Comments of the
Semiconductor Industry Association (SIA)
On
EPA Proposed Rule on TSCA Reporting and Recordkeeping Requirements
For Nanoscale Materials
80 Fed. Reg. 18,330 (April 6, 2015)

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The Semiconductor Industry Association (SIA) submits these comments to the U.S. Environmental Protection Agency (EPA) on the above-referenced proposal on TSCA Reporting and Recordkeeping Requirements for Nanoscale Materials (80 Fed. Reg. 18,330 (April 6, 2015) (the "Reporting Rule").

SIA is the trade association representing leading U.S. companies engaged in the design and manufacture of semiconductors. Semiconductors are the fundamental enabling technology of modern electronics that has transformed virtually all aspects of our economy, ranging from information technology, telecommunications, health care, transportation, energy, and national defense. Innovations in semiconductor design and manufacturing have resulted in increasingly smaller, more powerful, less expensive, and more energy efficient semiconductors, which has a "multiplier effect" that drives advancements throughout other sectors of the economy, resulting in increased growth, jobs, and productivity. In addition to the economic importance of this industry, semiconductors have strategically important applications that ensure U.S. military superiority. The U.S. is the global leader in the semiconductor industry, and continued U.S. leadership in semiconductor technology is essential to America's continued global economic leadership. More information about SIA and the semiconductor industry is available at www.semiconductors.org.

EPA's current proposal begins an important process of identifying chemical substances that have been designed and engineered to be discrete nanoscale materials, with a goal of improving EPA's understanding of the profile of such materials in U.S. commerce. Such information may assist EPA in determining whether and how to pursue further information about these materials to advance the protection of human health and the environment. SIA strongly supports this goal. It is important, however, that EPA design this initial information collection strategy in an efficient manner and proceed in a way that does not impede innovation in semiconductor manufacturing, which is essential for continued U.S. technology leadership. In the comments below, SIA offers specific recommended changes to the rule that will help achieve this balance.

I. Overview of SIA's Comments

SIA believes that EPA is on the right track in seeking to gain a general understanding of current commercial substances engineered as discrete nanoscale materials before it pursues further information collection, risk assessment or risk management activities. We also support EPA's intent to pursue that goal "without prejudging new technologies or creating unnecessary barriers to trade or hampering innovation," to be consistent with Administration policy.[1]

From SIA's perspective, this rule must yield three results if EPA's expressed objectives noted above are to be achieved:

- More clearly differentiate the nanoscale structures in semiconductor devices from the discrete nanoscale materials that are reportable under the rule – The semiconductor industry employs nanotechnology in its operations. To produce modern semiconductors it is necessary to design and create semiconductor structures with nanoscale dimensions. These structures, however, may be made with conventional chemical substances, rather than substances engineered as nanoscale materials for their unique properties. EPA should revise this rule to more clearly exempt nanoscale structures that are part of a semiconductor device. This is needed to avoid any implication that EPA is attempting to regulate semiconductor devices per se, which would present problematic, and completely unnecessary, disruption of technology development in the U.S.[2]

- Focus initial information collection efforts on manufacturers and importers, and exempt processors from reporting requirements at this time – The rule should collect information necessary for the general understanding that EPA wants to achieve in an efficient manner by targeting initial efforts on the right parties. As discussed in more detail below, the general design of this rule is extremely problematic for processors to implement and may be infeasible for processors to implement as a practical matter. Moreover, most of the information that EPA is seeking in this rule is not within the expertise of chemical processors. EPA's decision to include processors in this rule, which is inconsistent with historic EPA practice under Section 8, should be reconsidered.

- Eliminate the 135-day waiting period – The proposal would require a company that intends to manufacture or process a reportable chemical substance to file its

[1] Memorandum on Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials (June 9, 2011).
[2] A semiconductor is an "article" under TSCA, which is not within EPA's intended scope of this Reporting Rule.

report at least 135 days before initiating commercial manufacture or processing of the reportable substance. This waiting period is not consistent with EPA's general approach to Section 8 reporting rules under TSCA. Instead, it is more typical of Section 5 notification requirements, which anticipate EPA review of a substance, and thus is not appropriate in this context.

