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Submitted via email to freedhoff.michael@epa.gov.

Re: Docket No. EPA-HQ-OPPT-2021-0598

Dear Sir or Madam:

SEMI[1] appreciates the opportunity to submit comments on EPA's intent to propose amendments to the final persistent, bioaccumulative, and toxic (PBT) rules under TSCA section 6(h), including for Phenol, Isopropylated Phosphate (3:1) (PIP (3:1)) and Decabromdiphenyl ether (DecaBDE). SEMI submits this letter as its fourth communication to EPA regarding the PBT rules, having previously provided comments in response to EPA's requests on December 22, 2021, May 17, 2021, and February 12, 2021. SEMI provides revised and more finely focused comments today. Consistent with our previous comments, SEMI urges EPA to revise certain aspects of the PIP (3:1) and DecaBDE rules.

The equipment that SEMI members manufacture has a far-reaching impact on the U.S. manufacturing economy. This impact outstrips our size, which in number of products produced annually is smaller than many of the industries that rely directly on us (e.g., automotive, consumer electronics, etc.). At a time when many of these other industries are attempting to decrease reliance on foreign suppliers, impracticable regulation could undercut these efforts. Without the amendments proposed below, EPA's PIP (3:1) and DecaBDE rules risk disrupting U.S. domestic manufacturing.

[1] SEMI® represents more than 2,900 member companies to advance the technology and business of electronics manufacturing. SEMI members are responsible for the innovations in materials, design, equipment, software, devices, and services that enable smarter, faster, more powerful, and more affordable electronic products. Electronic System Design Alliance (ESD Alliance), FlexTech, the Fab Owners Alliance (FOA) and the MEMS & Sensors Industry Group (MSIG) are SEMI Strategic Association Partners, defined communities within SEMI focused on specific technologies. Since 1970, SEMI has built connections that have helped its members prosper, create new markets, and address common industry challenges together. SEMI maintains offices in Bangalore, Berlin, Brussels, Hsinchu, Seoul, Shanghai, Silicon Valley (Milpitas, Calif.), Singapore, Tokyo, and Washington, D.C. For more information, visit www.semi.org.

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SEMI's previous communications to EPA on the PBT rules were based on preliminary results from surveying our members, who in turn surveyed their suppliers. SEMI now has further results that support these key suggestions for amending the PIP (3:1) and DecaBDE rules:

- EPA should adopt a threshold limit of no less than 0.001% for the presence of PIP (3:1) in articles.
- EPA should adopt a threshold limit of no less than 0.1% for the presence of DecaBDE in articles.
- EPA should state whether the agency takes an interpretation of 'article' similar to the idea of 'once an article, always an article'.
- EPA should frame a due diligence approach to account for the complexity of the global supply chain and the time required to productize components compliant with the PIP (3:1) and DecaBDE rules.
- EPA should incorporate an exclusion for semiconductor manufacturing and related equipment (SMRE) replacement parts into both the PIP (3:1) and DecaBDE rules.

A. SEMI still has serious concerns with the October 31, 2024 deadline for PIP (3:1) because the restrictions are not practicable

In our December 22, 2021 letter to EPA, SEMI expressed its concern that extending key PIP (3:1) compliance deadlines to October 31, 2024 "on its own, would not suffice to make the PIP (3:1) rule workable." This statement was based on the preliminary supplier survey results we had in hand at the time. Subsequent survey results confirm this.

As SEMI has expressed to EPA in the past, SEMI members' supply chains are extraordinarily complex – a single SEMI member article can contain tens of thousands of parts. Supply chains can span the globe and go from five to eleven layers deep. Harmonizing communications with these many layers of suppliers for a chemical that has never been regulated in articles in any other jurisdiction – such as PIP (3:1) – is therefore a challenge.

As of our December 22, 2021 letter, our members had identified at least 349 parts that contained PIP (3:1). We informed EPA at the time that we expected this number to significantly increase as our members, and their suppliers, continued to investigate their supply chains. Our most recent survey results confirm that many thousands of parts containing PIP (3:1) have been identified. For a large number of these, the members do not believe they will be able to design, test, and qualify replacement parts by the current October 31, 2024 deadline. If members are not able to meet deadlines, this may result in significant disruptions to domestic production of semiconductors, which would have exponentially larger effects on the U.S. economy.

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It is fundamental for EPA to understand the differences between consumer product manufacturers – such as those that manufacture cell phones, computers, and domestic appliances – and semiconductor equipment manufacturers. We hope that the information in this letter will allow EPA understand these differences, which at a high level include the following:

- A consumer product manufacturer produces thousands of similar units of a product model each year. Semiconductor equipment manufacturers produce only hundreds of similar product models, and only small groups of product models will be of the same design due to end user customization requests with each order.

- A consumer product manufacturer represents a large market share for the suppliers of off-the-shelf components and so has significant economic leverage with its suppliers for obtaining detailed component information if it is not already available. Because of the low unit production rate and the frequently customized designs, semiconductor equipment manufacturers are not a large market share for most off-the-shelf components they purchase and therefore have little economic leverage with those suppliers.

- Consumer products tend to be directly assembled from simple lowest level components so that the number of supplier levels (or 'tiers') in the total supply chain is relatively smaller – in other words, consumer products have shallower supply chains. Semiconductor manufacturing equipment tends to incorporate many complex assemblies, meaning that our supply chains have many tiers.

