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Mr. Mark Margerum
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Mr. Margerum:

On behalf of SEMI – the industry association serving the global semiconductor design and manufacturing supply chain – we write regarding submitting comments on the Maine Department of Environmental Protection (DEP) proposed "Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances" (Rule). As currently drafted, this legislation on which the proposed rule is based would require reporting on thousands of PFAS substances that are estimated to be present in millions of components used in semiconductor manufacturing. While we fully support a goal of limiting the release of harmful PFAS substances into the environment, we cannot conceive of how to comply with the regulation in its current version.

According to the Semiconductor Industry Association's 2019 Maine fact sheet, Maine semiconductor establishments had a $440 million wage impact in the state with a $235 million export value, making semiconductors Maine's 4th ranked export by value. [1]

SEMI submits the following comments on the proposed Rule and respectfully requests that DEP fully consider these comments in developing the final Rule, including the potential impacts to Maine's economy should the significant impacts of the proposed Rule be realized.

A. Concerns Relating to Scope, Exemptions and Future Restrictions

The proposed Rule adopts an unnecessarily convoluted approach to the imposition of a blanket future restriction and consideration of exemptions from that restriction. We suggest two options by which DEP could rationalize the timeline and process for adopting future PFAS restrictions and exemptions, consistent with the current statute, while also avoiding potentially catastrophic impacts on the Maine economy.

1. ***Primary Option: DEP should delete from its rule the general 2030 ban on all PFAS containing products, and instead include a determination that identifies all products not subject to a specific or categorical restriction as "currently unavoidable uses" and adopt a stepwise approach to additional product category and PFAS sub-category prohibitions.***

First, consistent with the currently proposed bill that would amend the existing statute, L.D. No. 1214, the "any product" ban in 2030 in Section 5.C. should be deleted from the proposed rule. There is no

[1] Refer to https://www.semiconductors.org/wp-content/uploads/2022/05/Maine-2022.pdf

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provision in the existing statute that *requires* DEP to promulgate this 2030 prohibition by rule today. More importantly, neither the Legislature nor the DEP has provided any indication that either body has analyzed, or is even aware of, the economic upheaval such a ban would create, both in the State of Maine, and by ripple effect, in the U.S. and globally. Instead, DEP should implement the current statute in a stepwise manner that provides the time and process necessary to fully evaluate those implications and regulate accordingly.

Second, DEP should take advantage of the authority it possesses under the statute to adopt a more rational approach to PFAS restrictions across the state. Specifically, it should (a) take an expansive approach to its ability to issue exemptions under the statute by issuing a rule broadly exempting products from the 2030 ban; and (b) then develop, in a series of subsequent rulemakings, more targeted restrictions of product categories or PFAS groups, under an objective and robust set of criteria that balances human health and environmental impacts with social and economic impacts. More detail is provided below.

a. <u>Adopt a General Rule Deeming Products as Benefitting from the "Unavoidable Use" Exemption Until Expressly Prohibited by Rulemaking</u>

Although SEMI member companies support the clarity that L.D. 1214 would bring to the existing law by striking from the statute the general PFAS ban that takes effect in 2030, DEP could achieve a similar result under the current statutory framework through an assertive application of its existing exemption authority. Specifically, DEP could include in the final Rule a determination that existing uses of PFAS that continue beyond 2030 -- other than those expressly prohibited by statute or by regulation -- are to be deemed "currently unavoidable uses" and not subject to the prohibition.

Such a designation would involve a broad exercise of DEP's authority to exempt product categories from the 2030 prohibition, and would require adoption of an expansive interpretation of the terms "essential for … the functioning of society" and "not reasonably available." It would certainly be preferable to achieve this categorical exemption approach via a legislative amendment to the current statute. In the absence of legislative clarification, however, SEMI member companies suggest that these terms are sufficiently open-ended, and the risks of over-regulation are so significant, that an expansive approach to these exemptions is warranted, particularly if combined with more targeted category-based restrictions that DEP expands over time through targeted, risk-based rulemakings.