- Protect proprietary information – The rule must prevent the disclosure of Confidential Business Information (CBI) about semiconductor manufacturing operations. As explained below, the detailed nature of the reporting form to be used for this rule, coupled with the reliance on inadequate CBI protection procedures, do not provide the assurance that CBI will be protected from disclosure. The semiconductor industry is a highly competitive, global industry, and the protection of CBI is a top priority in our industry.

II. Background on Semiconductor Manufacturing and Nanomaterials

Modern semiconductors, sometimes referred to as integrated circuits (ICs) or chips, have billions of transistors that are interconnected together on a single chip that may be smaller than a centimeter. To achieve this level of complexity at such a small scale, the semiconductor industry is engaged in manufacturing at the nanoscale. This nanoscale manufacturing typically employs conventional "macro-scale" forms of chemical substances (in contrast to chemical substances as discrete nanoscale materials, as contemplated in the proposed rule) in very small quantities, using highly advanced manufacturing equipment to deliver specific chemicals in precise amounts at precise locations. Also, there are some situations where chemical substances engineered as discrete nanoscale materials are used as process aids in the manufacture of semiconductors (e.g., as a component of slurries in the chemical mechanical planarization (CMP) process). In those cases, however, the specific application would constitute chemical "use", rather than "processing", under TSCA and the relevant substances would not be within the scope of the proposed rule under Section 8.

Individual transistors within a semiconductor are measured at the nanoscale and are comprised of multiple nanostructures which are permanently bonded together. These nanostructures are bound to the semiconductor device, which is an "article" in the parlance of the TSCA regulatory program, in a homogeneous fashion and are not discrete engineered nanomaterials. Moreover, these nanostructures are not separated from the semiconductor device or released to the environment under normal or reasonably anticipated conditions of use or disposal. These nanostructures of a semiconductor are not chemical substances engineered as discrete nanoscale materials as set forth in the proposal.

As the industry continues to work towards smaller structures in order to produce ever more powerful, fast, and energy-efficient products, future advances in the semiconductor industry may increasingly lead to the adoption of additional elements of nanotechnology, including the potential for increased use and processing of specific

chemical substances engineered as nanoscale materials that could fall within the intended scope of the proposal. For decades, semiconductors have been produced using a process known as Complementary Metal Oxide Semiconductor (CMOS) technology, a highly-automated process of hundreds of carefully controlled steps where complex equipment apply specific chemicals in precise amounts to a thin, round slice of silicon (known as a "wafer") to create numerous patterned layers of the integrated circuit. This process is repeated to selectively deposit, modify, or remove materials from the wafer surface. Many researchers believe that CMOS is approaching its physical scaling limits, and new processes and materials, including engineered nanoscale materials, are being investigated in order to continue the pace of innovation in the semiconductor industry. These experts believe that nanotechnology holds the potential to drive future innovation in semiconductor technology. Much of this research is conducted in collaboration with the federal government and leading research universities as part of the Nanoelectronics Research Initiative (NRI). The NRI is a consortium that supports university research in novel computing devices with the goal of enabling technology advances that will carry the semiconductor industry beyond the approaching limits of the current silicon-based technology.[3] This activity involves research and development at this time and would not involve reportable chemical substances as contemplated by the proposed rule.

