

Prepublication Copy Notice:

The Director of Pollution Prevention and Toxics signed the following *Federal Register* document on September 16, 2015:

Title: Final Rule; Significant New Use Rule for Hexabromocyclododecane and 1,2,5,6,9,10-Hexabromocyclododecane (RIN 2070-AJ88)

FRL: 9927-44

Docket No.: **EPA-HQ-OPPT-2011-0489**

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For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the *Federal Register* document.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2011-0489; FRL 9927-44]

RIN 2070-AJ88

Significant New Use Rule for Hexabromocyclododecane and 1,2,5,6,9,10-Hexabromocyclododecane

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under the Toxic Substances Control Act (TSCA) for two chemical substances collectively referred to as “HBCD.” This action requires persons who intend to manufacture (including import) or process hexabromocyclododecane or 1,2,5,6,9,10-hexabromocyclododecane (HBCD) for use in consumer textiles (other than for use in motor vehicles) to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if appropriate, to prohibit or limit that activity before it occurs. In this SNUR, the exemption for persons importing or processing a chemical substance as part of an article does not apply to importers and processors of HBCD as part of a textile article (e.g., as part of a bolt of cloth or part of an upholstered chair). EPA is also making a technical amendment to the codified list of control numbers for approved information collection activities so that it includes the control number assigned by the Office of Management and Budget (OMB) to the information collection activities contained in this rule.

DATES: This final rule is effective *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0489, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), EPA Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Sue Slotnick, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-1973; email address: slotnick.sue@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process hexabromocyclododecane (Chemical Abstracts Service Registry Number (CASRN) 25637-99-4) or 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6) for use in consumer textiles other than for use in motor vehicles. Throughout this final rule preamble, the term “HBCD” represents both chemical substances, unless a specific CASRN is

also noted. The North American Industrial Classification System (NAICS) codes that are identified in this unit are not intended to be exhaustive, but rather provide a guide to help readers determine whether this rule applies to them. Potentially affected entities may include:

- Chemical Manufacturing (NAICS code 325).
- Painting and Wall Covering Contractors (NAICS code 238320).
- Textile and Fabric Finishing (except Broadwoven Fabric) Mills (NAICS code 313312).
- Curtain and Drapery Mills (NAICS code 314121).
- Other Household Textile Product Mills (NAICS code 314129).
- All Other Miscellaneous Textile Product Mills (NAICS code 314999).
- Upholstered Household Furniture Manufacturing (NAICS code 337121).
- Household Furniture (except Wood and Metal) Manufacturing (NAICS code 337125).
- Mattress Manufacturing (NAICS code 337910).
- Blind and Shade Manufacturing (NAICS code 337920).
- Furniture Merchant Wholesalers (NAICS code 423210).
- Home Furnishing Merchant Wholesalers (NAICS code 423220).
- Reupholstery and Furniture Repair (NAICS code 811420).

If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may affect importers and exporters of HBCD through pre-existing import certification and export notification rules under TSCA, regardless of the use of the HBCD.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use

of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. What Action is the Agency Taking?

This final rule designates use of HBCD in consumer textiles (other than for use in motor vehicles) as a significant new use. EPA has concluded that the only current use of HBCD for consumer textiles is in motor vehicles. That use and other current uses of HBCD (e.g., in non-consumer textiles and in building insulation) are not covered by this rule, not because EPA has determined that these uses are not “significant,” but because they are ongoing and thus not “new uses.”

This action requires persons who intend to manufacture or process HBCD as part of consumer textiles (other than for use in motor vehicles) to notify EPA at least 90 days before commencing that activity. The definition of “consumer textile” in this rule can include the following examples: bolts of cloth and draperies, as well as textiles that are part of household furniture and mattresses. The general provisions for SNURs include an exemption for persons who import or process chemical substances as part of an article (40 CFR 721.45(f)). However, for this SNUR, EPA is making the exemption at 40 CFR 721.45(f) inapplicable for importers or processors of HBCD as part of a textile article. Accordingly, importers and processors of HBCD as part of a textile article (whether or not it is a consumer textile) are subject to this SNUR. The term “textile article” is intended to be read in conjunction with the definition of “consumer

textile” and includes bolts of cloth and draperies, as well as textiles that are part of upholstered household furniture and mattresses. EPA proposed the rule on March 26, 2012 (Ref. 1) and received seven public comments. The comments and EPA’s responses to them (Ref. 2) are in the public docket for this rule (EPA-HQ-OPPT-2011-0489) and are also summarized below in Unit X.