The following language in either section 4 or 5 of the final Rule is suggested:

> *Intentionally-added PFAS in any product on the market in Maine as of the effective date of this rule are deemed to be "currently unavoidable uses" until such time as the Department promulgates a final rule restricting or prohibiting the sale of such product.*

b. <u>Adopt via sequential rules future restrictions by product category or by sub-category of PFAS substances.</u>

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At the same time as adoption of an "unavoidable use" exemption, the DEP could adopt in subsequent rules prohibitions or restrictions for additional product categories or PFAS sub-categories based on a prioritized evaluation of PFAS risks in Maine and consideration of product uses that have low socio-economic value and high health or environmental risks.

As the bill summary in L.D. 1214 correctly states, "[c]urrent law provides that the department may by rule identify products by category or use that may not be sold, offered for sale or distributed for sale in this State if they contain intentionally added PFAS and that products in which the use of PFAS is a currently unavoidable use as determined by the department may be exempted by the department by rule." Specifically, Section 5(c) of the existing statute clearly provides DEP with this authority, and also directs DEP to exercise that authority by prioritizing "product categories that, in the department's judgment, are most likely to cause contamination of the State's land or water resources if they contain intentionally added PFAS."

DEP could also potentially implement this categorical restriction process in a manner that defines product categories as products that contain particularly problematic PFAS compounds, such as PFOA, PFHxS, and other substances that have been targeted for priority phase-out due to their high persistence and potential toxicity. DEP also appears to have sufficient discretion to define product categories as "any product that includes" various sub-groups of PFAS compounds. This stepwise approach, which focuses on PFAS uses that present the greatest health and environmental concerns and also takes into account socio-economic impacts of new restrictions, is far preferable from both an environmental and an economic policy standpoint.

There is also precedent in the European Union and Canada for these approaches. For example, the EU adopted stringent restrictions under the (Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation[2] for a broad category of substances that can degrade to PFOA and PFHxS. It has nearly completed rigorous risk-based restrictions on virtually all uses of a class of long-chain perfluorocarboxylic acids (LC-PFCAs) that are defined by molecular structure, similar to an amended regulation passed by Environment Canada in 2022. And the EU is taking targeted action on a very broad class of PFAS substances used in a specific application – firefighting foams – that pose a particularly high environmental risk because of their dispersive uses[3]. Taking this targeted and stepwise approach, whether based on PFAS sub-classes or specific product categories of concern, would bring Maine in line with global PFAS regulations, which would in turn provide more regulatory certainty and consistency to regulated entities and greatly reduce the notification and research and development burdens on such entities.

2. ***Alternative Option: DEP should promulgate in the final Rule a schedule and objective standards for the development of "currently unavoidable use" exemption rulemakings.***

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Refer to https://echa.europa.eu/regulations/reach/understanding-reach

[3] It is worth noting that, unlike semiconductor equipment and materials, there are PFAS-free alternative substances that can broadly fulfill the demands of firefighting foams.

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If DEP chooses not to follow the preferred option above and instead retains the current structure of the proposed Rule to prohibit all uses by 2030 unless exempted, then DEP must at a minimum revise the proposed Rule to (a) clarify the process and timeline by which it will grant exemptions from that 2030 phase-out, and (b) revise and clarify the standards for considering exemptions.

a. Adopt a Clear Schedule and Process for Considering Exemptions

DEP must promulgate in the final Rule a sufficient and binding schedule for exemption rulemaking because the Act requires that DEP engage in major substantive rulemaking (a rule with legislative approval) to identify uses that will benefit from such exemptions. That rulemaking will be both time-consuming and complex; its implementation could require DEP to process an unprecedented volume of data relating to PFAS uses in an almost endless variety of applications.

Not only will DEP need ample time to undertake appropriate, reasoned, and objectively supported analysis to make exemption determinations, manufacturers will need ample time – at least 12 months – in order to pursue data collection to fully understand the potential presence, functionality, and alternatives to PFAS applications in their products. All of this must occur well in advance of the effective date to allow manufacturers time to make necessary changes or, in drastic situations, change entire product lines or cease business operations altogether if exemptions are denied. Small businesses are likely to be especially affected because of the limited resources to investigate alternatives to PFAS-containing products.