III. EPA Should Clarify that Nanoscale Structures Are Not Covered by this Rule

As EPA undertakes its efforts to understand the nature of nanoscale materials currently in U.S. commerce, it is important for EPA to distinguish between the use of conventional chemical substances in the manufacture of commercial products with nanoscale structures (such as semiconductors) from chemical substances engineered as nanoscale materials. Specifically, through this rulemaking, the Agency should clarify that the Reporting Rule requires information on a specific substance that constitutes a "discrete form of a reportable chemical substance," including the aspects of this definition that require that the substance exhibits "unique and novel characteristics or properties." EPA should also clarify, in contrast, that this rule is not intended to cover all chemical substances used in nanoscale manufacturing, nor is it intended to require reporting of nanoscale structures present in a manufactured article, such as a semiconductor. Given the nature of the semiconductor industry, and the potential for nanotechnology to play an increasingly important role in future advancements in our industry, making this distinction clear is a high priority for SIA.

A. Film Exemption

Proposed Section 704.20(c)(1)(iii) provides an exemption for "Chemical substances manufactured at the nanoscale as part of a film on a surface." SIA supports the intent of this exemption. It recognizes that modern technology may involve the application of films in very thin layers on the surface of substrates. These film layers may be so thin that they have a thickness (potentially including in-situ topographical structures) below

[3] Additional information on the NRI is available at https://www.src.org/program/nri/.

100 nm, and thus may be viewed as nanoscale materials. At the same time, such films often are made up of conventional chemical substances, and do not contain any particles, aggregates or agglomerates that would otherwise be "reportable chemical substances" under the Reporting Rule. Accordingly, it is important to clarify, through an exemption, that such films are not within the scope of this rule.

SIA recommends two refinements of the regulatory language that should be consistent with the intent of this provision:

- First, it would be useful to identify in the exemption the common techniques that are used in multiple industries, including the semiconductor industry, to deposit films with nanoscale dimensions on a substrate. This will help clarify that the key to the exemption is the application of chemical substances to a surface "as part of a film," rather than the use of any particular deposition technique. To achieve this goal, SIA recommends that EPA refer to techniques such as vapor and atomic layer deposition, ion implant, sputtering, diffusion, spin-on processes and plating, which are commonly used in our industry.

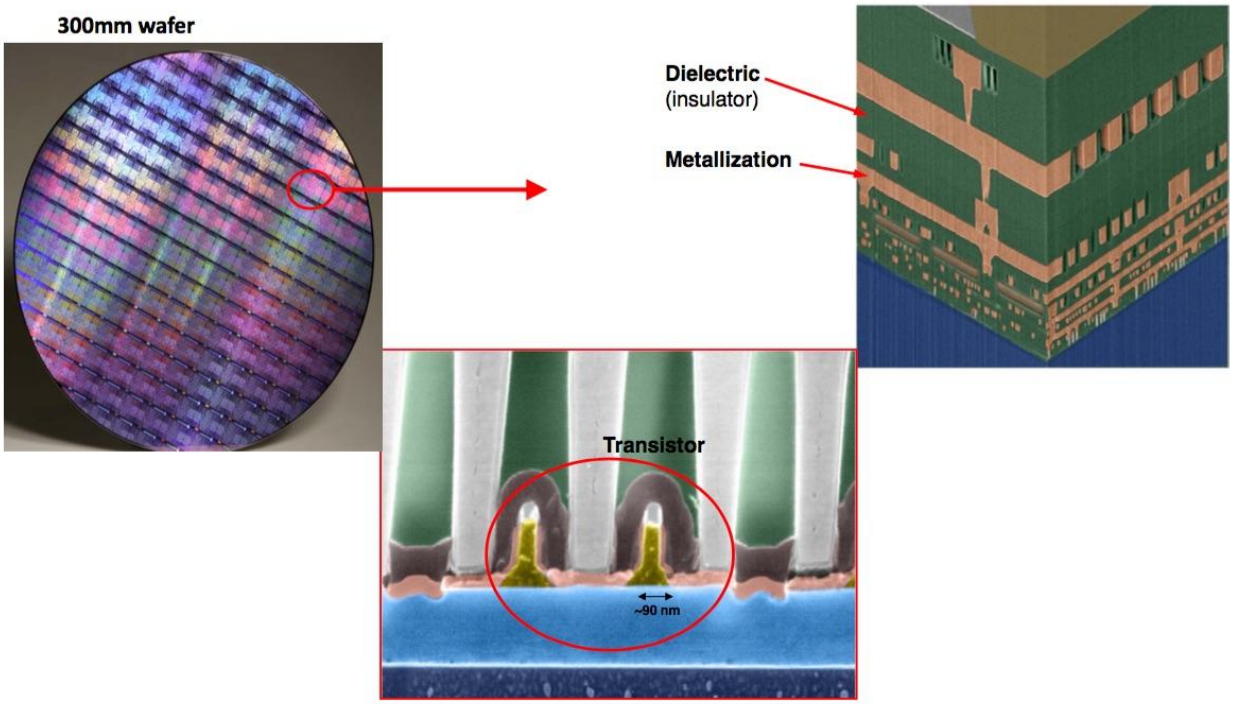
- Second, SIA recommends that EPA refer to chemical substances "manufactured or processed" in the exemption. Film deposition does not necessarily involve "manufacturing" of chemical substances as that term is understood under TSCA. Quite frequently, deposition of chemical substances as part of a film would constitute TSCA "processing". Clarifying the exemption in this manner would underscore that this exemption, as with the other exemptions in proposed Section 704.20(c)(1), is exempting certain chemical substances, regardless of whether they are manufactured or processed under TSCA.