- For any given consumer product model, the number of fundamental components produced throughout the supply chain is relatively small. Semiconductor manufacturing equipment has many more fundamental components.

SEMI would like to highlight again a basic context of our supply chain that was submitted in our comments to the PFAS reporting rule IRFA.[2] The IRFA notes that small entity representatives who are article importers explained to EPA that they would face extremely high hurdles in obtaining reportable information.[3] Similarly, SEMI's comments explained that larger article

[2] EPA, Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (IRFA) (Nov. 2022), https://downloads.regulations.gov/EPA-HQ-OPPT-2020-0549-0125/content.pdf.

[3] *Id*. at 5; *see also* EPA, Final Report of the Small Business Advocacy Review Panel on EPA's Proposed Rule: Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (SBAR Report) (Aug. 2, 2022) at 24-25, https://downloads.regulations.gov/EPA-HQ-OPPT-2020-0549-0123/content.pdf.

importers face the same hurdles.[4] The supply chains for SEMI members are complex, and many suppliers are outside the United States. The bottom line is that article importers cannot easily obtain substance information through outreach to their foreign suppliers for reasons which include:

- Article importers rarely if ever even know what substances are present in the articles they import. They certainly lack the kind of information EPA is requiring in the proposed rule.

- Foreign suppliers to article importers typically do not know such information either, as they are either simply distributors or are final assemblers of the articles. Substances are specified to be applied to article components by upstream suppliers to the final supplier in many cases. The final supplier would likely have no reason to know any substance information. This means that a foreign supplier would likely have no information to submit to the article importer or to EPA in a joint submission.

- In the experience of SEMI members, foreign suppliers are very reluctant to divulge composition information to article importers due to confidentiality concerns. Foreign suppliers are also unlikely to be willing to submit that information to EPA in a joint submission.

Nonetheless, we have found in our investigations that it is generally feasible for the suppliers of components containing PIP (3:1) or DecaBDE to redesign the components for compliance. For example:

- The supplier of a series of power supplies identified a capacitor they used in the supplies which was sealed around the leads with polyurethane containing PIP (3:1). The supplier was able get the capacitor manufacturer to seal the capacitor with an alternate material, and provide a schedule of release for the revised power supplies over several months.

- The supplier of a series of power supplies identified a piece of PVC tubing used for wire management in the supply which contained PIP (3:1). The PVC was used in several of the power supplies. The supplier was able to find alternate PVC produced without using PIP (3:1), and provide a schedule of release of the revised power supplies over several months.

- The supplier of an optical sensor identified DecaBDE being used in the casing of the sensor. The supplier was able to reformulate the resin, and eventually provide a sensor with the same mechanical and electrical specification.

[4] IRFA Comments Submitted by SEMI, Comment ID EPA-HQ-OPPT-2020-0549-0143 (Dec. 23, 2022), at 9-11, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0549-0143.

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We have not learned of any situation where a reduction or elimination of PIP (3:1) or DecaBDE was not technically possible. However, questions remain as to whether the supply chain robustly understands, and how it may determine, that the redesigned components contain zero quantity of PIP (3:1) and/or DecaBDE. In our initial survey, many suppliers had a rather relaxed understanding of 'zero' quantity. Below are some excerpts of the responses we collected that were provided in Attachment 3 of our previous submission to EPA. Suppliers were asked to express what 'Zero' meant to them, and to include some further explanation of content.

- Zero = 0.0001% (1ppm) / substance of concern (SOC) will not be used in any production part {NOTE: stating an SOC is not used [by the component original equipment manufacturer (OEM)] in any production part is different from saying the substance is not present in the part due to the decision of an upstream supplier of a material or part that is used to make the component}.

- Zero = 0.1% / We do not use SOC intentionally. We chose 0.1% as a general threshold for unintentional use.

- Zero = 0.001%

- Zero = 0.01% / Our internal documentation is calling only 2 digits past zero to specify chemical composition or substances present in the material.

- Zero = 0.1% / Typically supplier declarations (downstream) test to this level or parts per million /.

Therefore, SEMI's revised position is that invention of alternates for PIP (3:1) and DecaBDE in their various current use cases (whatever they may be) is not likely to be the bottleneck for compliance with a PBT restriction, but rather the bottleneck is proving to be clear communication of the restriction in a practicable manner into the supply chain, and the productization of revised components.

B. SEMI urges EPA to adopt a threshold limit for PIP (3:1) and DecaBDE in articles

SEMI asked for *de minimis* concentration thresholds in articles in its December 22, 2021 letter, and we reiterate that request here. Specifically, SEMI urges EPA to impose a 0.001% threshold for PIP (3:1)- and a 0.1% threshold for DecaBDE-containing articles.

SEMI members' supply chain communications and material tracking tools would benefit from a clear *de minimis* regulatory threshold imposed on the global component supply chain as a whole. This approach will enable SEMI members and suppliers to inquire about the presence of

the substances and to test for the substances using comprehendible criteria and sensible levels of detection.