It is therefore essential that the final Rule include a process for this subsequent exemption rulemaking, including a binding schedule for the consideration and adoption of these exemption decisions.

SEMI member companies recommend that the final Rule set deadlines from its effective date of:

- 12 months for DEP to publish a data collection rule or advanced notice of proposed rulemaking;
- 18 months for stakeholders to collect information and respond;
- 18 months for DEP to evaluate that data and propose all “currently unavoidable use” exemption rules; and
- 6 months for manufacturers to comment on those proposals, and 6 additional months for DEP to finalize those rules.

That schedule would allow DEP to establish the exemptions adequately in advance of the 2030 restriction date.

Without the above binding schedule, there is simply not enough time for manufacturers to collect all necessary data to support “currently unavoidable use” while at the same time engaging in R&D and product line changes (e.g., identifying and qualifying PFAS alternatives) to mitigate against such use being banned. And, similarly, there is not enough time for DEP to review, evaluate, and comprehensively understand the submitted data, then make a reasoned, supportable written determination and promulgate appropriate exemptions rules, then seek and receive legislative approval for such rules.

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If DEP cannot commit to this schedule, DEP should push back the January 1, 2030, effective date for the "all products" ban, through a temporary blanket exemption determination such as that proposed above. Indeed, recognizing the ambitious timeline, likelihood of widespread exemption requests to process, and limited DEP resources, SEMI member companies suggest that DEP effectively postpone the "all products" ban until January 1, 2035 at the earliest, by issuing a generally applicable exemption until that date.

b. Revise the Criteria in the Rule for Granting Exemptions for "Currently Unavoidable Uses"

It is absolutely critical that DEP promulgate in the final Rule objective decision-making standards that address precisely how DEP will determine that the use of PFAS in the product is a currently unavoidable use," and that these terms be interpreted flexibly and broadly. Relying on a narrow, ambiguous and, in its practical application, the almost completely subjective definition of "essential for the health, safety or the functioning of society" will lead to arbitrary and potentially harmful outcomes. As DEP may be aware, the European Commission has for many years been working on a potential amendment to their REACH chemical regulatory framework to incorporate an "essential use" standard for justifying exemptions from restrictions on highly hazardous substances. The complexity of that concept, and the risks of inadvertent omissions or adverse socio-economic impacts has resulted in numerous delays and drafting challenges, and the EU will not use the essential use standard in the broad PFAS restriction it is considering. DEP should likewise avoid this regulatory morass, and instead adopt practical and flexible definitions that exempt broad categories of PFAS uses until DEP has the time and resources to adopt restrictions in a targeted and prioritized fashion.

Specifically, the Rule should omit unnecessary and unhelpful definitions that go well beyond what the Act requires, and that improperly serve to restrict DEP's future discretion to make appropriate exemption determinations:

- The Act provides in 1612.B that "Currently unavoidable use" means "a use of PFAS that the department 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."

- The proposed Rule would unnecessarily constrain the scope of such exemptions well beyond what the statute requires, by narrowly defining the core term "Essential for Health, Safety, or the Functioning of Society." It would define that term as: "products or product components 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 or product components that are Essential for Health, Safety or the Functioning of Society include those that are required by federal or state laws and proposed Rule. *Essential for the Functioning of Society includes but is not limited to climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, and construction*." This constraint would be especially harmful because the proposed Rule would place on manufacturers the burden to prove both essential use and no available alternatives. For certain products, this burden could be impossible to prove, leading to

substantial economic disruption and unnecessary curtailment or elimination of certain products for which no harm to health or the environment has been established.