SIA Recommendation – To achieve these refinements, SIA recommends that the exemption language at 704.20(c)(1)(iii) be worded as follows: *"Chemical substances manufactured or processed at nanoscale as part of a film on a surface, utilizing vapor or atomic layer deposition, ion implant, sputtering, diffusion, plating, spin-on processing or other deposition technique."*

B. Nanostructures

SIA also recommends that EPA include an exemption for a class of physical structures that are present on semiconductors that are quite similar to films, but have a slightly non-uniform three dimensional structure. In the manufacture of semiconductors, it is fairly common to create structures with nanoscale dimensions on the surface of a substrate within the semiconductor. The common characteristics of these structures are that they have been formed to serve an intended function within the semiconductor and thus are integral to the design of the semiconductor. These structures are bound to the substrate on which they are formed, and would not be separated from that substrate for any commercial use. Such nanostructures would not exist in an unbounded form as a particle, aggregate or agglomerate that would be processed, distributed or used separate from the semiconductor on which they are formed.

A typical example of such a nanostructure would be a transistor that is part of an integrated circuit within a semiconductor chip. As indicated in the picture below, it would be common for such a transistor to have nanoscale dimensions.



Nanostructures can be formed through a variety of processes. They may be etched into the surface of a substrate, implanted into the substrate or grown on the substrate surface. In the future, such nanostructures may be created by self-assembly techniques. Whatever the technique of creating these nanostructures, the key point is that the structure is bound to the substrate surface at its formation, as an integrated component of the semiconductor design and as an integral part of its function. It would not, by definition, exist as a separate commercial product that might be distributed in commerce.

Other regulatory authorities have recognized that nanostructures should not be considered nanomaterials. For example, the European Commission issued a Commission Recommendation in 2011 addressing how the term "nanomaterial" should be defined for "legislative and policy purposes."[4] With the issuance of this Recommendation, the Commission also issued a questions and answers document explaining the intended scope of the definition.[5] This document indicates that the European Community's definition "excludes nanostructured materials (i.e., solid products, parts or components) with an internal or surface structure in the range between 1-100 nm, such as computer chips." EPA should adopt a similar approach.

