Appendix IV

Legal and Policy Rationale for SIA/SEMI's Request for a PFOS Exemption

SIA/SEMI has made it clear throughout this rulemaking that an exemption from the SNUR is needed and warranted for certain targeted uses of PFOS materials in the photolithography process. In our view, such an exemption is required by the legal standards in TSCA as applied to the record before the Agency.[1] Under Section 5(a)(2) of TSCA, EPA may regulate only "a use of a chemical that is a significant new use". TSCA's legislative history confirms the plain meaning of this statutory language – *i.e.*, that EPA may apply its SNUR authority only to uses that are both "significant" and "new."[2] As explained below in Sections I and II, PFOS uses in photolithography are neither "significant" nor "new", and hence, should be exempt from any final PFOS SNUR.

We also have indicated to EPA on several occasions that the risk-based framework developed by SIA/SEMI to support a SNUR exemption should apply to both existing and new PFOS chemicals used in critical photolithography applications. As explained in Section IV below, SIA/SEMI asks EPA to establish a written policy on how it will approach PMN's and LVE's for limited photolithography uses. It is imperative to our industry's competitiveness that the agency move forward on articulating such a policy based on the mass balance model results we have submitted.

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[1] In addition to the analysis provided in this letter, both SIA and SEMI have previously presented extensive comments indicating that the proposed SNUR, as it applies to uses in the electronics industry, does not meet the legal standards of TSCA. See letter from Charles L. Fraust, Director, Environmental Health and Safety, SIA (December 29, 2000), and letter from Victoria D. Hadfield, Vice President, Public Policy and North America, SEMI (December 29, 2000); Letter from McKenna & Cuneo on behalf of the photoresist industry (December 29, 2000); see also letter from Aimee Bordeaux, SEMI to Charles Auer, EPA (March 27, 2001). To the extent those comments are not summarized in this document, they are incorporated herein by reference.

[2] The Conference Report states that

> The conferees intend that any potential threats to health or the environment from the manufacturing, processing, distribution in commerce, or disposal of a substance associated with a *new use* be considered by the Administrator when determining the significance of the new use.

H.R. Conf. Rep. No. 1679, 94th Cong., 2d Sess. 66, *reprinted in* 1976 U.S.C.C.A.N. 4539, 4551 (emphasis added).

I. EPA Cannot Show that the Use of PFAS in Photoresists and ARCs is "Significant," as Required by TSCA Section 5(a)(2)

As a general matter, an agency must establish a record to support each of the key findings necessary to invoke its regulatory authority.[3] TSCA Section 5(a) establishes EPA's "significant new use" authority. In deciding whether a "use of a chemical substance is a significant new use", EPA must consider "all relevant factors, including":

(A) the projected volume of manufacturing and processing of a chemical substance;

(B) the extent to which a ***use*** changes the type or form of exposure of human beings or the environment to a chemical substance;

(C) the extent to which a ***use*** increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.[4]

This statutory language and structure makes plain that EPA may invoke its SNUR authority only when it has identified a particular chemical "use" that is both "significant" and "new" based on the potential for exposure and release of the chemical associated with such use and on any other "relevant factors". It is equally clear that the term "use" in Section 5(a) refers to activities distinct from "manufacture" or "processing" of a chemical substance,[5] and hence, that EPA may not invoke its SNUR authority based on findings that relate only to manufacture or processing, but instead, must examine and make findings specific to a particular chemical use.

EPA's general obligation to demonstrate that a particular use is significant before invoking Section 5(a)(2) is reinforced by other specific provisions in TSCA. In enacting this statute, Congress has been quite explicit when it determined that certain chemicals should be subject to regulation. In Section 5 itself, the Administrator must review all

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[3] TSCA § 19(c), 15 U.S.C. §§ 2618(a) & (c) (applying Administrative Procedure Act, 5 US.C. § 706 to judicial review of a SNUR rule based on "rulemaking record"); see 5 U.S.C § 706(2)(A) ("[t]he reviewing court shall * * * hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law").

[4] TSCA Section 5(a)(2), 15 U.S.C. § 2604(a)(2) (emphasis added).

