

November 10, 2022

By Email to: kerri.malinowski@maine.gov

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

RE: SIA Comments on Second Concept Draft for the Maine PFAS in Products Program

Dear Ms. Malinowski,

On behalf of the Semiconductor Industry Association (SIA)¹, thank you for the opportunity to provide comment to the Maine Department of Environmental Protection (DEP and the Department) on the second concept draft for the Maine PFAS in Products Program. We appreciate DEP's continued stakeholder engagement on this topic, as well as DEP's improvements from the first concept draft, though we believe the second concept draft language can be further improved and clarified to best implement Maine 38 M.R.S. §1614. SIA continues to have significant concerns about the revised concept draft and believes that compliance will be difficult, even impossible, if the concept draft is finalized as is.

In addition to implementing changes in the second concept draft on the basis of SIA's comments below, and the concerns being raised by other similarly situated organizations, the Department must clarify its position with regard to how DEP will enforce 38 M.R.S. §1614 given DEP's continuing insistence that the reporting requirements will become enforceable on January 1, 2023. To that end, the Department should issue a statement of compliance discretion or "no-action assurance" memorandum for stakeholders. The Maine DEP is unlikely to have a final rule before January 1, 2023. Although some manufacturers may receive a six-month extension from the DEP on the notification requirement, without a final rule in place, or some public-facing guidance or assurance to the contrary, the Attorney General of Maine could begin to enforce the statute. Such action would have great consequence to businesses and consumers in Maine, and therefore a no-action assurance from the State is both necessary and justified.

¹ The Semiconductor Industry Association (SIA) is the voice of the semiconductor industry, one of America's top export industries and a key driver of America's economic strength, national security, and global competitiveness. Semiconductors – the tiny chips that enable modern technologies – power incredible products and services that have transformed our lives and our economy. The semiconductor industry directly employs over a quarter of a million workers in the United States, and U.S. semiconductor company sales totaled \$258 billion in 2021. SIA represents 99 percent of the U.S. semiconductor industry by revenue and nearly two-thirds of non-U.S. chip firms. Through this coalition, SIA seeks to strengthen leadership of semiconductor manufacturing, design, and research by working with Congress, the Administration, and key industry stakeholders around the world to encourage policies that fuel innovation, propel business, and drive international competition. Additional information is available at www.semiconductors.org.

Furthermore, with regards to the six-month extension from DEP on the notification requirement, SIA recommends DEP confirm with manufacturers that the extension is for six-months from publication of the final rule, rather than six months from January 1, 2023. This would be consistent with DEP’s message to those who have received an extension thus far: “Therefore, pursuant to 38 M.R.S. § 1614(3), and for the above reasons, the Department has determined that more time is needed to comply with the Subsection 1614(2)(A) requirements, and that it is appropriate to extend the deadline for your submission until **six months after the effective date of the Department’s finally adopted rule.**”

We offer additional comments below for consideration of specific items in the second concept draft.

1. Definitions

a. “Currently Unavoidable Use”

SIA understands that DEP’s interpretation and application of the term “currently unavoidable use” will be subject to a separate rulemaking. It is untenable to have to wait for such a rulemaking given the January 1, 2023 reporting deadline which the Department currently appears prepared to enforce unless some form of “advanced waiver” of that requirement is granted on the basis of products which are expected to fall within the current definitions in the second concept draft. Further clarification from DEP is needed in the interim.

DEP should make an effort in the near term to explain what is considered “reasonably available” and provide details on how to meet this criterion. Alternatives might exist but these are not necessarily economically feasible and/or some will take many years to fully implement throughout all processes and the entire supply chain. A broader definition of “currently unavoidable use” is needed.

b. “Essential for Health, Safety, or the Functioning of Society”

Likewise, DEP needs to explain what will be the mechanism, criteria, and/or process that will be used to determine the designation of “Essential for Health, Safety, or Functioning of Society.”

Furthermore, the definition of “Essential for Health, Safety, or Functioning of Society” should be expanded to include the product components and supply chains of such products and categories ultimately deemed “Essential for Health, Safety, or Functioning of Society.”

DEP should provide examples of products and categories it currently considers to be essential for health, safety, or the functioning of society, and advise that such products need not be reported by January 1.