[4] Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial (2011/696/EU).
[5] Questions and Answers on the Commission Recommendation on the Definition of Nanomaterial, Memo/11/704 (Brussels, 18 October 2011)

SIA Recommendation – Accordingly, SIA recommends that EPA include an exemption in proposed 704.20(c)(1) to read as follows: *"Chemical substances present in nanostructures formed on the surface of or within an article where such nanostructure is a bound, integrated component of the article and is not intended for a purpose beyond its functionality in the article in which it is formed."*

C. Small Volumes of Non-Reportable Chemical Substances

The proposed definition of a "reportable chemical substance" indicates that such a substance is made up of primary particles, aggregates or agglomerates that "exhibit unique and novel characteristics or properties because of their size." In the preamble, EPA identifies examples of the kinds of characteristics or properties that are intended to be covered by this provision, mentioning electrical, magnetic, mechanical, thermal, optical, strength and hardiness attributes.[6]

EPA further states in that same discussion that "Small size itself can be a desirable property of nanoscale materials. The small size can be exploited for miniaturization of applications/processes and/or stabilization or delivery of payloads to diverse environments or incorporation into diverse products."[7] While it is not entirely clear what applications EPA is referring to in these statements, this description could capture a wide range of semiconductor uses, and the huge universe of products that semiconductors enable.

We assume that EPA does not intend to say that semiconductors and related technologies that advance miniaturization, and thus open up a range of new uses, are thereby within the scope of this rule. As noted earlier in these comments, nanoscale manufacturing may occur with conventional chemical substances that do not meet the proposed "reportable chemical substance" definition.

SIA Recommendation – EPA should revise this statement and make it clear that a chemical substance is not a "reportable chemical substance" when it is used to facilitate miniaturization through the creation of nanoscale structures on an IC or through use of chemical substances in nanoscale spaces within an IC.

IV. Processors Should Not Be Subject to Reporting Under this Rulemaking

SIA urges EPA to apply this rule only to manufacturers and importers, and to exclude processors from coverage. As a general matter, the information being sought by EPA can be more effectively and efficiently obtained by focusing EPA's initial information collection efforts on the manufacturer or importer of nanomaterials, rather than also requiring processors of these materials to report. Processors or users of nanomaterials are typically numerous steps removed in a complex supply chain from the manufacturer/importer of nanomaterials, who are best positioned to provide screening-level information on chemical identity, production volume, uses, and material

[6] 80 Fed. Reg. 18330 (April 6, 2015), at 18332.
[7] 80 Fed. Reg. at 18332.

characterization. Unlike manufacturers/importers, processors do not typically possess the expansive data called for in the EPA reporting form. EPA can achieve its preliminary information collection goals by requiring reporting only by manufacturers and importers of nanomaterials, and excluding processors.

A. EPA Can Achieve its Initial Information Collection Goals by Limiting Reporting to Manufacturers/Importers

EPA's goal in proposing this new reporting requirement is to improve its understanding of nanoscale materials in commerce. As an initial effort to obtain information on these materials, we believe that EPA's information collection goals can be achieved efficiently by limiting the collection requirements to manufacturers/importers.

EPA states that this proposal "would assist EPA in its continuing evaluation of chemical substances manufactured at the nanoscale," and that it "is not intended to indicate restrictions or conclusions about the risks of chemical substances manufactured at the nanoscale in general." Rather, EPA states, "the requirements would facilitate EPA's evaluation of the materials and its determination of whether any further action under TSCA, including additional information collection, is needed." 80 Fed. Reg. at 18,331-18,332.

SIA supports EPA undertaking this initial effort to evaluate nanoscale materials. As a preliminary data collection effort, however, we recommend that EPA should focus its efforts on manufacturers and importers of nanoscale materials and assess whether further reporting is warranted. This approach would enable EPA to obtain the key information elements needed to evaluate these materials and determine "whether any further action under TSCA, including additional information collection, is needed."

B. Processors May Not Be in a Position to Know the Substances to Report

Given the nature of the supply chain – coupled with the definition of a "reportable chemical substance" – processors will typically not know which substances to report which would make compliance with the rule infeasible. In contrast, manufacturers/importers have knowledge of the substances to be reported.