Adoption of a *de minimis* threshold is the only means for a product manufacturer to develop a compliance program that can be put into practice with meaningful results. Neither supply chain assurance nor any test method can ensure or demonstrate zero content of any substance. It is unworkable now, and will become increasingly so, to ban the presence of a chemical in an article with no *de minimis* threshold.

We are asking for different PIP (3:1) and decaBDE thresholds. We believe a threshold of 0.001% for PIP (3:1) is a reasonable approximation of 'zero PIP (3:1)' content, and this threshold provides more protection than inquiries based on whether the substance has been intentionally added. Further, a certified and well-known lab indicates a test method detection limit (MDL) of 0.0005% for PIP (3:1) using EPA methods.[5] A compliance limit of two times the MDL ds a reasonable limit to account for errors in the testing process and provide some indication of clearance for test results indicating a minimum passing value.

We ask for a higher threshold for DecaBDE to align with other major regulatory regimes that impose material restrictions on the substance, and because of the supply chain's familiarity with compliance with the EU RoHS DecaBDE restriction.[6] EU RoHS applies a 0.1% threshold for DecaBDE in the homogeneous material layers of articles in in-scope electrical and electronic equipment, and other laws have also adopted a 0.1% concentration threshold.[7]

Although not all articles in scope of TSCA are in scope of EU RoHS, many suppliers around the world already manage compliance with EU RoHS and have established compliance programs targeted to the 0.1% threshold. Getting this supply chain to understand that EU RoHS compliance is insufficient for business in the United States will be significant challenge with uncertain benefit. If EPA were to adopt an 0.1% DecaBDE threshold, it would significantly ease industry's compliance burden without compromising EPA's goals of environmental protection.

C. EPA should explicitly state its interpretation of an 'article' as placed into commerce

The United States TSCA restrictions and the European REACH and POPs restrictions are the most restrictive criteria globally for substances in articles. The definitions of 'article' in these restrictions are substantially aligned as shown here:

[5] SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch, Test Report (May 17, 2022), https://www.lhecn.com/wp-content/uploads/2022/07/TSCA.pdf.
[6] RoHS Directive 2011/65/EU.
[7] For example, this approach is consistent with the lowest action threshold for a substance in OSHA's Hazard Communication Standard (HCS). The HCS lists Threshold Value Limits (TVLs) for carcinogenic chemicals in mixtures as 0.1%. 29 C.F.R. § 1910.1200, App. A.

TSCA PBT definitions – 40 CFR §751.403 (as well as 40 CFR §704.3)	Article means a manufactured item: (1) Which is formed to a specific shape or design during manufacture, (2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.
EU REACH[8]	article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
EU POPs[9]	'article' means article as defined in point 3 of Article 3 of Regulation (EC) No 1907/2006 {EU REACH}

While these definitions are substantially aligned, regulator interpretations of the definitions are not and more explicit clarity is needed from EPA to reduce these interpretive differences.

In Europe prior to 2015, the European Chemical Agency's (ECHA) interpretation of 'article' applied as a whole to an item as that item was placed on the EU market. This meant that concentrations of a substance present in components of an assembly were measured against the total weight of the assembly as it was placed on the EU market. For example, if there was a 10-gram capacitor that contained .01 grams of PIP (3:1) in a sealant that was present in a 1-kg power supply placed on the EU market, the concentration of PIP (3:1) in the article placed on the market could be understood as 0.01 grams/1 kg = 0.001% PIP (3:1).

However, in 2015, in response to a lawsuit brought by several member states, the European Court of Justice set a new interpretation known as "once an article, always an article." This essentially meant that if an article ever existed independently, concentrations of substances in that article would be measured against it even if the article was incorporated into another assembly. With this change of interpretation, when the example power supply was placed on the market, the capacitor in the power supply would be considered independently. This would result in an article (the capacitor) with 0.01 grams of PIP (3:1) placed on the market = 0.1% PIP (3:1), which is a concentration of PIP (3:1) that is significantly different from the 0.001% determined under the alternate interpretation.

As far as we understand, EPA **has not** adopted an interpretation similar to "once an article, always an article." The EPA interpretation is understood to be aligned with that of the EU prior to 2015. However, in the absence of a specific position statement from EPA acknowledging this interpretation, industry reliance on the interpretation is uncertain. An EPA position statement is therefore needed for clarity in supply chain communications and in our own compliance programs. We ask that EPA provide such a statement to the effect of:

[8] EU Regulation 1907/2006.
[9] EU Regulation 2019/1021.

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> "EPA's interpretation is that the definition of 'article' applies to an item as a whole as it is imported or distributed in commerce, and article concentrations may be determined against a denominator representing the weight of the whole item."

D. EPA should frame a due diligence approach to allow for the complexity of the global supply chain and the time required to productize components compliant with the PIP (3:1) and DecaBDE rules

As explained above, the supply chain for large, complex, and high-tech products in a global marketplace is equally complex and global as the products themselves. Further, some industries, such as the semiconductor manufacturing equipment industry, depend highly on commodity parts selected from catalogs and each equipment manufacturing company represents a small market share to the part supplier. This means there is little economic leverage to enforce or encourage compliance. Combine that fact with the technical complexity of new component productization and a variety of regulatory definitions, and it becomes clear that while there are few fundamental barriers to finding alternatives for PIP (3:1) and DecaBDE in components, there are significant barriers of comprehension and supply chain pass-thru that must be overcome.