[5] In several previous SNUR rulemakings, EPA has asserted that the term "use" in TSCA Section 5(a) refers to "any activity that potentially exposes human beings or the environment to a chemical substance" and that "[m]anufacture, import, and processing of a chemical substance are just three of many possible uses of a substance." 49 Fed. Reg. 39,703, 39,705 (Oct. 10, 1984). See also 65 Fed. Reg. 62319, 62320 (Oct. 18, 2000) ("this proposed [PFOS] rule would designate certain manufacturing and importing activities as significant new uses"). As SIA's original comments on the proposed SNUR amply demonstrate, however, both from a purely definitional standpoint as well as from the statutory language and juxtaposition that refers to "manufacture or process a chemical substance ***for a use*** which the Administrator has determined is a significant new ***use***", it is clear that the term "use" refers to an activity distinct from – and not one and the same as – manufacture and processing. See SIA Comments, Section 1, at 2-4.

new chemicals to determine whether regulation is warranted.[6] Yet, for existing chemicals -- which include the 90 PFOS chemicals that would be subject to the proposed SNUR[7] -- a SNUR is appropriate under Section 5 only where EPA has made a finding that a particular "use" of these PFOS chemicals is both a "significant" and a "new" use.

Importantly, where EPA wishes to regulate either "existing" (as opposed to "new") chemical "uses" or to regulate all chemical "uses" (whether "existing" or "new") on a broad basis, Congress provided EPA that authority -- ***not*** in TSCA Section 5 – but in TSCA Section 6. Under TSCA Section 6, EPA may engage in a range of regulatory actions from a complete ban on manufacture, processing and use, to use-specific bans, to product distribution requirements (such as labeling requirements), where EPA finds that such activities "presents or will present an unreasonable risk of injury to health or the environment." TSCA Section 5(a), in contrast, does not authorize EPA the authority to restrict either "existing" uses or all uses on a blanket basis, but instead, limits EPA's authority to regulate "a use" that EPA has determined is both "new" and "significant" -- ***not*** based upon a finding of "unreasonable risk" as to the specific chemical or class of chemicals -- but, instead, based upon factors relating to whether the chemical release and exposure that would occur in conjunction with such a "new" "use" are "significant".

In the proposed SNUR, EPA appears to ignore this statutory structure of TSCA and attempts to regulate all manufacture, processing and uses of the 90 PFOS chemicals on a blanket basis. Indeed, the Preamble to the proposed SNUR contains no analysis mandated under Section 5(a)(2) for why particular uses of PFOS qualify as "significant" under TSCA. EPA's analysis of the current situation indicates that PFOS substances in general are potentially toxic to humans, based on animal data, and have a tendency to persist in the environment and bioaccumulate in organisms. Yet these elements of EPA's hazard concerns about PFOS typically are not sufficient for determining that particular uses of PFOS are responsible for the risks that the Agency perceives.[8] Certainly, EPA has not made any findings that relate directly to the photolithography process in the electronics industry.

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[6] Section 5(a)(1).

[7] TSCA defines "new chemical substance" as any substance not listed on the TSCA Inventory. 15 U.S.C. § 2602(9). By implication, therefore, all Inventory-listed chemicals are considered "existing chemical substances." POSF itself and the many derivative chemicals produced by 3M in the United States and imported by 3M and others into the United States either were listed on the initial TSCA Inventory or were subsequently added to the Inventory through PMN submissions. All PFOS SNUR materials, therefore, qualify as "existing chemical substances".

[8] To the extent that EPA indicates what uses may be causing human exposure to PFOS, the Agency has emphasized that surface treatments and paper protection uses present the greatest potential for widespread human and environmental exposure. See 65 Fed. Reg. at 62326.

A. EPA Has Not Made Any of the Required Findings Under TSCA Section 5(a)(2) to Support the Proposed SNUR

Looking at the primary factors that TSCA enumerates for determining that a chemical use is "significant" under Section 5(a)(2), EPA has not made any specific findings related to the use of PFOS in photolithography in the electronics industry. EPA, for instance, has not explained why the "volume of manufacturing and processing" of PFOS in our industry is a concern (Section 5(a)(2)(A)). Nor can it, given the very small quantities of PFOS manufactured, imported and processed for all applications in our industry (let alone photolithography, the subject of our exemption request).

EPA also has not asserted that the continued use of PFOS in photolithography "changes the type or form of exposure of human beings or the environment to a chemical substance" (Section 5(a)(2)(B)). This statutory factor, with its focus on "changes", underscores that EPA's SNUR authority is intended to address industry actions that alter or go beyond the status quo. The statute does not contemplate a general or broad-based examination, but rather, one keyed directly to the particular "use" in question -- *i.e.,* "the extent to which a use changes the type or form of exposure . . . ." Clearly, continuation of existing uses of PFOS in photolithography does not change any aspect of human or environmental exposure to the chemical. EPA's effort in this rulemaking to recast the continued use of PFOS in the electronics industry as a "significant new use" for regulatory purposes represents a tortured logic that TSCA does not authorize.