Based on the experience of SIA members, EPA should not expect that chemical suppliers will notify their customers about substances within their products that have been engineered to nanoscale. For purposes of compliance with requirements concerning Safety Data Sheets, and as a general business practice, it is considered acceptable to identify a substance by its common chemical name or Chemical Abstract Service number. These conventions for identifying chemicals in commerce are related to the chemical structure of the substance, not their physical characteristics or the fact that they may be engineered as nanoscale materials. Thus, processors have no assurance that they will be alerted to the presence of a "reportable chemical substance", as EPA has defined that term, in the chemical products they receive from

manufacturers and importers. The proposal does not include any provisions that would correct this problem.

In addition, the proposal introduces a further level of complexity into what must be reported that will make this problem even more acute. EPA has proposed that reports should be filed on each discrete form of a reportable chemical substance. Based on statements by manufacturers of nanomaterials, EPA's definitions of "discrete forms" of reportable substances, could require manufacturers to identify up to 100 different discrete forms of a reportable substance.[8] These discrete forms can only be defined by the manufacturer because the forms are defined in comparative terms, based on what the manufacturer is producing. A processor is unlikely to have knowledge of this information, and there is no objective standard of what is reportable that a processor can apply independent of the manufacturer's determinations. Further, the proposal does not require manufacturers to alert their customers about what discrete forms of a substance are separately reportable. Thus, expecting processors to be adequately notified about "discrete forms of a reportable chemical substance", a concept that is unique to this proposal, in a global chemical distribution system that cannot be expected to inform processors that the products they receive have any nanoscale materials is an invalid assumption.

Processors would not be in a position to know what substances to report on until EPA clarifies the scope of substances to be reported, manufacturers begin reporting on these substances, and this information is made available to processors and downstream users of these materials. Processors have no list of covered substances to work from. EPA needs to clarify the definition of reportable substance (see comments above), and manufacturers/importers should determine the universe of reportable substances and what substances are "discrete forms" for purposes of reporting. The manufacturers would then have to notify processors about the substances they deliver that are distinct for purposes of EPA reporting under this proposal.

C. Manufacturers/Importers are Best Positioned to Provide the Information Being Sought by EPA

EPA's reporting form, which is provided in the docket to this proposed rule, sets forth expansive expectations on reporting, and manufacturers and importers are best positioned to provide the information sought by EPA. Processors will not have information on the extensive data elements being requested by EPA. Instead of imposing a considerable burden on processors to report on information they likely do not possess, EPA should focus its efforts by targeting manufacturers and importers for reporting on nanoscale materials.

The proposed reporting form included in the rulemaking docket includes expansive data requirements. The requested data includes the following: (a) information describing the substance to be reported, its impurities and byproducts, production volumes, the forms

[8] Comments supporting this conclusion were offered by the Nanotechnology Panel of the American Chemistry Council at EPA's public meeting on the proposed rule, held on June 11, 2015.

of the substance, the Safety Data Sheet for the substance; and an explanation why the substance is being produced at nanoscale; (b) information on the manufacturing process for the substance; potential exposure to workers and controls for those exposures, potential releases to the environment and controls for those releases; (c) information on a life cycle overview of the reported substance, an estimate of the number of non-workers (e.g., general population, consumers) exposed to the substance, training programs for employees and customers, product labeling and other risk management measures; potential pollution prevention benefits of the substance; and (d) information on the physical-chemical properties of the reported substance.

Individual processors may have information on a limited portion of these data elements. But most of these data elements are typically beyond the knowledge of processors. As a result, imposing this reporting requirement on processors will be unlikely to yield useful information for EPA, particularly where EPA's stated goal is to obtain screening level information to improve its general understanding of nanoscale products in commerce. This goal can be more effectively achieved by obtaining useful information solely from manufacturers and importers, who are better positioned to possess this information.

D. Other EPA Reporting Requirements Apply Only to Manufacturers/Importers

Applying the requirement to report on nanoscale materials only to manufacturers and importers would be consistent with other EPA reporting programs under Section 8(a) of TSCA. In these other programs, EPA has recognized the likelihood that manufacturers and importers possess superior knowledge of the chemicals and materials they are supplying to users of these materials, and therefore various reporting requirements have been applied only to manufacturers and importers, and not processors. EPA should adopt the same approach in this context.