- ***This definition should be deleted***. It is not clear why DEP would want to constrain its future authority to consider appropriate exemptions beyond the limits already imposed by the statute. For example, DEP might determine that a product is essential for "health", in a manner completely consistent with the statute, without being required to demonstrate that the product is also essential to avoid "significant … healthcare outcomes." And while DEP may have intended the examples of activities or sectors that are "essential for the functioning society" to be illustrative only, the functioning of society depends on myriad activities, products and processes that are not encompassed in DEP's short list. We are concerned that the use of these examples in the Rule will lead DEP to read its authority as more circumscribed in the future than the statute allows. Missing activities that Maine residents might well consider essential to the functioning of society include, for example, communication, food production, social interaction, recreation, education, law enforcement, research and development, energy production, etc. Such a constraint would exacerbate the already problematic socio-economic circumstance created by the Act of allowing the State to pick winners and losers, potentially without any demonstrated impacts to health or the environment.

- DEP should instead adopt a *broad* concept of "essential" that is both consistent with the requirements of the statute and flexible enough to accommodate the possibility that broad exemptions may be required to avoid adverse impacts on the functioning of society. SEMI member companies suggest a provision in section 4 of the proposed Rule such as:

> The department shall grant an exemption under § 1614.5.C for PFAS applications or end products, and for the supply chain production activities required to produce such PFAS applications or end products, when a manufacturer has submitted evidence that an application, product or category of products provides benefits relating to health, safety, or the functioning of society and that there are no reasonably available alternative substances or technologies for that use. A product shall be deemed to provide benefits to the functioning of society where the manufacturer has submitted evidence that the product fulfills identified consumer, commercial, or industrial demands for the product in Maine.

This approach would strike an appropriate balance that we believe reflects the legislative intent behind the Act: it would place a burden on manufacturers to assess and provide evidence that PFAS substitutes are not available, but would presume that ongoing uses where substitutes are not available would be permitted to continue, subject to more targeted DEP rulemakings, as described above. Further, this burden shifting will promote an objective, fact-based standard where DEP can prohibit or restrict products for which adequate evidence of harm to health or the environment exists.

- As indicated in the suggested language above, the final Rule should be drafted to clarify that uses of PFAS-containing products in manufacturing operations that take place in Maine would be included in the exemption wherever the manufacturing process produces an end product that is itself deemed "essential." In other words, the final Rule should make it clear that the "essential" designation and related exemptions should apply not only to the end product itself, but to each of the products and processes in the supply chain that are necessary to produce that exempted product.

- Also as indicated above, the final Rule should be drafted to make it clear that DEP "*shall*" – not "may" -- grant an exemption if the evidentiary standard is met. The final Rule should make it clear that, if a manufacturer meets the evidentiary burden to establish a product as essential, then DEP is required to grant that exemption.

Curiously, on a separate note, the "currently unavoidable use" exemption provision seems to be mis-located in the proposed Rule – the provision should be in section 5.C., not 7.A.2. The exemption language makes no sense in section 7 where it would appear to only apply to products that have been prohibited solely because notification was not timely filed, as opposed to allowing any manufacturer (including those who timely submitted notifications) to seek an exemption.

3. ***In addition to either of the above options, DEP's final Rule should include a* de minimis *threshold value.***

As others have previously proposed to DEP, we believe that the effectiveness of the proposed notification and restriction requirements would be significantly enhanced by the adoption of a generally applicable de minimis threshold level for manufactured articles. A 0.1% threshold by weight, evaluated against the weight of sub-components that meet the definition of "articles" under well-established material restriction regimes such as EU REACH, would significantly facilitate notification compliance and dramatically reduce the cost of compliance on the regulated community and Maine consumers and businesses. This threshold has been in place for nearly fifteen years and provides a rational, reasonable threshold that promotes the safe use of substance of very high concern in Europe, 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.

B. Concerns Related to the Reporting Obligation & Mechanics

1. ***Well-defined confidential business information (CBI) provisions are essential to protect valuable intellectual property (IP).***

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It is currently unclear how, practically, a notification entity could assert a CBI claim or trade secret under the proposed Rule, or how that protection would be executed by DEP. A well-defined CBI framework for all notification and future rulemaking (e.g., for future exemptions) will be essential for the protection of valuable IP that might otherwise be jeopardized. DEP has made note of the need for CBI provisions and SEMI member companies urge DEP to adopt highly protective and enforceable CBI protections in its final rule.