Once an alternate component is found it can take significant time and effort to fully implement the alternate into the design. The following are normal considerations relevant particularly to semiconductor equipment manufacturers. In the following, SEMI explains some of the challenges in finding where the decisions to add substances occur in the supply chain, and our control or influence over those decisions.

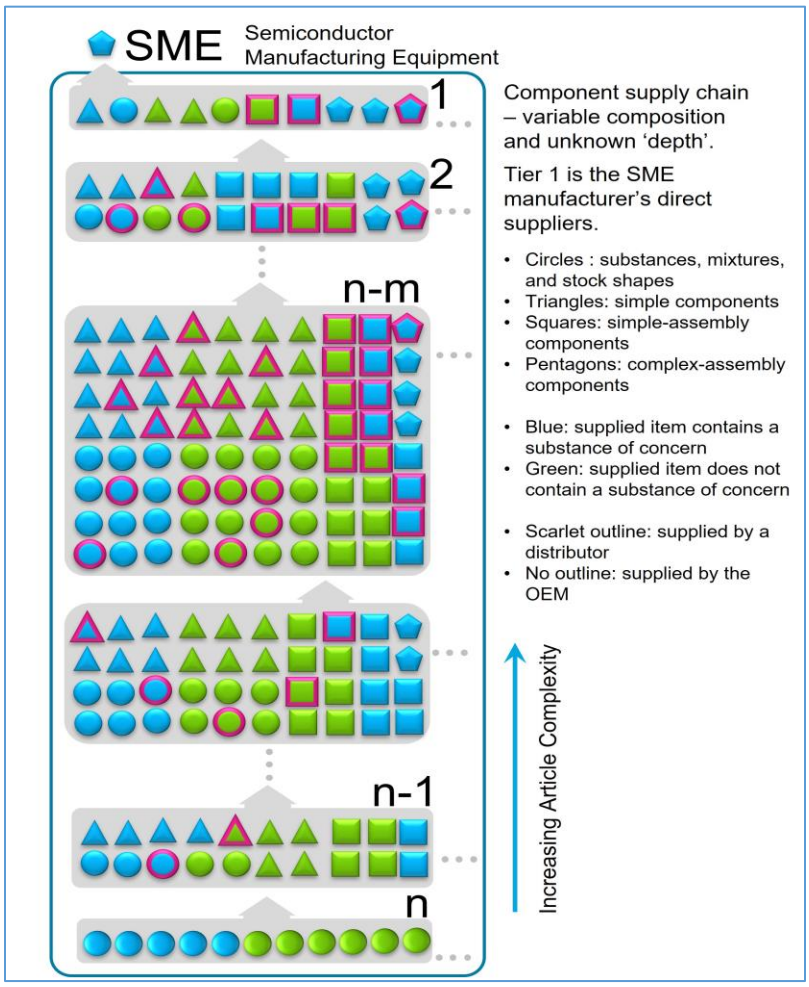

Figure 1 SME Supply Chain Tiers

- Approximately 50% of the components in semiconductor manufacturing equipment will have a design controlled by the manufacturer; these tend to be simple components. The other 50% will be off-the-shelf components purchased from catalogs and websites.

- Some component suppliers only sell through distributors. Also, it is often easier for a manufacturer to work with a distributor to acquire the components they need, because this simplifies fundamental procurement negotiations such as supplier qualification, cost and delivery schedules. Consequently, distributors will supply many components. One implication of distributor supply is that the OEM for a component acquired from a distributor must then be at a deeper, more upstream supply-chain tier. Because distributors are typically situated only as a commercial intermediary and do not have (and are not conversant in) material specification data for the parts, it can be more difficult for a specifying manufacturer to get detailed information about a particular component.

- Entry into the supply chain of any substance, such as PIP (3:1) or DecaBDE, can occur at any tier. In Figure 1, circles without scarlet borders represent these instances.

- Each tier of the supply chain also represents the possibility of storing components (sometimes large quantities of components) in warehouses. Storage practices occur because of the need to have stock on hand to satisfy orders quickly; the cost savings from purchasing large quantities at one time; and sometimes, because a component will be going obsolete, necessitating a large lifetime purchase to delay a product redesign. Product manufacturers also sometimes produce quantities of subsystems to their

products and keep these quantities in storage. A particular component might be in storage on its own, or in stocked subsystems. Thus, it can sometimes take a long time before a modified component saturates the supply chain.

- At some tier of the supply chain (represented by "n-m" in Figure 1), the number of suppliers contributing to an SMRE will be at a maximum. This will not be the first tier of direct suppliers, and it is unlikely to be the last tier (represented by "n" in Figure 1). Adding to this swell in contributing suppliers is the fact that many manufacturers designate more than one supplier to source a particular component to ensure business continuity. For example, if a manufacturer needs a 10-µF capacitor for an assembly, they might authorize three different suppliers to supply it. This designation amplifies the number of components that must be investigated for any purpose, because the component provided from supplier No. 1 could be different that the component provided by supplier Nos. 2 or 3.

- Some of the circled items in Figure 1 represent mixtures that are, of course, created from substances supplied by the next upstream tier. Only the shallower tiers of the supply chain will include complex assemblies; the base of the supply chain (tier n) will always be substance and mixture suppliers.