The Agency is promulgating the SNUR as proposed with two exceptions. The first exception is the scope of the exemption for persons who import or process HBCD as part of an article. EPA had proposed to make the exemption at 40 CFR 721.45(f) completely inapplicable in the HBCD SNUR, which would have meant that importers and processors of HBCD as part of any article would be subject to the rule. As stated above in this section, the final rule makes the exemption inapplicable only to importers and processors of HBCD as part of textile articles. The second change from the proposed rule is EPA’s clarification to the proposed definition of “consumer textile.” For further explanation of both changes, see Unit X.

D. Why is the Agency Taking this Action?

This SNUR is necessary to ensure that EPA receives timely advance notice of any future manufacturing and processing of HBCD for new uses that may produce changes in human and environmental exposures. The rationale and objectives for this SNUR are explained in Unit III.

E. What are the Estimated Incremental Impacts of this Action?

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substances included in this final rule. This analysis, which is available in the docket, is discussed in Unit IX., and is briefly summarized here. In the event that a SNUN is submitted, costs are estimated to be less than \$8,600 per SNUN submission for large business submitters and \$6,200 per SNUN submission for

small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. Persons that must submit a SNUN under this SNUR who are first-time submitters of any TSCA section 5 notice must register their company and key users with the Central Data Exchange reporting tool, deliver a CD electronic signature to EPA, and establish and use a Pay.gov E-payment account before they may submit a SNUN, for a cost of \$200 per firm. However, these activities are only required of first-time submitters of section 5 notices. The rule may also affect firms that import or process articles that may contain HBCD, because, while not required by the SNUR, these parties may take additional steps to determine whether HBCD is part of the articles that they are considering to import or process. Since EPA is unable to predict whether anyone might engage in future activities that would require reporting, potential total costs were not estimated. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country, which is estimated to cost less than \$80 on average per notification.

II. Overview of the Chemical Substances Subject to this Rule

A. What Chemicals are Included in the SNUR?

This SNUR applies to two chemical substances: Hexabromocyclododecane (CASRN 25637-99-4) and 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6).

Hexabromocyclododecane is manufactured by adding bromine to technical grade 1,5,9-cyclododecatriene to make a chemical substance where the positions of the six bromine atoms are not specified on the cyclododecane ring, corresponding to CASRN 25637-99-4. The specific 1,2,5,6,9,10-hexabromocyclododecane isomer (CASRN 3194-55-6) is the major component of CASRN 25637-99-4.

B. What is the Production Volume of HBCD?

The most recent production volume submitted to EPA for Chemical Data Reporting was in 2012 and was claimed as Confidential Business Information (CBI). Earlier Inventory Update Rule (IUR)¹ submissions to EPA reported annual U.S. import/production volumes of 10-50 million pounds (lbs.) in 2002 and 2006 for CASRN 3194-55-6 (Ref. 3). IUR submissions to EPA reported annual U.S. import/production volumes of 10,000 to 500,000 lbs. in 2002 for CASRN 25637-99-4; no import/production was reported in 2006 (Ref. 4).

C. What are the Uses of HBCD?

The major use of HBCD is in polystyrene foam insulation boards used in construction. In the IUR data from 2006, one manufacturer/importer of HBCD (CASRN 3194-55-6) reported the use of the chemical substance under the NAICS code for textile and fabric finishing mills. This use constituted less than 1 percent of the total production volume of the chemical substance. The reporting does not distinguish between commercial and consumer use (Ref. 4). However, as explained below, and in greater detail in the Economic Analysis for this rule, EPA concluded that HBCD is not used in consumer textiles (as defined by this regulation) other than for use in motor vehicles (Ref. 5).

Information available to EPA indicates that the use of HBCD in textiles is as a coating to function as a flame retardant. EPA conducted research to determine whether HBCD was used in textile applications for end products sold to consumers. In 2010, an HBCD expert with the Consumer Product Safety Commission (CPSC) expressed to EPA his understanding that HBCD is used only in non-consumer textiles such as firefighters' suits (Ref. 6). In 2011, EPA requested information from current and former manufacturers of HBCD. The responses indicate that only

¹ As of August 16, 2011, the Inventory Update Rule (IUR) was renamed "Chemical Data Reporting rule (CDR)." See the TSCA Inventory Update Reporting Modifications; Chemical Data Reporting final rule in the **Federal Register** issue of August 16, 2011 (76 FR 50816).

one manufacturer sells HBCD for textile uses. The company does not know whether the end use of any of those textiles is a consumer article (Ref. 7). Additionally, a representative of Herman Miller, a company which manufactures commercial and consumer furniture, told EPA that HBCD is not in its products (Ref. 8).