Nothing in the statute authorizing these regulations and establishing the notification obligation compels DEP to make information submitted under the statute publicly available. The notification requirement is instead understood as an information-gathering tool to assist future DEP regulatory initiatives. SEMI member companies therefore urge DEP to adopt an approach that starts with the premise that information will be treated as CBI if claimed as such, and to adopt clear measures to prevent the public release of information claimed as CBI.

Semiconductor production, as well as the technology sector in general, treats the chemical composition of materials as proprietary information that is carefully protected and of significant commercial value. The proposed Rule, therefore, needs to be amended to include detailed provisions about how such information can be reported while respecting its status as CBI and trade secrets, how DEP will protect the information or decide what non-CBI elements can be made publicly available, and how the information in DEP's possession will be protected from disclosure. The disclosure of trade secrets by DEP, whether intentionally or inadvertently, would give rise to significant concerns about the violation of Maine law. Information that requires careful protection could include (for example) the identity of any PFAS present in a product, the volume and concentration of such a substance, and any information relating to sales volumes or production volumes.

DEP should amend its proposed Rule to permit the use of generic chemical names or ranges instead of CAS numbers in any information that is made available to the public. SEMI member companies recommend that DEP refer, for example, to the U.S. Environmental Protection Agency's (EPA) rules and practices for protecting CBI and limiting the disclosure of information to avoid release of valuable trade secrets under the *Toxic Substances Control Act* (TSCA). See, for example, the detailed provisions at 40 CFR 711.30, which could serve as a model for DEP's development of CBI procedures.

At a minimum, these procedures should include:

- A clear statement that entities making notifications may assert a confidentiality claim for information at the time of its submittal, and that information claimed as confidential in accordance with the procedures will be treated as confidential and protected from release by DEP to the extent possible under Maine law.
- A provision setting out specifically what measures should be included to substantiate a claim of confidentiality (such as, for example, a certification by an appropriate company official, a requirement to mark and identify information claimed as confidential, confirmation that the submitter has taken steps to protect the confidentiality of information claimed as confidential and that its release will cause harm to the company's competitive position).

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2. ***The notification deadline should be extended by at least 18 months after the effective date of the final Rule.***

SEMI appreciates the notification extensions that DEP has granted to date to specific entities. However, DEP has vastly underestimated the global reach of the proposed Rule. A blanket extension beyond the six-month period is absolutely necessary given, for example, the complexity and geographic reach of the semiconductor equipment supply chain, as well as the even more complex, global supply chains for other complex manufactured articles. These products might contain thousands or tens of thousands of components, sourced from suppliers that sit in a far-flung global supply chain. None of these global suppliers are currently required by any rule or industry practice to either assess or communicate information about the presence of any but a small handful of the substances covered by the proposed Rule.

It is unrealistic to expect the global supply chain to establish a material declaration and notification system within a short period of time that could effectively manage the notification and disclosure requirements for our sector. Again, DEP (and the Legislature) has vastly underestimated the global reach of Maine's proposed PFAS notification and ban. The statute affords DEP wide latitude to grant such additional extensions. DEP should consider a blanket extension or, absent a blanket extension, be liberal about granting additional extensions when requested. Extensions on the notification obligation should be for at least 18 months after the effective date of Rule.

3. ***DEP must add concentration ranges and a "Known to or Reasonably Ascertainable by" standard to the notification provisions.***

Compliance with the notification requirement, for many PFAS, will be impossible without ranges promulgated by DEP because there is no commercially available methodology for identifying an exact quantity of PFAS. As part of this rulemaking, DEP should specify concentration ranges for all PFAS or groups of PFAS subject to notification. Failure to do so will add to the already excessive notification burden on the regulated community. The Department should determine and add the notification ranges to the draft before the rulemaking process is finalized.