- For electronic simple components and simple assemblies, the supply chain is very much concentrated in Asia, which introduces significant complexity in supply chain communications. Plus, the deeper tiers of the supply chain often have no idea where their products are headed, and it is possible they are operating in regions with relaxed regulations.

- To populate a semiconductor manufacturing fabrication plant (also known as a fab), the number of different pieces of SMRE, materials, and infrastructure equipment required can be in the tens of thousands for an advanced node. Each supplier of SMRE, materials and infrastructure equipment in turn has a supply chain of their own (known as tier 2 or tier 3 suppliers from a factory architect perspective). The interdependency of the tools, infrastructure equipment and general materials (as well as their subcomponents) are often intricately interwoven, such that a change to any component – even something as seemingly insignificant as a valve in a tool, the delivery system of a bulk chemical, or the container of a chemical formulation used in chip manufacturing – can impact the yield or a performance parameter of the end-product integrated circuit. The complexity of making changes to this deeply interconnected supply chain cannot be overstated and often requires intensive change-point management.

There are various ways to specify the components and materials present in semiconductor manufacturing equipment:

- **Fabricated Components Designed by the Equipment Manufacturer (EM)** – The specification for fabricated components is typically a drawing that indicates one or several basic raw materials from which the component will be made, the dimensions and shape of the component, and a finish or finishes (such as anodization, paints or other coatings) that could be applied to the component. What is quite variable from one EM to the next is whether the specified materials and finishes are searchable. The drawings may be in a database that does not provide specific materials of finish fields, or the drawings may be simple digital images.

- **Assemblies Designed by the EM** – Assemblies will certainly contain the materials in the components listed on the assembly bill of materials (BOM). But there can also be substances and mixtures applied to the assembly in addition to the components such as adhesives, lubricants, and coatings. There can be some variety in how companies track these materials. Some companies might require the inclusion of these materials in the electronic BOM (meaning a digital record of the BOM), while others might allow the materials to be called out in notes on the assembly drawing, which prompts for them to be taken from floor stock, and they are not listed in the electronic BOM. So again, extensive manual analysis of drawings could be necessary to characterize all of the materials contributing to an assembly.

- **Contract Manufacturing** – After defining an assembly, some EMs farm out the manufacture of that assembly to other companies. These contract manufacturers are often obligated to follow the EM's component specifications, but in some cases the contract manufacturer can source components from any supplier as long as they fulfill the overall functional specification of the assembly. Therefore, determining the materials going into the assembly would require discussion with the contract manufacturer to learn which components they have specified over time at their own discretion.

- **Off-the-Shelf Components** – Off-the-shelf components are components presented for sale on webpages or in catalogs. The EM acquiring the component does not control the material content of the component except to the extent that material information (or material restriction regulation compliance, such as under RoHS) is indicated in the catalog, technical specifications, etc. EMs mostly select off-the-shelf parts because of their functional characteristics, such as the component being a 100-kΩ resistor or a programmable logic controller. If the off-the-shelf component is a complex assembly, the specific constituents of that component can change from time to time, with no change to the marketing description or part number from the supplier. An off-the-shelf component with the same name and part number might contain PIP (3:1) or DecaBDE from a sub-tier supplier in one week of production but not another.

Depending on the particular design methods of the off-the-shelf component supplier, the specific composition of all of their components might not be available – for all of the same reasons already mentioned for the EM. For more complex assemblies, it is unlikely that their own supply chain will be narrow and fixed. Rather, this supply chain will be wider to allow for alternate sub-tier suppliers, and it will change from time to time as opportunities for cost reductions arise, because of company dissolutions and mergers, or other matters.

It is likely that only larger companies will have employees dedicated to materials topics who can comprehend and competently respond to material inquiries. Even if such employees are available, customer inquiries do not usually get directed to them initially, since initial cold contacts are usually directed to a salesperson or account team. It can take some time to find the correct person to respond to material questions in any company.

All articles have their origin in fundamental chemicals (mixtures and substances). An article manufacturer is only aware of the substances in their articles to the extent that these substances have been revealed in material information such as safety data sheets (SDSs) from upstream chemical suppliers. Chemical suppliers have a vested interest in keeping as much of their formulation information out of SDSs as regulations will allow. If they were to reveal all of the details of their formulations, they would quickly lose any market advantage.

Time and Resources Required to Change Components

When considering the speed with which a company could switch from using one particular component to another, the following aspects are relevant:

- **Identifying the new part requires making or modifying drawings** – This typically involves having a complete commercial description of the part, an image of relevant web pages or catalog PDF pages offering the part, and the part number option codes for the part code/part number being purchased.

- **Planning the disposition of existing EM factory stock** – Options include disposing of the previous component, returning it, using it until all of the units are gone, and reworking it in some way (for example, by removing the undesired article within an assembly and replacing it with another article supplied by the OEM). There may also be other disposition considerations. All of these choices have both time and financial impacts. The more costly the unit, the more stakeholders in the decision process.

- **Having a new component supplier go through onboarding** – In the semiconductor industry this includes such elements as vetting the vendor to Responsible Business Alliance code of conduct expectations and other socially focused regulations and commitments for fair and humane employment practices.