Similarly, EPA has not asserted, nor does the record support, any conclusion that continued use of PFOS in photolithography "increases the magnitude and duration of exposure of human beings or the environment" to the chemical (Section 5(a)(2)(C)). Maintaining the status quo under the types of rigorous manufacturing and environmental controls our industry has implemented does not increase exposure.[9] Surely, all oral feedback from the Agency on the mass balance model for our industry does not indicate otherwise. Again, the examination as to this factor does not involve a general or broad-based analysis of the chemical substance, but rather, must occur as part of "[a] determination . . . that a use" is as a "significant new use." EPA's own regulations, which apply when a SNUR is issued for a new chemical substance in the absence of a Section 5(e) order, indicate that in general the Agency will issue such a SNUR only if it determines that uses of the chemical not described in the PMN "may result in significant changes in human exposure or environmental release levels and/or [that] concerns exist about the substance's health or environmental effects." See 40 C.F.R. § 721.170. Numerous factors -- including the minute quantities of these compounds in use; the highly automated manufacturing process which, along with personal protective equipment, limits exposure; the careful handling and disposal of these compounds

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9 As explained in Section II.B.3 of Appendix I, the electronics industry has a longstanding record in providing worker protection in its facilities, a philosophy which is reinforced by the high level of quality control that must be maintained in electronics manufacturing -- a key element of which is highly automated processes.

through incineration; and the very small wastewater discharge for the industry as a whole – confirm why EPA cannot conclude that continuing use of PFOS in limited photolithography applications "result in significant changes in human exposure or environmental release levels and/or [that] concerns exist about the substance's health or environmental effects."

Finally, EPA has not provided an explanation why "the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal" of PFOS related to photolithography warrants a "significant new use" designation (Section 5(a)(2)(D)). As discussed below, our methods of manufacturing, processing, distribution and disposal for the limited applications for which we seek an exemption result in insignificant environmental impact; thus, no "significant" use designation can be made based on Section 5(a)(2)(D).

EPA has not been able to make the findings outlined above because there are no available data demonstrating that the use of PFOS in the photolithography process plays a significant role in the levels of PFOS found in the general human population or in wildlife species. Moreover, we do not believe there is a plausible scientific basis for assuming that such a link exists.

B. Data Submitted by SIA/SEMI Indicate Our Industry's Use of PFOS in Photoresist Materials and ARCs is Insignificant

As noted earlier, SIA and SEMI have now completed a comprehensive survey of the use of PFAS materials in photolithography and have modeled the potential releases to the environment using reasonable worst case assumptions. This analysis indicates the aggregate contribution of PFAS to the environment from the photolithography applications for which we seek exemption – photoresist materials and ARCs – is insignificant. For example, the model demonstrates that aggregate releases of PFAS to wastewater from these photolithography applications during an entire year will decline to 56 kilograms once PFOS is eliminated from developer products. Moreover, recent data suggests that this very small release to wastewater may not even fully enter the environment in a manner available for exposure.[10] As the model indicates, the other pathways of potential release to the environment would be even smaller than the wastewater pathway.

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[10] See AR-226 docket, 3M Fluorochemical Data Submitted on CD as follows: Battelle Multi-City Study (detecting little or no PFOS in drinking water, plant effluent, surface water and landfill leachate; detecting marked levels of PFOS in POTW and facility sludge and in sediment); 3M Sorption/Desorption Study On PFOS (finding PFOS sorbed to sludge very strongly (>96% sorbed) within the first few hours of exposure, with Kd values for sediment and sludge of 7.42 mL/g and 120 mL/g respectively; finding little PFOS desorption, even when extracted from organic solvent); Modeling Of Incineration Process By University Of Dayton (concluding that "the perfluoroinated alkyl sulfonyl compound would have relatively low thermal stability" due to the carbon-sulfur bond in the perfluorooctane sulfonate molecule being "a fairly weak bond," which suggests that the PFOS molecule, itself, would be destroyed in solid and hazardous waste combustion units").

In addition, SIA and SEMI also do not see any significant potential for the requested exemption to create localized impacts of concern. The photolithography applications of PFAS in photoresist and ARCs that we have focused on for a SNUR exemption occur broadly across the industry. As a result, the aggregate amounts of PFAS coming from these applications are distributed among approximately 80 manufacturing facilities in diverse geographic locations. Likewise, the environmental management practices we have described, such as the incineration of solvent wastestreams, are broadly employed in the industry. These factors, coupled with the small aggregate amounts of PFAS released to the environment from these photolithography applications, indicate that any marked concentration of PFOS releases in a particular locality is very unlikely.