DEP should also expressly incorporate a "known to or reasonably ascertainable by" standard that allows notifying entities to rely on supplier declarations, and to limit the scope of the due diligence that manufacturers would be expected to undertake with respect to upstream suppliers. EPA has proposed to apply the "known to or reasonably ascertainable by" standard that it otherwise uses in chemical data notification obligations for its own PFAS reporting rule and its Chemical Data Reporting (CDR Rule) under TSCA, consistent with TSCA section 8(a)(2). Maine DEP should avoid reinventing the wheel and instead expressly harmonize the proposed Rule to mirror that standard. See, e.g., 40 CFR 711.15. EPA has also proposed to utilize the same standard in its proposed PFAS reporting rule under TSCA. As EPA explained in the preamble to that proposed rule, "EPA has also provided CDR reporting guidance materials on this reporting standard, including hypothetical examples of applying the "known to or reasonably ascertainable by" reporting standard in the context of collecting processing and use data for CDR …. Therefore, EPA anticipates many reporters under this proposed rule will be familiar with this reporting standard, and resources are available to support those reporters who may not be familiar with the

standard." For the same reasons of efficiency and clarity, DEP should employ the same reasonable inquiry and due diligence-based standard here.

For example, DEP could include a new subsection (3) under Section 3.A of the draft rule, providing "A manufacturer is only required to report information under this Section 3.A. to the extent such information is known to or reasonably ascertainable by that person. Whether information is known to or reasonably ascertainable by a manufacturer shall have the same meaning as those terms are given under the U.S. EPA Chemical Data Reporting Rule."

C. Other Comments to Facilitate Implementation of the Proposed Rule

1. We support the exclusion of PFAS without a CAS#.

SEMI member companies strongly support the language in the proposed Rule clarifying that, consistent with the Act, PFAS that have not been issued a CAS number are not subject to the notification and restriction provisions of the Act. The use of a structural definition in the statute, rather than a detailed list of PFAS that are subject to these requirements, dramatically increases the scale and costs of the chemical tracking and notification burden that the statute will impose. While it is strongly preferred that DEP issue a list of PFAS substances that are subject to the rule, at a minimum it will be critical for purposes of implementation to exclude PFAS that do not have a CAS number. Only those substances that are issued a CAS number will be capable of being tracked through the existing databases that we and our suppliers use for chemical and material restriction compliance globally.

SEMI member companies also believe that the second "Note" under the PFAS definition should be deleted. If a supplier has withheld a CAS number from a downstream manufacturer, and the manufacturer has not otherwise determined the identity of that substance through methods consistent with the "known to or reasonably ascertainable by" standard, then the manufacturer should not be held responsible for any incomplete notification that results from that lack of knowledge.

2. We support the "reasonably available" definition in the proposed Rule.

SEMI member companies support DEP's balanced interpretation of the term "reasonably available" in the proposed Rule. The evaluation of a potential alternative's availability must take into account consideration of commercial availability (not just theoretical availability) as well as its cost. It is also critical that alternatives be considered available only where they provide equivalent or better performance. There are several applications in our sector where there are no currently available alternatives that meet those requirements.

3. We support the exclusion for used products and recommend its extension to spare parts.

Finally, SEMI member companies appreciate and support DEP's proposed exclusion of used products from the scope of the notification obligation and future restrictions, which the statute requires. The

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ability to trade and sell used components and equipment forms an essential element of the growing circular economy.

SEMI member companies also suggest that this exclusion be expanded now to exclude future controls on spare parts intended for use in any equipment that was manufactured prior to the effective date of the proposed Rule. The equipment used in our sector involves a significant capital expenditure, and if properly maintained can continue to productively operate for many years into the future, after 2030. Spare parts for equipment produced before the proposed Rule takes effect should be pre-emptively exempted from the scope of any future restriction, to avoid premature obsolescence of legacy equipment.

SEMI appreciates your attention to these comments and welcome the opportunity to respond to questions or engage with you further as DEP finalizes its Rule proposal.

Respectfully,

John Cooney
Vice President of Global Advocacy and Public Policy
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