November 10th, 2022

Kerri Malinowski Farris
Maine Department of Environmental Protection
Office of the Commissioner
17 State House Station
Augusta, Maine 04333-0181

SENT VIA ELECTRONIC DELIVERY: PFASProducts@maine.gov

Re: Second Concept Draft for the Maine PFAS in Products Program (October 2022)

Dear Ms. Farris:

We would like to thank you for the opportunity to comment on the "Concept Draft for the Maine PFAS in Products Program" (hereafter "Concept Draft"). MilliporeSigma is a leading supplier to the global Life Science Industry, providing solutions and services for research, development, and production of biotechnology and pharmaceutical drug therapies. We are also members of the American Chemistry Council's Performance Fluoropolymer Partnership (ACC PFP).

Background on PFAS at MilliporeSigma

As stated in our extension request letter, our use of PFAS is important for the production of pharmaceuticals and lifesaving therapies, as well as for research and innovation. These uses can be divided into two main subgroups:

1. PFAS used in the production of articles used in laboratory settings, including the research, development, and production of critical vaccines and therapies within the pharmaceutical and biotechnology industries.
2. PFAS contained in equipment and articles used for manufacturer of products used in laboratory settings, including the research, development, and production of critical therapies.

Specifically, MilliporeSigma uses PFAS to produce filtration membranes used in the development and manufacturing of a variety of specialty products that require high purity. This includes pharmaceuticals, biologics, vaccines, and novel therapies including cell and gene therapy; in articles and equipment used in production where equipment needs to be chemically inert, heat resistant, oil and liquid repellent; and as coatings on single-use articles. We also supply many universities, laboratories, and analytical departments with PFAS and PFAS containing reagents in very small quantities for use in scientific research, routine analytics, and reference materials.

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We want to thank the Maine Department of Environmental Protection (DEP) for granting MilliporeSigma a 6-month reporting extension. We understand the DEP is working hard to make updates to the Concept Draft as quickly as possible in order for companies to have more clarity on the requirements for reporting, with some companies reporting as early as January 1st, 2023. MilliporeSigma has concerns regarding Confidential Business Information (CBI), the Interstate Chemicals Clearinghouse (IC2) database, criteria for products that are "essential for health, safety, or the functioning of society" as well as questions on some of the definitions, and lack of clarity on parts of the notification requirements. We asked for further clarification on some of these points from the DEP in a letter sent through ACC's PFP dated on July 18th, 2022, and will expand on some topics that were added in the second Concept Draft.

Confidential Business Information (CBI)

We appreciate DEP's acknowledgement of this topic, as well as the reference to the Uniform Trade Secrets Act (10 M.R.S. §1542(4)(A)(&B)); however, specific questions have not been answered on how the DEP plans on protecting highly sensitive, proprietary information, especially from competitors. MilliporeSigma asks the DEP to provide details on what types of information will quality as CBI, the process in which manufacturers can make CBI claims, how IC2 plans on protecting CBI information including potential breaches of information, and how CBI claims will be handled if a final rule is not in place by the time of reporting, including the January 1st deadline.

MilliporeSigma considers estimated sales volume, the purpose of PFAS in the product, the amount of PFAS as an exact quantity, and the chemical abstract service (CAS) registry number to be confidential business information unless otherwise noted publicly on our website, Safety Datasheet (SDS), or other publicly available marketing materials. We understand that this information is helpful for decision-making by the DEP, however, we would like to have this information protected from competitors and omitted from the publicly available part of the database.

Interstate Chemicals Clearinghouse (IC2) Database

The DEP should expect to receive notification for hundreds of thousands of products that use this critical chemistry from MilliporeSigma alone. As with many others, we are concerned that the database will not be developed in a way that can handle this influx of information. We think stakeholders should be included in the building and testing of the database to ensure the system is robust enough to handle the volume of submissions and accurately captures all of the requirements from the DEP in a way that is easy for manufacturers to submit notifications (e.g., appropriate drop-down menus, automatic entries, easy uploads of multiple products at one time, etc.). MilliporeSigma is open to being involved in a group of stakeholders that can help the DEP and IC2 create a robust database that will cover all sectors of the economy and supply chain. Additionally, we are concerned that IC2 will not be able to deliver a database even by the July 1st, 2023 extension causing manufacturers to bear the extra burden of reporting to the DEP twice. The accuracy of data will be directly impacted by how far in advance submitters know what information will be required. It is in the best interest for the DEP, the general public, and the submitters to have adequate time to gather the appropriate data needed for submission, once the IC2 database has been finalized, in order to have the most robust information available.

Essential for Health, Safety, or the Functioning of Society

MilliporeSigma would like to thank the DEP for providing a clearer definition for "essential for health, safety, or the functioning of society" in the new version of the Concept Draft. Many of our PFAS-containing products, like those using polyvinylidene fluoride (PVDF) and polytetrafluoroethylene (PTFE), are critical for pharmaceutical development and manufacturing, biological, toxicological, and pharmaceutical research, and many other applications used in a laboratory setting, all related to improving the quality of life and health of society.

We appreciate that the DEP will be providing more clarity on this topic in a separate rulemaking as early as summer 2023. MilliporeSigma looks forward to helping provide input to better understand the overall process including, but not limited to, establishing exemption criteria for unavoidable uses, the application process to obtain an exemption, appropriate timelines, clear definitions, and more.

Definitions

Alternative. When thinking about alternatives to PFAS, economic impact must also be considered, not just the safety profile of the PFAS material. Every step of the process for which an alternative is used to replace PFAS should be evaluated to ensure that no additional harm is done to human health and the environment, including energy consumption and pollution creation, at any point within the supply chain and manufacturing process. Additionally, not all PFAS materials have shown to be a risk to human health or the environment and as such we recommend that "equivalent and safer" be added to the definition. It is also important to keep in mind that lack of toxicity data does not equate to a safer alternative.