EPA also received information from a group of textile formulators that the end uses of HBCD-containing textiles are for military, institutional, and aviation uses only (Ref. 9). EPA found that a small amount of HBCD is used in motor vehicles sold in the United States, including in floor mats, headliners, and possibly other interior fabrics. EPA received a public comment stating that although automakers are working towards ultimately phasing out the use of HBCD in consumer textiles in motor vehicles, there is concern about whether viable substitutes will be available. Thus, after considering the available information, EPA concludes that HBCD is not used in consumer textiles other than for use in motor vehicles.

D. What are the Potential Health and Environmental Effects of HBCD?

This section summarizes results of laboratory testing of 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6). The results are also valid for unspecified hexabromocyclododecane (CASRN 25637-99-4) and therefore relevant to both chemical substances in this rule.

1. *Human health effects.* Animal studies give an indication of potential human health effects of HBCD. Repeated exposure of HBCD to rats showed disturbances in thyroid hormone system and effects on the thyroid in males and females (Ref. 10). A 2-generation reproductive toxicity study in rats exposed to HBCD showed a treatment-related reproductive effect (a significant decrease in the number of primordial follicles in the F1 females) (Ref. 11). Although this decrease in ovarian follicles did not affect any reproductive parameters in this study, this

effect is suggestive of potential reproductive toxicity. Developmental effects were observed, including delays in eye opening in the second (F2) generation and transient changes in learning and memory in F1 males, but exposure did not cause any changes in spontaneous behavior. In addition, there was high and dose-dependent pup mortality during lactation (Ref. 11).

2. *Environmental effects.* Laboratory studies have shown that HBCD is capable of producing adverse effects in a variety of organisms including algae, fish, invertebrates, and soil-dwelling organisms at environmentally relevant concentrations. HBCD is toxic to algae and acutely toxic to fish embryos (Ref. 12), (Ref. 13). A number of sub-lethal effects (e.g., altered thyroid status, protein metabolism, oxidative stress, reproductive activity), have also been observed in fish (Ref. 14), (Ref. 15), (Ref. 16), and (Ref. 17). One study reported a reduced number and size of daphnid offspring in first and second generations (Ref. 18). Thyroid hormone-dependent developmental effects were observed in tadpoles (*Xenopus laevis*) exposed to HBCD (Ref. 19). HBCD has been reported to reduce egg production and lower biomass in soil-dwelling organisms (*Lumbriculus variegatus*) (Ref. 20). HBCD administered to chicken (*Gallus domesticus*) embryonic hepatocytes *in vitro* resulted in significant alterations in expression of genes (mRNA) associated with liver and thyroid function (Ref. 21). Thinner egg shells were measured in American kestrels exposed to a combination of polybrominated diphenyl ethers and HBCD (Ref. 22).

E. What are the Potential Sources and Routes of Exposure to HBCD?

There is potential for HBCD to be released at any point in the lifecycle of consumer textiles treated with HBCD. There is potential for release when the HBCD is being formulated into the textile coating, as well as when it is applied to the textile material. In addition, because HBCD is not chemically bound to its substrate (the protected textile material), HBCD can be

released during the service life of the textile material containing it, including release into water used to wash the treated textiles or into the air via dust particulates. Workers and the general population can be exposed to HBCD through direct contact as it migrates across land, in air, and in water by diffusion or environmental transport. Other opportunities for release can occur at the end of the lifecycle of HBCD-treated textiles when they are transported and incinerated or landfilled (Ref. 23). Evidence strongly suggests there is potential for exposure to the general population from HBCD in the environment and also from products and dust in the home and workplace. HBCD is found worldwide in the environment and wildlife (Note: only the specific 1,2,5,6,9,10-hexabromocyclododecane isomer (CASRN 3194-55-6) or the alpha, beta, and gamma isomers are monitored in biota and the environment, not the unspecified hexabromocyclododecane (CASRN 25637-99-4)). Human exposure is evidenced from its presence in breast milk, adipose tissue, and blood (Ref. 24). The chemical substances bioaccumulate and biomagnify in food chains. The frequent detection of HBCD over a large geographic area, with increasing exposure in remote locations such as the Arctic, where no demonstrable local sources exist that can account for these exposures, suggest that HBCD is persistent and undergoes long-range transport (Ref. 25).