- **Applying any relevant regulations to the new component** – Such regulations include those from the EU, South Korea, Taiwan, China, Japan and the U.S. For example, if the component uses a hazardous voltage then electric shock and fire safety regulations apply; if the component contains a microprocessor or other high-frequency circuit, then electromagnetic compatibility regulations apply.

- **Establishing appropriate procurement contracts** – Some components are simply purchased off the shelf from a website catalog. Others, however, can be semi-bespoke versions of the off-the-shelf item that include customizations negotiated between the EM and the supplier. Such cases require much more detailed procurement contracts to express all of the terms and conditions of the customization, with legal and engineering reviews on the EM and supplier sides as well.

- **Dispositioning global warehouses of the EM if the part is a replacement part** – Any equipment downtime in the semiconductor industry can represent hundreds to several thousands of dollars of lost production opportunity. Therefore, many EMs keep stores of anticipated replacement parts distributed around the world near their locations or even in end-user facilities. Some equipment end users might keep their own replacement part stocks on hand, particularly when their equipment is no longer under EM warranty. Just like local EM manufacturing stock, it will be necessary to locate all of these remote stocking locations and decide on disposition for the component units on hand. This can sometimes require a surprising amount of manual investigation entailing emails and phone calls, because all of the stocking location databases are not unified.

- **Modifying every EM-designed assembly drawing to which the component is a part** – Assembly drawings show in a series of figures how to assemble the various components in an assembly. These drawings are often accompanied by a longer descriptive assembly document that explains the assembly process step by step, with a series of diagrams and photographs for use on the equipment manufacturing floor (sometimes called “operations management systems drawings” or OMSs). In addition to these drawings, most companies use a 3D rendition of each component so that they can review assemblies made from the components in 3D for sizing, ergonomics, and other aspects. Therefore, changing a component in an assembly is likely to require the modification of three types of assembly drawings, some of which require in-process photographs or hand measurements if the component OEM does not offer standard 3D computer-aided design images of the component.

- **Redesigning other components of the assembly if the new component has a different electrical or mechanical interface** – For example, different mounting holes for a new component could require revising the object to which the component mounts. A new

component that uses different electrical connections or has a different arrangement of terminals will require modifications to the interfacing cable assemblies.

- **Renumbering higher-level assemblies to comply with form, fit and function rules** – Most EMs have a set of rules that define when a change in a component will allow a revision of the existing component part number (such as changing from 12345-678 rev C to 12345-678 rev D) or require the issue of a new part number. The importance of this decision is that companies usually store parts of different revisions in the same bin, and it does not matter which revision is selected to go into an assembly. The BOM for an assembly usually references part numbers only, and not part revisions. Thus, an assembly BOM calling for the revised part does not need to be modified. If, however, the EM's form, fit and function rules require the issue of new part number when a component is changed from a PIP (3:1)- or DecaBDE-containing to a non-PIP (3:1)- or non-DecaBDE-containing component (all other component features being equal) this will require revision to the immediate assembly part numbers. Likewise, the assemblies that incorporate that assembly will also have to get new part numbers, and so on up to the highest-level assembly. This cascading of new part numbers can have further impacts on manuals, other assembly documentation, and more.

- **Reworking or scrapping immediate assemblies that are also stocked** – This concern is similar to the disposition concern of the basic component. It relates to the possibility that beyond stocking the component on its own, an EM might also stock intermediate assemblies that include the component. EMs may do this because it is an efficient way to run operations, the intermediate assemblies may have some demand as replacement parts, or making intermediate assemblies can provide some work for staff when overall product demand declines. Of course, intermediate assemblies have more value than the component alone, so the disposition impacts can be more resource-intensive, requiring revisions to maintenance and service documents.

- **Revising various maintenance and service documents if the component is a replacement part** – These documents explain how to remove a failed unit and install a new unit and will have at least a reference to the component part number, as well as photographs, drawings or other media references, and even videos. A new component that has a new part number because of form, fit, and function rules or any other differing characteristic relevant to its identification or installation/removal process will require revisions to service and maintenance documents and new procedure photos or redrawn illustrations. A component significant to the operation of equipment (directly involved in an operator task, for example) will require revised operation manuals.

- **Redoing or revising equipment safety evaluations if the component has a significant safety role** – Many components have a critical role in regulatory evaluations. For example, an AC line filter might be critical to an electromagnetic compatibility

evaluation. A sensor might be critical to a process chamber lid-lifting assembly evaluation. The size and location of process chemical tank input port might be critical to a safety evaluation. The related assessment reports will tend to list which components are critical for compliance. Therefore, changes to any critical components will require modifying reports to reflect the change (including engineering rationale as to why the new component is acceptable). If changing many critical components at once, most cases will require redoing assessment testing and inspection, which is generally a significant project requiring the hiring of and coordination with a third-party assessment firm.

- **Conducting process requalification studies if the component has a significant process role in the equipment** – Generally speaking, a component has a significant process role in equipment if it comes into contact with any process chemicals or provides control in the process control system (such as a process voltage controller, vacuum controller or chemical temperature controller). Because semiconductor processes require precise control, and process disturbances are only detectable as the outcome of several serial processes, changing process-critical parts can require requalification process runs that require thousands of substrates and taking the entire multi-process chain to its conclusion before it is possible to detect any impacts – translating to many weeks and thousands of dollars of effort. Changing multiple components requires even more effort in requalification experiment definitions, in order to ensure definitive information about the impact of any individual component change as soon as possible.