In summary, EPA has not made or supported any specific findings that the use of PFAS materials in the photolithography process could plausibly account for the widespread presence of PFOS in humans or wildlife that is the impetus for this rulemaking. Numerous factors -- including the minute quantities of these compounds in use; the highly automated manufacturing process which, along with personal protective equipment, limits exposure; the careful handling and disposal of these compounds through incineration; and the very small wastewater discharge for the industry as a whole -- confirm that use of the PFOS compounds in photolithography by the semiconductor industry does not qualify as "significant" by any measure. Based on the information that SIA and SEMI have now assembled and presented, the Agency has affirmative evidence that the environmental releases attributable to photolithography process are insignificant. In light of this evidence, the Agency may not sweep this industry into a broader presumption that all uses of PFOS are significant new uses under TSCA.[11]

II. EPA's SNUR Authority Under TSCA Section 5 Does Not Extend To Ongoing Uses -- But Only To "Uses" Which Are "New"

As noted earlier, neither TSCA nor EPA's implementing regulations in 40 CFR Part 721 define "significant new use." Absent a statutory definition, the words must be given their plain meaning[12].

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[11] In addition, under the Administrative Procedure Act, EPA must establish, through the rulemaking record, that there is a rational relationship between the operations of potentially regulated parties and the assumptions underlying the policy and technical framework for a rule. See, e.g., Edison Electric Institute v. United States Environmental Protection Agency, 2 F.3d 438 (D.C. Cir. 1993) (remand of hazardous waste classification under RCRA as applied to mineral processing for failure to respond to submitted factual data showing that waste mismanagement scenario assumptions were inapplicable.)

[12] Under the circumstances, Congress is presumed to have intended an ordinary meaning. Williams v. Taylor, 120 S.Ct. 1479, 1488 (2000)(internal quotations omitted) ("We give the words of a statute their 'ordinary, contemporary, common meaning,' absent an indication Congress intended them to bear some different import."); Jones v. United States, 120 S.Ct. 1904, 1910 (2000)(*quoting Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995))("'When terms used in a statute are undefined, we give them their ordinary meaning.'"); see also Johnson v. United States, 120 S.Ct. 1795, 1804, n.9 (2000)(citation omitted) (a court must depart "from the rule of construction that prefers ordinary meaning" only "when the ordinary meaning fails to fit the text and when the realization of clear congressional policy . . . is in tension with the result that customary interpretive rules would deliver.").

Specifically, "significant new use" would typically mean a use of some importance that has not yet occurred or that is sufficiently distinct from current uses that an unreasonable risk of injury to human health or the environment is created. The factors in Section 5(a)(2) that EPA must consider in identifying a "significant new use" support this interpretation. For example, EPA must consider "the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance." TSCA Section 5(a)(2)(B)(emphasis added). Existing uses of a chemical do not change human health or environmental exposures, especially where such exposures are insignificant because of well-established manufacturing and environmental controls. In addition, Congress also directed EPA to consider "the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance." TSCA Section 5(a)(2)(D) (emphasis added). If Congress meant for EPA to regulate existing uses under Section 5, then no such "anticipation" would be necessary, as EPA would be able to consider already existing manufacturing, processing, distribution and disposal methods for the chemicals at issue.

The legislative history and language of TSCA Section 5 both clearly indicate that only "new" uses satisfying certain criteria may be regulated under Section 5. When Congress decided to vest EPA with authority to regulate "existing" uses, it knew how to accomplish its objectives – *i.e.*, unlike Section 5, TSCA Section 6 is not limited to "new" uses, but rather, applies to all uses.[13]

SIA understands that EPA has frequently relied on its TSCA Section 5 SNUR authority to regulate "new chemical substances" and has promulgated generic regulations to address new chemical SNURs. As noted above, however, all of the compounds covered by the proposed SNUR for PFOS qualify as existing -- and not new -- chemical substances under TSCA's statutory framework.[14]

In the case of existing chemical substances, EPA has exercised its SNUR authority on less than fifteen occasions since the inception of the TSCA program in the 1970s.[15] On each and everyone of these occasions, EPA has recognized that its SNUR

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13 See *Brown v. Gardner*, 513 U.S. 115, 118 (1994) (*quoting Russello v. United States*, 464 U.S. 16, 23 (1983)). ("'[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'").

14 Notably, as information submitted to EPA by SIA and SEMI members as well as by other chemical manufacturers and suppliers indicates, PFOS itself, and its many derivative chemicals, have been produced and imported into the United States not just by 3M, but by others as well prior to the proposed SNUR.