Consumer. MilliporeSigma proposed to change this to "purchaser" as the definition for consumer is rather broad.

Comments Regarding the Notification Requirements

MilliporeSigma appreciates the DEP has elaborated on some of the requirements regarding the notification process. However, we still have several concerns about the lack of clarity and addition of criteria from the first Concept Draft.

Section A. This section has the most room for individual companies to interpret as they wish, resulting in inconsistent and misaligned information across many different sectors of industry, and even within the same sectors of industry.

While we agree that some sort of category and code system should be used, however, we are not aligned with using the Global Product Classification (GPC) system. We find that laboratory-type of products, equipment, and components are difficult to classify or are completely overlooked within this system. One possibility is to use the US EPA's Chemical Data Reporting (CDR) categories[1, 2] instead, or even in addition to the GPC System, in order to give submitters more options. Shown below is a small sampling of products that MilliporeSigma would need to register, which would not fall under the GCP brick codes and categories. We are more than happy to share additional examples if needed.

Durapore Membrane Filter, 0.22 µm – Some are not registered as medical devices.

PVDF Western Blotting Membranes – Used in R&D settings in both academia and pharma

PTFE Beaker – Used in laboratory settings

Rigid PTFE Sleeve – Used in laboratory settings

As previously mentioned, sales volume is extremely sensitive information for a company to share publicly. Furthermore, we are left to wonder how reporting sales volume will help decision-making in Maine. Given the complexity of global, multi-tier supply chains, sales volume could be misleading depending on who sells the product (direct to distributors vs. direct to retailers or individuals) and how the product is sold or re-sold. For example, the Concept Draft seems to require that retailers, importers, and distributors *all* need to notify DEP, which is likely to compound sales volume of each product or component from reporting it at every level of the supply chain. We agree with the inclusion of PFAS quantity as a requirement for notification and think that that is a better measure of how much PFAS is used. Additionally, the DEP could ask for total volume of PFAS per CAS number instead of sales volume, which aligns with the ask from the United States Environmental Protection Agency under their PFAS Reporting Rule.

MilliporeSigma asks that the DEP provide more clarity on (1)(a)(iii) "The general type of product" and (1)(a)(iv) "Its intended use." Additionally, products often do not have a single purpose or intended use, which can often be determined by the purchaser(s) and not the manufacturer. Furthermore, without a standardized structure for reporting "general type of product" and "intended use," the DEP should expect to receive responses that vary from notifier to notifier, which will likely lead to confusion and misunderstandings when the DEP and others attempt to understand the reported information in aggregate. The DEP should provide additional detail on how "general type of product" and "intended use" will be implemented in the IC2 database so companies can understand and appropriately plan their notification responses in advance of the reporting deadline. MilliporeSigma recommends drop-down selections for each category in the IC2 database and recommends EPA's CDR categories[1, 2] as a starting point.

The same can be said for (1)(b) regarding the purpose for which PFAS are used in the product. It would be helpful for companies to have a structured way of reporting this information so, again, information is consistent and aligned in a way that also better helps the DEP make decisions in the future. In the IC2 database, we recommend creating drop-down selections for this category. The DEP may want to consider reviewing EPA's CDR categories[1, 2] as a starting point for PFAS purpose as well. Although time is of the essence, MilliporeSigma would be willing to be involved in a group that could help the DEP draft the different categories and entries in the IC2 database.

In (1)(c)(i), MilliporeSigma greatly appreciates the opportunity to report PFAS quantity within a range. It would be helpful for all submitters, and less work for the DEP, if the DEP would identify those threshold ranges in the next version of the Concept. If ranges are pre-approved by the DEP and written in the Concept document, then it will save the DEP's time reviewing each application as well as submitter's time waiting to register PFAS containing products. Regardless of reporting exact quantity or a threshold range, companies should be able to report using calculations specific to the inputs and outputs of their manufacturing process without using commercially available analytical methods. Not only will this be easier for manufacturers, and more consistent with current workplace methods, it also won't limit what PFAS can be measured. Currently, analytical methods have not been developed to measure the many different chemicals in the PFAS family and can only differentiate a small subset available on the market.

Section C. MilliporeSigma appreciates and agrees with reporting products as a category or type. However, we ask the DEP to provide more clarity on the notification system and application process for allowance of reporting products as a category. As previously mentioned, we would happily help with planning the IC2 database with the DEP to work out what this process could look like.

Section D. In (2), MilliporeSigma recommends to also include updates to products that are no longer available for purchase by also changing their status to "inactive."

MilliporeSigma agrees and believes that a deeper understanding and quantification of PFAS is needed in every aspect of the supply chain. Many different industrial sectors are affected by this rulemaking, and we want to ensure every aspect of the Draft Concept is detailed in a way so everyone can follow along in a consistent and concise manner. We greatly appreciate the opportunity to provide comments on the Draft Concept and look forward to working with the DEP in the future. Thank you for your time and hard work, please do not hesitate to reach out with any questions.

Sincerely,

Ellen Baker

Ellen Baker
Senior Regulatory Affairs Expert, North America
Life Science, Hazard Communication and Chemical Regulations

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A business of Merck KGaA, Darmstadt, Germany

References:

1. Chemical Data Reporting under the Toxic Substances Control Act: https://www.epa.gov/chemical-data-reporting
2. Instructions for Reporting 2020 TSCA Chemical Data Reporting, https://www.epa.gov/sites/default/files/2020-12/documents/instructions_for_reporting_2020_tsca_cdr_2020-11-25.pdf
   Appendix D outlines descriptions of *Processing or Use Operations*, *Industrial Sectors*, *Function Categories*, and *Consumer and Commercial Product Categories*