

April 7th, 2023

Mark Margerum
Maine Department of Environmental Protection
Office of the Commissioner
17 State House Station
Augusta, Maine 04333-0181

SENT VIA ELECTRONIC DELIVERY: rulecomments.dep@maine.gov

Re: Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances Draft Rule

Dear Mr. Margerum and the Maine Department of Environmental Protection:

We would like to thank you for the opportunity to comment on the "Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances Draft Rule" (hereafter "Ch 90 Draft Rule"). 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.

Background on PFAS at MilliporeSigma

As stated in our extension request letter, our use of PFAS, mainly fluoropolymers such as polyvinylidene fluoride (PVDF) and polytetrafluoroethylene (PTFE), is critical to the production of pharmaceuticals and lifesaving therapies, as well as for research and innovation. These uses can be summarized 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.



The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

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We understand the Department of Environmental Protection (DEP) is working hard to make updates to 38 M.R.S. §1614 as quickly as possible to give companies clarity on the requirements for reporting. 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, the impending deadline for reporting, 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 American Chemistry Council’s Performance Fluoropolymer Partnership (ACC’s PFP) dated on July 18th, 2022, and November, 10th, 2022 as well as in a letter sent directly from MilliporeSigma on November 10th, 2022.

Confidential Business Information (CBI)

We appreciate DEP’s acknowledgement of this topic, as well as the reference to Maine’s Freedom of Information Access Act Title 1, Chapter 13, subchapter 1; however, specific questions have not been answered on how the DEP plans on protecting highly sensitive, proprietary information, especially from competitors. MilliporeSigma greatly appreciates that claims of confidential business information may be made at the time of notification. However, the DEP needs to provide specific details on what types of information will qualify as CBI, 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 by the July 1st extension 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 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, to ensure 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”. 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.

We are also supportive of removing the overall ban on any product with PFAS by January 1st, 2030. This provision is unnecessary and duplicative given that the law states DEP can by rule identify products or categories of products that cannot be sold or distributed.

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. Data on alternative substances or chemicals must be generated to ensure that a regrettable substitution does not occur.

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.

Section A. We want to thank the Maine Department of Environmental Protection (DEP) for granting MilliporeSigma a 6-month reporting extension. However, MilliporeSigma is asking that the DEP propose or support a one-year extension of deadline for reporting of products containing intentionally added PFAS. As outlined below, clarification is still needed on the requirements for registration. The creation and access to the IC2 database has not been finalized and as such there is no defined process for submitting information to IC2. There have been significant delays in the finalization of rulemaking, for example, the most



recent round of commenting is due a little over a month before registration is required (or 5 months after registration for some companies) making it unlikely the DEP will finalize the draft rulemaking before July 1st, 2023. Finally, there is a lack of clarity on how the DEP plans on protecting confidential business information. At minimum, a one-year extension of the reporting requirement date would allow manufacturers and the DEP to work through these issues.

MilliporeSigma appreciates the decision to add the United States International Trade Commission's Harmonized Tariff System (HTS) codes if Global Product Classification (GPC) system codes are not applicable for the product type. We find that laboratory-type of products, equipment, and components are difficult to classify or are completely overlooked within the GPC system. HTS codes are more readily available and used for many different types of products.

As previously mentioned, sales volume is extremely sensitive information for a company to share publicly. 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. We agree with the decision to remove this as a requirement for notification and hope that it does not re-appear in future iterations of the rule.

MilliporeSigma has repeatedly asked 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.

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 (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 Draft Rule. If ranges are pre-approved by the DEP, 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.



Conclusion

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 38 M.R.S. §1614 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 Ch 90 Draft Rule 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
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Life Science, Hazard Communication and Chemical Regulations



A business of Merck KGaA, Darmstadt, Germany