Finally, although semiconductors, semiconductor components, and the semiconductor supply chain likely already fall under the DEP's concept draft definition, the definition should be expanded to specifically include semiconductors, integrated circuits, critical technologies, and/or microelectronics. The Department would be well served to clarify that it intends to consider the presence of PFAS in electrical components that are used in complex equipment, such as semiconductor manufacturing tools, in medical devices, and in materials used in national defense, will ultimately be deemed to be within the scope of "currently unavoidable."

Some proposed updated language for the definition is provided below:

I. Essential for Health, Safety, or the Functioning of Society. "Essential for Health, Safety or the Functioning of Society" means **Products, Product Components, and their supply chains** that if unavailable would result in a significant increase in negative healthcare outcomes, an inability to mitigate significant risks to human health or the environment, or significantly interrupt the daily functions on which society relies. **Products, Product Components, and their supply chains** that are Essential for Health, Safety, or the Functioning of Society include those that are required by Federal or State Laws and Regulations. Essential for the Functioning of Society includes but is not limited to climate mitigation, critical infrastructure, **critical technology, semiconductors**, delivery of medicine, lifesaving equipment, public transport, and construction.

c. "Perfluoroalkyl and polyfluoroalkyl substances (PFAS)"

SIA considers the definition of PFAS used in the concept draft (any substance "containing at least one fully fluorinated carbon atom") to be overly comprehensive, and it will create reporting requirements that are confusing and unnecessarily burdensome.

38 M.R.S. §1614(1)(F) defines PFAS as meaning "substances that include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." Meanwhile, the DEP second concept draft definition added the word "all" before substances. This unnecessarily and counterproductively expands the scope of the notification requirement, the added word "all" should be omitted in the final rules. Notwithstanding that the statute employs a broad definition carried over into the Concept Draft, SIA considers the statute to enable DEP to exempt substances or to delay reporting on certain classes of chemistries that are determined to present comparatively fewer risks, such as fluoropolymers. SIA recommends that DEP implement such an exclusion or exemption. Exempting or excluding fluoropolymers from the final regulatory definition of PFAS for purposes of the reporting requirements will allow the DEP to require notification on products containing only those PFAS that may be of greater concern than fluoropolymers. Such a list should include the Chemical Abstract Services Registry Number for the chemicals and should exclude low-risk substances, such as fluoropolymers.

d. “Intentionally added PFAS”

SIA appreciates the updated definition of “Intentionally added PFAS,” including the clarification that “intentionally added PFAS” does not include materials that are unintentionally present or which might remain following a manufacturing process as an unwanted (and non-functional) contaminant such as an impurity. Nevertheless, SIA encourages the DEP, in the rule preamble or other guidance document, to provide examples of what “specific characteristic, appearance or quality or to perform a specific function[s]” would look like in practical, real-world applications. It’s impossible to tell if the criteria apply to a manufacturing stage, a facet of a part or component, or only to an end product. It’s also impossible to tell what matter of degree the criteria should be weighed, i.e., how important the characteristic is to the product.

DEP should also clarify the definition in its implementing rules that further define the idea of the timing of “added” – e.g., added as pure PFAS; added as part of a substance, mixture, or compound; added before, during, or after production; added by the end product manufacturer or another entity along the value chain.

Clarification in the form of examples and further detail on “intentionally added PFAS” is needed for the regulated community to fully understand the concept draft language.

2. Notification

In general, the DEP should seek to reduce the burden of the notification reporting requirement on both manufacturers and itself. This can be implemented and is permissible under the statute in a number of ways.

a. Relying on information provided by suppliers

Manufacturers of products subject to the notification requirement should be able to rely solely on documents provided by suppliers in order to determine whether such products contain intentionally added PFAS.

The notification rule should make clear that a manufacturer’s inquiry regarding PFAS content with respect to any supplier ends with the existing information provided to manufacturers by suppliers for parts, components, etc. Manufacturers should be able to rely on the information they receive from their supply chain, to conclude that the components, parts, etc. they purchase, and which are incorporated into their end products, do not contain PFAS in the absence of contrary information provided by suppliers.