15 See 61 Fed. Reg. 52,287 (Oct. 7, 1996) (benzidine-based chemicals); 58 Fed. Reg. 63,500 (Dec. 1, 1993) (18 acutely toxic EPCRA 313-listed chemicals); 56 Fed. Reg. 56470 (Nov. 5, 1991) (Erionite fibers); 54 Fed. Reg. 18286 (Apr. 28, 1989) (pentabromoethylbenzene); 54 Fed. Reg. 12447 (Mar. 27, 1989) (certain benzenamines); 53 Fed. Reg. 2845 (Feb. 2, 1988) (1-chloro-2-bromoethane); 52 Fed. Reg. 41,300 (Oct. 27, 1987) (trichlorobutylene oxide); 52 Fed. Reg. 19,865 (May 28, 1987) (11-aminoundecanoic acid); 52 Fed. Reg. 1,1825 (Apr. 13, 1987) (methyl n-butyl ketone); 51 Fed. Reg. 9453 (Mar. 19, 1986) (hexamethylphosphoramide); 48 Fed. Reg. 20,668 (May 6, 1983) (proposal to promulgate SNUR for chlorinated naphthalenes).

authority extends only to "new" uses of a chemical and that "new" "describes a use of a chemical substance that is different from what is currently ongoing".[16] Thus, as EPA has stated "[t]o establish a significant new use, EPA must determine that the use is ***not ongoing***".[17] Such a determination, however, simply cannot be made for the two photolithography applications for which SIA/SEMI are seeking an exemption -- *i.e.*, photoresist materials and ARCs.

These applications are longstanding in the semiconductor manufacturing process, and PFAS use in these applications was occurring prior to the date of the proposed SNUR. Although, as discussed in Appendix I to this submission, semiconductor manufacturing technology is dynamic, it is important to recognize that current cutting-edge as well as future generations of manufacturing technology will involve even greater materials efficiency and will not otherwise differ from current technology in terms of the PFAS profile presented in the photolithography mass balance model discussed in Appendix III. Thus, the PFAS uses in these applications simply do not qualify as "new" in any way, shape or form.

III. The Apparent Legal Premise Of The PFOS SNUR Proposal -- That 3M's Phase-Out of the Manufacture of "Existing" PFOS Compounds Means any Production of the Same Chemicals Therafter is a "New" Use -- - Clearly is Inconsistent With The Language of TSCA Section 5(a) And its Structure

The proposed SNUR would appear to be based on the legal premise that the agency can use 3M's voluntary phase-out of PFOS chemicals to "recharacterize" the status of existing chemicals so that any manufacture or import of such existing chemicals after the 3M phase-out become "new uses." The dependence on 3M's voluntary phase-out to define all manufacture or import of SNUR listed PFOS chemicals as new uses poses several significant problems.

⇒ First, as discussed in detail in SIA's prior comments to EPA, the statutory language and context make clear that 3M's "manufacture" of PFOS involves an activity distinct from PFOS "use" which, in our industry, includes PFOS used as (i) components of photoresist blends and (ii) surfactants in anti-reflective coatings.[18] Thus, 3M's voluntary cessation of manufacture and import of these compounds cannot convert all genuine ongoing "uses" of these compounds into "new" uses – regardless of whether 3M or another company is now supplying the compounds for such uses. As SIA has indicated before, the "use" of PFOS

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[16] 49 Fed. Reg. 39,703, 39,705 (Oct. 10, 1984).

[17] 55 Fed. Reg. 17373, 17,380 (Apr. 24, 1990).

[18] As discussed above, SIA's prior comments to EPA explain why the term "use" in the TSCA statute refers to activities involving a chemical substance separate and distinct from the manufacture, import and processing of a chemical substance. See SIA Comments, Section 1.A.1; see also *supra* note 4.

compounds in the semiconductor industry is unquestionably current and ongoing and not "new" in any sense of the word.[19]

⇒ Second, even if the term "use" somehow could be interpreted to include "manufacture", "import" and "processing" of the PFOS compounds, SIA, along with several other commenters, have plainly demonstrated that 3M is not the only company involved in such activities. Indeed, SIA's photoresist suppliers have been importing the PFOS compounds into the United States as components of the photoresist blends. Several SIA member companies also have engaged in the importation of these materials as well.