For example, in the Preliminary Assessment Information Rule ("PAIR") rule, EPA collects information about chemical uses and exposures only from manufacturers and importers, and not processors. Similarly, under the Chemical Data Reporting (CDR) rule, EPA requires submission of chemical-specific processing and use information from manufacturers and importers, rather than processors. EPA recently updated its Workplan Chemical List by relying on CDR data, which is only collected from manufacturers/importers.

EPA itself has questioned the value of requiring processors to report certain data under TSCA. In response to a report by the General Accounting Office that recommended issuance of reporting requirements for processors, EPA questioned the value of processor data and acknowledged that "processors" are not always end-users of products, and end users "often have little exposure-relevant data."[9]

[9] U.S. General Accounting Office, "Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach," GAO-13-249 (March 2013) at 39.

Further, placing the reporting obligation on manufacturers and importers would be consistent with recent action by Environment Canada to gather information on nanomaterials[10] and thereby promote the goals of the Canada-United States Regulatory Cooperation Council, which are intended to align a range of regulatory policies between the two nations.

E. If Necessary to Meet its Information Needs, EPA Can Request Targeted Information from Processors in the Future

If, after EPA reviews the reports from manufacturers and importers, EPA determines that more information is needed, EPA could request targeted voluntary information collection with downstream processors/users as needed. If that proves to be insufficient, EPA could develop a processor-specific reporting rule for certain industries requesting targeted data where needed to conduct more in-depth risk analysis. Any such requirement should be deferred until EPA has reviewed the reports submitted by manufacturers and importers and determines that additional information is warranted. Moreover, manufacturers/importers would first need to determine what discrete forms of nanomaterials are reportable and have notified customers of what is in their products.

EPA should revise the proposal and remove processors from the final version of this rule. Based on what is reported by manufacturers and importers, EPA would then have several options for moving forward. EPA may determine that it has sufficient information to establish priorities and take needed action for the foreseeable future without seeking further information from processors, as it has determined for the CDR rule. EPA might also determine, as suggested in its response to GAO, that further engagement of the processor community might be useful to acquire needed information, which can then be pursued through appropriate voluntary or regulatory measures.

SIA Recommendation – EPA should remove processors from reporting under this rule. Based on the results of reporting by manufacturers and importers, the Agency can then determine whether, and how, to collect additional information from the processor community.

V. The 135-Day Waiting Period Should Be Removed from the Rule

Although EPA states that the purpose of this reporting proposal is to obtain general information on nanomaterials in commerce, the proposal also sets forth a 135-day waiting period after a report is filed before processing of a reportable nanomaterial can begin. This waiting period is misguided and not in line with a Section 8 reporting obligation. Instead it is typical of a Section 5 review obligation. Also, this lengthy waiting period is unrelated to the purpose of the rule and would needlessly impose a disruption on the operations of the semiconductor industry. EPA should remove this waiting period.

[10] "Notice with respect to certain nanomaterials in Canadian commerce," Canada Gazette, Part I, Vol. 149, No. 30, (July 25, 2015).

Under proposed section 704.20(f)(2), a processor who "proposes to process" a discrete form of a reportable chemical substance must file the information required by this rule "at least 135 days before commencing" processing of the substance. This waiting period would be very disruptive to the fast-paced semiconductor industry characterized by the rapid introduction of new products. The 135-day waiting period would have significant economic impact on the US semiconductor industry and would harm the competitive position of US companies.

The business disruption associated with this provision is not warranted because a 135-day waiting period is not logically related to the purpose of this rule. As with any Section 8(a) rule under TSCA, EPA is requiring manufacturers, importers and processors to report information about chemical substances in commerce. Once that information is reported, the purpose of the rule has been served. Imposing additional constraints on the regulated parties after the information is submitted, particularly requirements that impede product commercialization, cannot be justified. It is worth noting that EPA has not created a waiting period of this nature in any other TSCA Section 8(a) rule. Instead, EPA has established reporting requirements and set a reporting deadline. Once timely reporting has occurred, the regulated parties face no additional requirements.