SEMI has fundamentally changed its position on requesting an extension to the deadline for PBT compliance, particularly for the PIP (3:1) and DecaBDE rules. We simply do not have access to sufficient information to understand when compliance could be achieved for a complete PIP (3:1) and DecaBDE ban. Therefore, we ask that EPA take into account the realities of our supply chain and the engineering processes typically required in identifying a non-compliant component and designing an alternate into distributed products. Certainly, an extended timeline would be necessary if threshold criteria and a due diligence framework are not provided in the rule. However, if the rule is modified to provide the requested thresholds and practicable due diligence framework, and the requested explicit statement about the interpretation of the meaning of 'article' is provided by the EPA, it is more feasible to work within the existing rule timeframes.

SEMI understands and appreciates EPA's recognition that equipment manufacturers should flexibly manage due diligence in their communications with suppliers. The preamble to EPA's proposed rule states that, "[t]he customer can include a specification in their purchase contracts with suppliers that articles be made without PIP (3:1). The customer can also request that their suppliers provide them with a written statement or certification that the purchased or supplied goods are made without PIP (3:1)." 86 Fed. Reg. 59684, 59689 (Oct. 28, 2021). SEMI

members are committed to complying with the PBT rules but require assistance from EPA in understanding what would be considered appropriate due diligence.

Therefore, we ask that EPA provide a due diligence framework in the rules to the following effect:

- First, due diligence should be executed using TSCA's "known to or reasonably ascertainable by" standard.

  This would limit to manageable levels the scope of due diligence that manufacturers would be expected to take with upstream suppliers. EPA already applies this standard to its TSCA Chemical Data Reporting Rule and has also proposed to apply it to the agency's PFAS reporting rule.[10]

- Second, affected companies should communicate with their direct suppliers, in writing, that the parts they supply must comply with TSCA PBT restrictions.

  SEMI recognizes that while many suppliers are located outside of the United States, domestic suppliers may be much more familiar with TSCA regulations. We thus anticipate that in situations involving domestic suppliers, this communication will be more straightforward – and thus will occur more quickly.

- Third, affected companies should ask direct suppliers to provide a written declaration of compliance for parts that are compliant with the PBT restrictions.

  Again, SEMI anticipates that this step may be more streamlined for domestic suppliers.

- Fourth, and if possible, concurrently with step 3, an affected company should weigh these declarations against their independent assessments of the likelihood that the part could contain restricted substances.

  The affected company could engage in other means to confirm compliance, considering the type of component involved.

- Finally, and if necessary and appropriate, affected companies should consider conducting testing on representative part samples as a method of confirming compliance.

  However, due to the significant costs and time involved, such testing need only be considered where a less time- and resource-intensive approach would not suffice.

[10] *See, e.g.*, 40 C.F.R. § 711.15; 86 Fed. Reg. 33928 (June 28, 2021).

- Despite the above precautions, if an affected company discovers that a non-compliant part has been inadvertently distributed, the company should create a phase-out plan and cease distribution of the part.

  The company would then further consider appropriate steps, which might include self-disclosure to EPA and follow-up discussions.

This due diligence approach is consistent with approaches suggested by most regulators outside the United States. For example, EU RoHS imposes material restrictions on certain electronic equipment. The relevant EU harmonized standard regarding due diligence states that the appropriate level of due diligence depends on the probability of the restricted substance being present and the trustworthiness of the supplier. IEC 63000:2018. Regarding the former, the manufacturer may apply its technical judgment of the likelihood that a supplier or sub-supplier would have added the substance. Regarding the latter, the manufacturer may apply its historical experience with the supplier and the result of past audits or inspections. This EU RoHS harmonized standard does not envision testing in every case. Instead, in most situations, the appropriate due diligence would be to obtain a compliance certification, or contractual agreement, with the supplier regarding the regulated substance.

SEMI is pleased that EPA appears to be amenable to a similar approach and urges EPA to consider the due diligence steps that SEMI has proposed as practicable, efficient, and appropriate for managing compliance to the PBT rules. SEMI also notes EPA provided guidance on similar concepts of due diligence in the IRFA for the PFAS reporting rule, and particularly that "EPA recognizes that there is a range of factors that make obtaining data on substances in articles from suppliers easier or more difficult."[11] Therefore, SEMI is hopeful that similar guidance could be provided for the PBT rules.