⇒ Third, by misapplication of the term "use", the PFOS SNUR likewise avoids engaging in the examination required by TSCA Section 5(a)(2) to deem a use "significant." As indicated in Section I above, the proposed rule contains no analysis or findings on whether or how any semiconductor manufacturing uses of PFOS might qualify as "significant". Indeed, under EPA's legal theory, if anyone manufactures or imports SNUR-listed PFOS in any amount after the 3M phase-out, then this is a statutory significant new use – notwithstanding that EPA made no finding as to whether such amount "changes the type or form of exposure of human beings or the environment to a chemical substance" or "increases the magnitude and duration of exposure of human beings or the environment" to the chemical (Section 5(a)(2)(B) & (C)). Although the SIA/SEMI coalition respects 3M's decision to phase-out of the PFOS compounds on a voluntary basis, 3M's rationale for and approach to implementing its voluntary decision do not – indeed can not -- substitute for the Agency's obligation to engage in independent analysis and decision-making.[20]

In brief, SIA/SEMI believe that the proposed SNUR is not on sound legal footing. Nevertheless, even assuming for the sake of argument that EPA has the legal authority to use 3M's phase-out as a means for implementing a broad-based SNUR restriction on PFOS manufacture, processing and use under Section 5(a), the Agency still must grant SIA/SEMI's requested exemption as specified in Appendix VI. As discussed in Sections I and II above, the uses of existing SNUR-listed PFOS in the limited photolithography applications for which SIA/SEMI seek exemption -- *i.e.*, photoresist materials and ARCs -- simply do not constitute "significant" or "new" uses under the exposure and release factors set forth in Section 5(a)(2). Instead, PFOS used in these applications would not

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[19] EPA has consistently recognized that its Section 5(a) SNUR authority does not extend to ongoing uses and has exempted such uses -- on a categorical basis -- from past SNUR rules. With the PFOS SNUR Proposal, EPA has deviated from this prior precedent without even any explanation as required by TSCA Section 19 and APA Section 706. See *supra* note 2.

[20] See, e.g., Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1229-30 (5th Cir. 1991) (remanding to EPA its decision under TSCA to prohibit manufacture of asbestos on grounds that EPA imposed rule without articulating a reasoned basis for its decision); Chemical Mfrs. Ass'n v. EPA, 899 F.2d 344, 359 (5th Cir. 1990) (stating that EPA "must 'cogently explain why it has exercised its discretion in a given manner' and must offer a 'rational connection between the facts found and the choice made'") (citation omitted).

be expected to have any discernable health or safety impact.[21] Moreover, Section 5(a)(2) admonishes EPA to consider "relevant factors" other than those specifically identified in the statute. SIA/SEMI would submit that the technologically critical nature of PFOS use in the photolithography applications in question, coupled with the severe economic consequences that could result from SNUR regulation of PFOS use in these applications, are two additional "relevant factors" that make the case for SNUR exemption even more compelling.[22]

IV. The Risk-Based Framework Developed By SIA/SEMI Should Apply to Both Existing and New PFOS Chemicals Used in the Same Applications for Which SIA/SEMI has Requested a SNUR Exemption

As we explained in the cover letter to this submission, SIA/SEMI is generally aware of situations where EPA has reviewed pre-manufacture notices (PMN's) and low-volume exemptions (LVE's) for higher homologue PFAS chemicals and rejected the chemicals because they are viewed as "persistent, bioaccumulative and toxic" chemicals. We are aware of other situations where EPA has accepted LVE's for lower homologue PFAS chemicals with a stipulation that the LVE might be withdrawn in the future.

It is extremely important to our industry that EPA establish a predictable risk-based framework for the evaluation of new chemical substances that contain a PFAS moiety. We believe that the data and model that we have developed for purposes of the SNUR provide a reasonable foundation for assessment of chemicals used in the photolithography process.

Since the model provides a framework for overall use of PFAS-containing materials in photolithography, there is no reason to limit its use to the SNUR chemicals. To do otherwise, would be to act arbitrarily without sound policy judgment.[23] The model is equally relevant to new chemicals that may be used to substitute for existing materials in the photolithography process. Moreover, the predictions of environmental releases generated by the model are grounded in the process itself and the general waste management practices that can be expected for particular types of wastestreams.

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21 Notably, EPA has the well-recognized authority to carve out exemptions from general, broad-based regulations under the Alabama Power Co. v. Costle, 636 F.2d 323 (D.C. Cir. 1979) de minimis doctrine. That doctrine allows EPA to promulgate a "categorical exemption . . . as an exercise of agency power inherent in most statutory regimes" where (1) "Congress has [not] been extraordinarily rigid," id. at 361, and (2) "the burdens of regulation [would] yield a gain of trivial or no value," id., "in the sense of furthering goals of the statute." Sierra Club v. EPA, 719 F.2d 436, 462 (D.C. Cir. 1983).

22 See Appendix I for information on the critical nature of PFOS use in the photolithography applications in question and the severe economic consequences that could result from SNUR regulation of such applications.

23 See, e.g., 5 U.S.C § 706(2)(A) ("[t]he reviewing court shall * * * hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law").

Substitution of a new chemical for an existing material would not materially alter the basic algorithms or results of the model.