It would be unreasonable for the notification rule to require manufacturers to mount a burdensome due diligence effort to prove the absence of PFAS in parts, components, etc. that go into their end products. Most manufacturers have had little or no reason to collect information from their foreign suppliers about the presence of PFAS in the components and parts they use. End product manufacturers typically have complex

global supply chains, and each end product can have thousands of individual parts and components sourced from a variety of suppliers. As contemplated, it appears the notification rule might require manufacturers to inquire of each and every one of these multitude of suppliers. This would prompt manufacturers to spend untold hours and resources inquiring of hundreds and possibly thousands of suppliers all the way up the supply chain regarding PFAS content for each and every part and component in their end products. This is simply not reasonable, even if feasible (which it likely is not).

Moreover, manufacturers should not be required to pursue information collection where a supplier claims any such information is a trade secret or confidential business information. At that point, no further inquiry should be required.

In other words, DEP should limit the notification requirement to instances where intentionally added PFAS is “known” to manufacturers. And, what is “known” to manufacturers should be limited to information provided by their suppliers of component, parts, etc. without any requirement to perform additional due diligence or other information gathering up the supply chain.

SIA recommends the requirement in 3(G) to “provide, upon request by the Department, evidence sufficient to demonstrate the accuracy of information reported” should be revised to require that a manufacturer provide “evidence sufficient to demonstrate the accuracy, *to the best of the manufacturer’s knowledge*, of information reported.” This modification in the Concept Draft would reflect DEP’s awareness that, as a practical matter, manufacturers of highly complex products must ultimately rely upon the information provided by their suppliers (and the “upstream” suppliers of their immediate suppliers).

b. Including a de minimis threshold exclusion for products that contain PFAS equal to or less than 0.1% by weight.

A de minimis level of 0.1% is generally understood by manufacturers and distributors of products that move thorough international markets because this aligns with the level imposed in European Union for identifying the presence of substances of very high concern (SVHCs) when present in articles.

This threshold has been in place for nearly fifteen years and provides a rational, reasonable threshold that promotes the safe use of SVHCs without overly burdening the supply chain by requiring, for example, excessive due diligence and destructive testing to determine whether trace amounts of these substances are present in articles. The 0.1% by weight threshold is an appropriate threshold for Maine DEP to employ for purposes of the notification requirement. It would reasonably limit the volume of notifications, particularly for parts and components sold into Maine. Otherwise, Maine DEP could be burdened with hundreds of thousands of notifications related to parts and components that contain only trace concentrations of PFAS, which would be insignificant from a safety and health perspective.

In addition, promulgating a notification rule without a de minimis threshold would overly burden the supply chain. All end product manufacturers that sell any of its products into Maine would be required, in the absence of a de minimis threshold, to spend considerable time and effort to attempt to determine whether any part or component, whether sourced locally or globally, that goes into their end products might contain a trace concentration of PFAS.

While SIA appreciates the updated definition of “intentionally added PFAS” to exclude instances of contamination, some of which would be covered by a de minimis threshold, this is insufficient to address the substantial issues of a notification requirement for all PFAS, including those equal to or less than 0.1% by weight.

Moreover, manufacturers would also need to determine whether such PFAS was “intentionally added,” which based on the current definition must be assumed, and the specific purpose and amount of PFAS. Such data gathering would place an enormous burden on manufacturers to pursue with their suppliers, some of which are second, third, and even more tiers removed in the supply chain from end product manufacturers. This information would be difficult, if not impossible, to obtain.

c. Reducing the granularity of detail being requested

DEP did not provide additional information on reporting as a category or type and if it is feasible and consistent with the purposes of the program if a group of products may be reported together by category. As described above, there are substantial burdens associated with the notification requirements as currently drafted. The affected products are complex and have hundreds of components. Accordingly, DEP should allow for grouping at the highest level practical, for example by machine type level, rather than requiring reporting for each individual component.

The concept draft indicates that for reporting by type all products would need to have the same profile (C(2)), but this would only be possible if using concentration ranges (C(3)(b)). Regarding C(1) of the concept draft, not every manufacturer uses the UPC brick system, so it will be important for DEP to allow manufacturers to group products at the highest product level practical (e.g., machine type level) so that grouping can correspondingly remain in the same brick code. DEP needs to help manufacturers harmonize the products, components, and categories with the brick system and for compliance with the statute.