To the extent HBCD is present in household applications (e.g., building foam, furniture upholstery, carpeting), children could be exposed, especially given children's increased exposure to dust and the hand-to-mouth ingestion pathway. *In vitro* experiments conducted to demonstrate leaching of HBCD from textiles showed that the presence of simulated biological fluids (sweat, saliva) and fruit juices enhances the leaching of HBCD from back-coated samples (Ref. 26). HBCD exposure values for children have been estimated from mouthing of textiles and from ingestion of dust (Ref. 27).

HBCD has been measured in air and sediment in Scandinavian countries, North America and Asia (Ref. 24), (Ref. 28). HBCD has also been measured in marine and Arctic mammals, freshwater and marine fish, aquatic invertebrates, birds and bird eggs, and one plant species (Ref. 24), (Ref. 28), and (Ref. 29).

For more information on HBCD concerning its physical-chemical properties, fate, releases, and human and environmental exposure, see EPA's HBCD Problem Formulation and Initial Assessment dated August 2015 (Ref. 30).

III. Rationale and Objectives

A. Rationale

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to issue a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that, if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

As summarized in Units II.D., and II.E., EPA has concerns regarding the potential exposure to and human health and environmental effects of HBCD. EPA believes that, in the future, HBCD could be manufactured or processed for consumer textile uses (in addition to the current textiles in motor vehicles). Accordingly, EPA wants the opportunity to evaluate and

control, where appropriate, activities associated with consumer textile use, if such manufacturing or processing were to commence in the future. The required notification provided by a SNUN will provide EPA with the opportunity to evaluate activities associated with the significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to HBCD.

B. Objectives

Based on the considerations described in the proposal (Ref. 1), and in the response to public comments, EPA expects to achieve the following objectives with regard to the significant new use that is designated in this final rule:

1. EPA will receive notification of any person's intent to manufacture or process HBCD for the described significant new use before that activity begins;
2. EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing HBCD for the described significant new use; and
3. EPA will be able to regulate the prospective manufacturing or processing of HBCD before the described significant new use of the chemical substance(s) occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

IV. Significant New Use Determination

As required by section 5(a)(2) of TSCA, EPA considered the four specific factors contained in that section along with other relevant factors in making its determination of the significant new use of HBCD for this rule. The first factor is the "projected volume of manufacturing and processing of a chemical substance" (TSCA section 5(a)(2)(A)). The potential increase in volume of this persistent, bioaccumulative and toxic chemical from

consumer textile use weighs in favor of determining that consumer textile use (other than for use in motor vehicles) is a significant new use. The second factor is “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)). Human exposure to consumer textile use may differ from exposure to commercial textiles and other current uses. The third factor is “the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance” (TSCA section 5(a)(2)(C)). Because HBCD is a persistent, bioaccumulative, and toxic chemical that has potential for long range transport (Ref. 1), even a small increase in the amount that is manufactured and processed, and thus subsequently used, would have a larger impact on potential exposures in terms of the number of people exposed and/or the amount of exposure. The potential for exposure would last for longer periods of time over a significant area as compared to a chemical that is not persistent and bioaccumulative with the potential for long range transport. The fourth factor is “the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance” (TSCA section 5(a)(2)(D)). Should a significant new use be planned, EPA anticipates that the new use would raise important questions such as what the impacts would be on consumer exposure, worker exposure, user exposure, or release of the substance to the environment, and what potential controls are available to limit such exposures and releases (see Unit II. E.).

In addition to considering the four factors in section 5(a)(2) of TSCA, EPA considered relevant information about the toxicity of HBCD, and likely human exposures and environmental releases associated with possible uses (see Unit II.D. and II.E.). EPA has concluded that the factors taken together weigh in favor of determining that manufacture or

processing of HBCD for any consumer textile use (other than for use in motor vehicles) would be a significant new use such that the Agency should have an opportunity to analyze the new use before such use (and potential exposures) occurs. Further explanation of EPA's consideration of those factors is contained in the Response to Comments document (Ref. 2) in the docket for this rule (EPA-HQ-OPPT-2011-0489).

V. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, and exemptions to reporting requirements.