As the photolithography mass balance model indicates, there is no reason to expect significant releases of PFAS moieties from the the use of PFAS-containing materials in photoresist and ARC applications. We believe these facts provide an ample basis for the granting of LVE's that are limited to these targeted applications, viz., photoresist and ARC.

In its discussions with the Agency, SIA/SEMI has made this point several times. EPA has not addressed our concern directly. Agency staff has expressed the view that new chemical review is a process that is separate from the SNUR now under consideration. At the same time, EPA has indicated that it wants to achieve a consistent approach to PFAS under both its new and existing chemical programs.

SIA/SEMI believes that it is time for EPA to clarify the policies it will employ in the new chemical program to evaluate PFAS-containing substances in the photolithography processes of the electronics industry. Specifically, SIA/SEMI asks EPA to establish a written policy on how it will approach PMN's and LVE's for these uses. We ask EPA to move forward to articulate such a policy, based on the model results we have submitted, as soon as possible. EPA has issued guidance before on how to review new chemicals for which PMN's or LVE's are submitted that may raise concerns as a class, but not necessarily individually. Specifically, EPA has issued a document entitled "New Chemicals Program (NCP) – Categories of Concern" (hereinafter "NCP Document"), which was last revised in June, 2001.[24] In the NCP Document, for each chemical category EPA lists the hazard conditions; boundary conditions under which types of chemicals within the class may raise or not raise concerns; and applicable testing requirements. To our knowledge, EPA does not have any similar document at present for PFOS.[25] Yet, based on the recent EPA practice of denying LVE's and PMN's for new PFOS chemicals, EPA now appears on an internal basis to have flagged PFOS as a chemical category warranting scrutiny and limits on new

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[24] The revised version is available at http://www.epa.gov/oppt/newchems/chemcat.htm (listed as the"Chemical Categories Report" on the web page).

[25] The NCP Document sets forth the Agency's policy for persistent, bioaccumulative and toxic (PBT) materials as a category of concern, and SIA/SEMI recognize that PFOS compounds generally would fall within this category. The PBT category of concern as presented in the NCP Document, however, is broad and general and does not address issues specific to PFOS hazards. Hence, this category fails to provide sufficient transparency for the semiconductor industry. It is important to emphasize in this context that SIA/SEMI essentially are seeking specific guidance which would recognize the appropriateness for EPA to approve new PFAS compounds in photolithography under circumstances consistent with the parameters of PFAS use presented in the SIA/SEMI mass balance model. As demonstrated amply by this model as well as by the other factual and policy information contained in this submission, such new chemicals guidance for PFAS use in photolithography would accord fully with the fundamental tenet of the PBT category of concern set forth in the NCP Document – *i.e.*, that even highly persistent and bioaccumulative substances will not be prohibited by EPA where either (i) there will be minimal-to-no human or environmental exposure to the substance or (ii) the substance does not present a risk to humans or the environment.

chemical approvals. SIA believes, consistent with EPA's prior practice as reflected in the NCP Document, EPA should provide greater clarity and transparency for the boundaries of its approach to new PFOS chemicals. Importantly, consistent with this prior practice, even chemical classes for which EPA believes that, as a general matter, it has the basis to scrutinize and to limit new chemical approvals, it is nevertheless appropriate for EPA to exempt certain types of uses from such general restrictions.

For example, with regard to acrylamides, EPA notes on page five of the NCP Document that "[t]ypically, concerns are confined to those species with molecular weights <1,000 whenever inhalation (or environmental) exposure is expected, and to species < 500 when dermal, but not inhalation, exposure to humans is expected." The agency also points out that "[s]tructures with an acrylamide equivalent weight of ≥5,000 are presumed not to pose a hazard under <u>any</u> conditions," and hence, generally would allow new chemical approvals for this subclass of compounds. <u>Id</u>. As another example, the NCP Document states on page 64 that, for epoxies, "health concerns are restricted to species with molecular weights of <500 if exposure is limited to the dermal route." Hence, typically new chemical approvals for epoxies would be allowed except for such restricted compounds. Finally, according to the new chemicals branch, hindered amines "are only of concern if there is significant inhalation exposure associated with their manufacture, processing, or use." NCP Document at p. 73. EPA could likewise make a distinction, in this document or in separate written guidance, between (1) PFOS use in photolithography applications where there is no dermal or inhalation exposure and insignificant environmental releases, and (2) other PFOS uses with greater human health and/or environmental exposures.

For us, time is of the essence on the new chemical issue. We know that LVE's that could be critical for our industry are not being accepted by the Agency. In many ways, this result is the most immediate, detrimental effect on our industry that has resulted from EPA's expressed concerns about PFOS.