E. EPA should incorporate exclusions for replacement parts into the PIP (3:1) and DecaBDE rules.

EPA should ensure that replacement parts for SMRE are not unreasonably subject to PIP (3:1) and DecaBDE restrictions. As we explained in our previous comments to EPA, the equipment that SEMI members fabricate is designed to last for decades, and replacements are critical to keep this equipment running. Many replacement parts were designed and fabricated well before the introduction of the PBT rules, and stockpiles of these parts should not be made obsolete – and thus requiring disposal – by the PIP (3:1) and DecaBDE rules. This negative environmental outcome would be a distinct possibility under the rules as they currently stand. Based on data collection efforts to answer EPA's questions in the agency's request for comments, the documented service life for semiconductor articles can extend from one year to beyond 25

[11] EPA, PFAS Reporting Rule IRFA, *supra* note 3, at 5.

years. The need for replacement parts while articles are still in operation are generally for some or all of the following needs:

- Repairs to existing articles
- Consumable replacement parts
- Non-consumable replacement parts
- Planned and unplanned service intervals

As we noted in our December 22, 2021 letter, EPA has already provided exclusions for replacement parts for other industries, including "for use in new and replacement parts for motor and aerospace vehicles, the new and replacement parts to which PIP (3:1) has been added for such vehicles, and the motor and aerospace vehicles that contain new and replacement parts to which PIP (3:1) has been added." 40 C.F.R. § 751.407(b). EPA recognized "that it would not be practicable to regulate processing and distribution of PIP (3:1) for use in new and replacement parts for automobiles as they are important to the performance and safety of automobiles, have no currently available feasible alternatives, and there is low potential for consumer exposure." EPA adopted similar exclusions for DecaBDE in replacement parts for aerospace and motor vehicles. EPA's rationale above would also apply to SMRE.

In addition, the semiconductor, aerospace, and automotive industries are intertwined. The aerospace and automotive industries would be adversely affected by any disruption in the availability of semiconductor equipment or parts. However, SEMI emphasizes that the semiconductor equipment industry produces fewer units per year than the automotive industry, and those SMRE units (unlike most automobiles) are all professionally managed and handled. These factors suggest that the environmental impacts of an exclusion for SMRE would be less than that of the automotive industry.

It would be a negative environmental outcome for existing replacement parts for SMRE to be scrapped where, as here, there is both a low potential for consumer exposure and new alternatives have yet to be developed. If an existing replacement part does contain PIP (3:1) or DecaBDE, an alternative replacement part without PIP (3:1)- or DecaBDE-containing materials will likely not have been created, and thus may not be available immediately. An alternate engineering solution would then have to be developed. Such a solution could take a significant amount of time, depending on the part involved and its electrical and mechanical interfaces in the equipment. If the replacement part is for a key piece of equipment in the device manufacturing process of the equipment customer, it can impede the availability of many thousand end-use devices (semiconductor chips) per day. Indeed, rushing alternatives could snowball significant hazards in upstream supplies and disrupt the manufacture of critical SMRE articles.

Therefore, we ask that EPA provide the following exclusions:

- An exclusion to the DecaBDE rule for replacement parts for:
    - Articles manufactured prior to March 8, 2021, and
    - Articles distributed in commerce prior to January 8, 2022.
- An exclusion to the PIP (3:1) rule for replacement parts for:
    - Articles distributed in commerce prior to October 24, 2024.

F. Alternative Approach

SEMI has been working diligently to understand the realistic challenges our members face in bringing semiconductor manufacturing equipment into compliance with the DecaBDE and PIP (3:1) rules. We have modified our requests to EPA based in part on data from our supply chain regarding the relatively low difficulty in finding the replacement for a non-compliant component once it is identified, how suppliers understand the 'zero content' criterion, and the time it has taken for some component assemblies to be redesigned and deployed. We are also concerned with confusion about how the term 'article' frustrates communications and investigations, and the impact the rules will have on replacement parts required to maintain a large population of long-lived equipment.

Our high-level requests, as detailed above, are for EPA to:

- Adopt a threshold limit for PIP (3:1) and DecaBDE in articles of 0.001% and 0.1%, respectively,
- State its interpretation of 'article' particularly in light of the European Court of Justice's ruling regarding the same term as used in EU REACH,
- Provide a framework of due diligence that accounts for the real inertia in a multi-tiered, complex, and global supply chain, and
- Provide exclusions in the two rules for replacement parts needed for legacy equipment.

Failing those requests, we ask that EPA provide the longest possible extension in the compliance dates for semiconductor manufacturing equipment that is proportional to the risks potentially posed by DecaBDE or PIP (3:1), or that EPA provide an enforcement statement for semiconductor manufacturing equipment regarding both substances similar to the

enforcement statement issued by the agency for certain uses of DecaBDE in nuclear power generation facilities.[12] Such an enforcement statement should be issued with due consideration of the resources and information required to demonstrate that the semiconductor manufacturing industry is diligently working to identify and qualify alternative components.

G. Conclusion

SEMI is grateful for the opportunity to comment on the PBT rules. We hope that the additional detailed data we provided herein gives EPA a clearer picture of the challenges that these rules present to our members and member suppliers. For the foregoing reasons, SEMI urges EPA to amend the PIP (3:1) and DecaBDE rules as described above. Should EPA have any questions, please reach out to Ben Kallen, SEMI Sr. Manager, Public Policy & Advocacy, at bkallen@semi.org.

[12] EPA, Enforcement Statement Regarding the Prohibition of Processing and Distribution in Commerce of Decabromodiphenyl Ether (DecaBDE)-Containing Wire and Cable Insulation in Nuclear Power Generation Facilities under 40 C.F.R. § 751.405(a)(2)(ii) (May 2, 2023), https://www.epa.gov/system/files/documents/2023-05/Enforcement%20Statement%20Regarding%20DecaBDE%205%202%202023.pdf.