The circumstances could be different in situations where EPA is requiring "notification" of certain information that triggers a review by the Agency (e.g., for Pre-Manufacture Notices on new chemicals, for Significant New Use Notices on significant new uses of existing chemicals) or a further action by the Agency (e.g., export notification to a foreign government). Those circumstances, however, are not present in this rule. Thus the 135-day waiting period serves no public purpose and only causes unnecessary burden for the semiconductor and other businesses.

SIA Recommendation – EPA should remove the 135-day waiting period which does not support EPA's goal and causes unnecessary burden and economic hardship for US businesses.

VI. CBI Protection Should Be Upgraded to Protect Downstream Companies

SIA is concerned that the proposal does not adequately protect CBI of downstream companies. Manufacturers and importers would be required to provide extensive information about the uses of nanoscale materials by their customers, and this information, gained from interaction with customers, may include information the customer deems to be CBI. The proposal should be revised to provide sufficient protection of CBI for processors.

During the course of interaction between a supplier and a customer, the supplier may obtain information that the customer deems to be CBI. A supplier may gain knowledge of the customer's facility or types and quantities of materials used in manufacturing processes, and the reporting form under the proposal requires suppliers to report such "known or reasonably ascertainable" information to EPA. For example, Section II.B. of

the proposed reporting form ("Industrial Sites Controlled by Others") requires a diagram showing the major unit operation steps and chemical conversion steps (including points of storage and transport) of the downstream customer's production process, including disclosure of identity, weights, and entry points in the process of all feedstocks, along with all products, recycle streams and wastes. Taken as a whole, these reporting elements would cover a customer's full production process and information that provides insights into the capacity and production rates of the customer's facility. Coupled with other available information, an informed competitor could use this information to gain insights into competitive details of the customer's operations.

When information of this nature is reported by a supplier, the customer may not have notice about what specific information the supplier is reporting nor how the supplier is approaching the subject of CBI, and therefore does not have an opportunity to make a claim of its own concerning CBI. Proposed section 740.20(h) addresses claims for protection of CBI by making a cross-reference to 40 CFR 704.7, the general provision for CBI protection that applies to all Section 8(a) rules. That provision, in turn, refers to EPA's general rules for presentation and resolution of CBI claims, as specified in 40 CFR Part 2 ("Part 2 Rules").

The existing Part 2 Rules, however, do not provide sufficient procedural protections for downstream companies in this circumstance. The downstream customer may not be aware of the information being provided by their supplier, and therefore may not have an advance opportunity to request protection for this information. Under the Part 2 rules, if the supplier does not present a CBI claim for the information about its customer at the time it files the proposed reporting form, EPA would not have any duty to notify potential "affected parties", which would logically include the supplier's customers, to give them a chance to file a CBI claim. Under such a plausible scenario, the interests of the downstream customer would not be protected.

SIA Recommendation – EPA must establish a procedure that would provide notification, and an opportunity to file a CBI claim, to downstream customers of an upstream manufacturer, importer or processor if the Agency intends to disclose publicly the contents of the reported form.[11] In implementing such a procedure, it would be reasonable for EPA to focus its evaluation on the downstream customer information included in pages 11-12 of the form and the Lifecycle information on p. 13, Section C. EPA should also include in the form instructions a statement that reporters should consult with their customers on these sections of the form and an explanation that reporters should assert CBI claims for information that they expect to be considered CBI by their customers. Without such measures, EPA's CBI protection scheme is not legally sufficient.

[11] If EPA accepts SIA's recommendation that reporting be limited to manufacturers and importers, the notification and opportunity to submit a CBI claim should apply to all processors characterized in the reported form.