that would be able to meet the needs of industry. Considering the number of resources needed to accomplish the testing that would be required, and viable test methodologies may not exist for all complex mixtures and articles, making it impossible for regulated entities to ascertain the amounts of PFAS reasonably and responsibly in their product through analytical testing, HCPA recommends allowing theoretical calculations to be used for notification of intentionally added PFAS.

Lastly, HCPA encourages Maine DEP to work with industry and intergovernmental agencies to ensure that the analytical testing requirements allow for robust and accurate results.

[7] Shoemaker and Jones, 2021

VIII. HCPA Comment Regarding Fees

Any administrative fee that is collected under this program should be used to administer the program.

IX. HCPA Requests Clarification Regarding Certificate of Compliance

Section 8 of the Concept Draft refers to a "Certificate of Compliance" in the event DEP believes a product contains intentionally added PFAS and is being sold, offered for sale, or distributed for sale in violation. However, HCPA is not clear on the threshold DEP would need to come to believe a violation has occurred or what the certificate requires companies to show and attest in the event that a violation has not occurred. HCPA would greatly appreciate clarity for the Certificate of Compliance.

X. HCPA Requests an Extension on the Implementation Timeline

HCPA is concerned that the current timeline for companies to report is not sufficient. As Maine's statutory definition of PFAS is very broad, many of the substances that are captured within the definition have never been viewed or regulated as PFAS. The presence of these substances has not been monitored or otherwise controlled by many that would be subject to the reporting requirements. As a result, companies are going to need to expend significant time and resources working with their supply chains to understand their potential requirements.

In addition, once companies have their information and determine that they do have a reporting requirement, they'll need sufficient time to enter the information DEP is requesting for each product. Depending on a company's product portfolio, this has the potential to require significant human resources by companies to provide complete notifications. The timeline for when the development of the notification process will be completed is unknown; therefore, HCPA urges DEP to extend the notification deadline by at least six months so that all stakeholders have sufficient time to gather and input their information.

Further, HCPA believes that the fabric treatment ban starting in 2023 also need to be delayed while DEP builds out this program. It is unclear to HCPA whether or not alternatives for PFAS in fabric treatment exist. HCPA recommends that the process for "currently unavailable alternatives" becomes established before the ban is effective. Lastly, HCPA believes that the effective date of the ban should be a manufactured or imported effective date to ease the burden on an already disrupted supply chain. Therefore, HCPA requests that DEP allow fabric treatment products already on store shelves to be sold after the delayed effective date.

XI. Conclusion

HCPA appreciates the opportunity to provide these comments and requests. HCPA looks forward to working with DEP and other stakeholders to ensure the residents of Maine continue to have access to the products that improve their daily lives. Please do not hesitate to contact HCPA if the Department would like to discuss our comments.

Respectfully submitted,

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