V. The Risk-Based Framework Developed By SIA/SEMI Should be Shared With Other Countries Which May Broadly Regulate PFOS

At the same time that EPA has issued the PFOS SNUR Proposal, SIA understands that EPA has been working on a risk assessment of PFOS through the OECD.[26] We understand that this assessment may be near completion, and that other OECD countries involved in the assessment have not yet taken any regulatory action with regard to PFOS. SIA/SEMI's concerns regarding international activities on PFOS are two-fold:

A. Avoiding "U.S. Only" Restrictions On Critical PFOS Uses

With the very short phase-out period proposed in the PFOS SNUR, EPA has moved the United States out ahead of other countries around the world. Yet, the proposed SNUR does not attempt to assess the potential disparate impact such early

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[26] <u>See generally</u>, "OECD Meetings Agrees To Expand Evaluation Of PFOS Environmental Threats", BNA Daily Environment Report, No. 224, A-6 (Nov. 20, 2000).

unilateral action by the United States might have on U.S.-based industries and manufacturing operations. In this regard, the proposed PFOS SNUR would seem premature and arguably also inconsistent with the OECD's observations regarding any phase-out of the PFOS compounds: [27]

If the proposed SNUR goes forward and SIA/SEMI's exemption request is denied in whole or in part, the U.S. semiconductor industry would be placed at a significant competitive disadvantage as compared to its foreign competitors. As noted in Appendix I, the effectiveness of the photolithography process determines our ability to meet the demand for increasing miniaturization of electronic components. Similarly, if EPA does not grant SIA/SEMI's request that the same risk-based framework underlying the proposed SNUR exemption be applied to the review and approval of new PFAS chemicals for photolithography, we will risk losing our leadership in the semiconductor industry. Without a cutting edge in photolithography, U.S. semiconductor manufacturers simply will not be able to compete effectively against their Asian or European counterparts.

B. The Importance of Consistency in How EPA Treats PFOS Both in the U.S. and Internationally

Given EPA's leadership in the OECD efforts and its knowledge of our industry's use of PFAS, SIA/SEMI requests assistance from the Agency to ensure our critical uses in photolithography are preserved both in the U.S. and internationally. Specifically, EPA should not and cannot take a position outside of the U.S. on PFOS regulation that is inconsistent with its position on critical photolithography uses under the SNUR. Such a course of action would be arbitrary and capricious (see *supra* note 2).

Moreover, if and when OECD members decide to restrict the manufacture and/or use of PFOS, we respectfully request that EPA use its influence to help them adopt the same type of analysis and a relatively equivalent exemption process it has undertaken with our industry. Notably, the OECD (i) has recognized the need to protect critical uses; (ii) encouraged the sharing of information on PFOS among OECD members; and (iii) is committed to the joint development of an initial risk assessment.[28] The OECD also has made it clear, however, that individual member countries are engaging in their own regulatory and pre-regulatory activities. [29]

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[27] See "Existing Chemicals Programme Progress In The Assessment Of Perfluorooctanyl Sulphonate (PFOS) And Related Chemicals", OECD 97486, ENV/JM/RD (2000) 20 (Nov. 7, 2000) (recognizing foreign production facilities, the significant implications associated with the loss of PFOS specialty uses where adequate alternatives do not yet exist, and the difficulties in gathering all relevant information associated with PFOS uses).

[28] Id. at 4 and Annex I.

[29] Id. at p. 3.

If SIA/SEMI's SNUR exemption request and proposal for handling new PFOS chemicals used as photoresists and ARCs are approved, but foreign regulatory authorities decide to be more stringent in regulating our critical uses, such action also could significantly hurt our global business. As stated earlier, we are a global business engaged in the perpetual development of new products. In brief, SIA/SEMI's concern is that our industry could be swept into a broad foreign PFOS ban that fails to recognize the minimal environmental impact from our critical photolithography uses.

Conclusion

For all of the legal and policy reasons identified in this submission, SIA/SEMI believes that if EPA proceeds with a PFOS SNUR, then any agency action must exempt from that regulation photolithography uses of SNUR listed PFOS compounds not included in Appendix V. As a matter of product stewardship and sound environmental management, the SIA/SEMI coalition has (i) limited its exemption request to the two most critical semiconductor applications, and (ii) narrowed the list of chemicals subject to the SNUR that it needs to be included in the exemption. SIA/SEMI's exemption request is very reasonable in light of EPA's questionable authority to use the SNUR mechanism for such a broad-based ban. In addition, SIA/SEMI believes that it is entitled to a written policy that, barring any significant changes to PFAS management and environmental controls, allows use of new PFAS compounds in two specific and limited applications -- photoresists and ARCs.

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