Finally, DEP should remove the requirement to provide PFAS substance name and CAS registry number. This information may not always be known to the manufacturer because it is confidential business information to the supplier, which is why manufacturers likely would not be able to provide this information.

d. Including a de minimis threshold exclusion for sales volume

Regarding 3(A)(1)(a)(ii), there ought to be a sales volume of PFAS that is not considered an “unreasonable risk” for the estimated sales volume in the state or nationally for the full calendar year following the year in which the product is being reported. Adding a de minimis threshold for a given sales volume could be beneficial for replacement parts and product components in the long term. The de minimis should also apply to the product as a whole or by category (e.g., machine type level), rather than its components.

e. Allowing for a reasonable time to report “significant changes” and exempting specific types of changes

SIA is concerned that the Concept Draft would consider the omission of a PFAS or the removal of a substance containing PFAS as a trigger for “significant change” reporting. SIA suggests DEP minimize unnecessary reporting such as these changes. Due to the complexities of acquiring the data and information necessary to report, a reasonable time (e.g., 90 days) should be provided for such reports to be filed following receipt of information triggering the requirement to report.

Additionally, DEP should clarify the exemption to reporting significant changes to include the removal of spare parts, the use of replacement products, the use of parts used to repair products, and the like. In these cases, it is impractical for manufacturers to predict a) how much of a product is sold into the State of Maine, or b) when the supplier will notify the manufacturer of the use of a component (e.g., spare part, replacement product, etc.) that contains intentionally added PFAS, as defined by the concept draft.

Finally, SIA recommends DEP allow manufacturers at least 90 days to report/update PFAS data based on actual sales or to use past sales in order to calculate future sales. It takes an extended period of time for manufacturers to collect and gather information based on actual sales in order to determine if a change is significant.

f. Other clarification needed

Related to the last paragraph of A(1)(c), during the stakeholder meeting on October 27, the DEP suggested that reporting was focused on components. However, the second concept draft says “the manufacturer may report total PFAS in the product including its components.” Stakeholders need further clarity on this new language in the second concept draft, and SIA would recommend that this apply to the product, not its individual components.

3. Waiver of Notification

Stakeholders need further clarity of the process associated with applying for and receiving the waiver of notification if the DEP determines that substantially equivalent information is publicly available. The DEP should make this process available as soon as possible to allow for compliance by January 1, 2023, including such information as the timeline for the waiver process, expectations for the substance of the waiver application, the waiting period for response, which authority will administer the waiver, etc. DEP should also provide an extension to those seeking a waiver of notification while the DEP reviews any potential applications. DEP should also allow for a waiver application by category (e.g., machine type level), rather than by individual component because that will make it near-impossible for DEP to review in a reasonable time all waiver applications, and application by component would create a substantial and unreasonable burden on manufacturers. A waiver for the use of spare parts, replacement products, and the like should also be covered by this process. Additional detail on this process is important because companies need to predict how much money to allocate internally to this process.

The DEP should also confirm that the definition of substantially equivalent information that is publicly available, with respect to the waiver of notification, would include, for example, a manufacturer publishing a list of covered products on a publicly available webpage and a profile of the products' PFAS content. Additionally, fees should not be required if a full waiver is granted for posting the necessary data on a publicly available platform.

Finally, with respect the answer to the FAQ "How are refrigerants used in HVAC applications handled under this program?", SIA is pleased that DEP recognizes that some or all of the notification requirements could be waived for refrigerants. Semiconductor manufacturers use specific refrigerants that may contain PFAS chemicals without which semiconductor processing is not possible. Because there are no known replacements, identifying and implementing PFAS-free replacements will require at least 10 years once a replacement is identified. And, waiting to "closer to 2030" for determining that the refrigerant gas is an "unavoidable use" will not provide enough time to complete the work. Therefore, SIA agrees with DEP's suggestion to waive all notification requirements for refrigerants especially if they are used in point-of-use chillers necessary for semiconductor manufacturing.

4. Confidential Business information (CBI)

SIA appreciates the DEP adding a CBI provision, but it needs to be included as part of the rule text, not a note (non-binding). Additional detail should be included to describe how CBI claims should be made and how they will be processed (e.g., secure system, etc.)

5. Other

SIA would request DEP have the Q&A on its website include a revision date at the end of each answer for better tracking, rather than a revision date at the bottom of the page.

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We look forward to further engagement with the Maine DEP. If you have any questions about our comments, please contact David Isaacs at disaacs@semiconductors.org.

Thank you for your attention and consideration of these important concerns.

Sincerely,



David Isaacs
Vice President, Government Affairs
Semiconductor Industry Association