Provisions relating to user fees appear at 40 CFR part 700, subpart C. Additional provisions governing SNUN submissions appear in 40 CFR part 720, which are the notice requirements and EPA regulatory procedures that submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A) must follow (see 40 CFR 721.1(c)). SNUR requirements also include the information submission requirements of TSCA sections 5(b) and 5(d)(1), and companies may wish to consider whether they are eligible for the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5). Once EPA receives a SNUN, EPA may take regulatory action under TSCA sections 5(e), 5(f), 6 or 7 to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in a **Federal Register** notice its reasons for not taking action.

Exemptions from SNUR requirements are found at 40 CFR 721.45. For this SNUR, 40 CFR 721.45(f), which exempts persons who import or process a chemical substance as part of an article, does not apply to importers and processors of HBCD as part of a textile, regardless of whether the textile is a consumer textile, as further explained in Unit X.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127 (see also 19 CFR 127.28). Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B (see 40 CFR 721.20). The TSCA section 13 import certification requirement applies to articles containing a chemical substance or mixture if so required by the Administrator by a specific rule under TSCA. At this time EPA is not requiring import certification for these chemical substances as part of articles.

VI. Applicability of the Final Rule to Uses Occurring Before the Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376) (Ref. 31), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notification requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who began commercial manufacture or processing of HBCD for a significant new use after the publication of the proposed rule must cease any such activity before the effective date of the final rule. To resume their activities, these persons must comply with all

applicable SNUR notification requirements and wait until the notification review period, including all extensions, expires. EPA has promulgated provisions (40 CFR 721.45(h)) to allow persons to comply with this SNUR before the effective date. If a person meets the conditions of advance compliance under 40 CFR 721.45(h), that person is considered to have met the requirements of the final SNUR for those activities.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. There are two exceptions: (1) development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)); and (2) development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)). In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 720.50 and 40 CFR 721.25). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA would take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical. SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

1. Human exposure and environmental releases that may result from the significant new use of the chemical substance.
2. Potential benefits of the chemical substance.
3. Information on risks posed by the chemical substance compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>. For first-time submitters of a TSCA section 5 notice, see requirements at Unit I. E.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of HBCD in consumer textiles. The evaluation is in the “Economic Analysis of the Final Significant New Use Rule for Hexabromocyclododecane (HBCD)” (Ref. 5). It is briefly summarized here and is available in the docket for this rule (EPA-HQ-OPPT-2011-0489). EPA added additional information to the economic analysis for HBCD in response to public comments.

A. SNUN Submission

The costs of submitting a SNUN would be incurred when a company decides to pursue a significant new use of one of these chemicals. In the event that a SNUN is submitted, costs are

estimated at approximately \$8,600 per SNUN submission for large businesses and \$6,200 per SNUN submission for small businesses, and include the cost to prepare and submit the SNUN and the payment of a user fee. Businesses that submit a SNUN are either subject to a \$2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (40 CFR 700.45(b)(1)). In its evaluation of this final rule, EPA also considered the potential costs a company might incur by avoiding or delaying the significant new use in the future, but these costs have not been quantified.

B. Import or Processing HBCD as Part of a Textile

Persons who import or process HBCD, including as part of a textile article, are covered by this rule. As explained in Unit X., EPA is making the exemption at 40 CFR 721.45(f) inapplicable for importers or processors of HBCD as part of a textile article. Accordingly, importers and processors of HBCD as part of textile articles including consumer and non-consumer textile articles, are subject to this SNUR. This provision is explained in Unit X.

Some firms have an understanding of the contents of the articles they import or process. However, EPA acknowledges that importers and processors of articles may have varying levels of knowledge about the chemical content of the articles that they import or process. These parties may take steps to become familiar with the requirements of the rule. And, while not required by the SNUR, these parties may take additional steps to determine whether HBCD is part of the articles that they are considering importing or processing. This determination may involve activities such as gathering information from suppliers along the supply chain, and/or testing samples of the article itself. Costs vary across the activities chosen. Cost ranges are presented in the “Economic Analysis of the Final Significant New Use Rule for

Hexabromocyclododecane (HBCD)” (Ref. 5). Given existing regulatory limitations on HBCD internationally, industry-wide processes, and resources that support companies in understanding and managing their supply chains, EPA believes that article importers who choose to investigate their products would incur costs at the lower end of the ranges presented in the Economic Analysis as a result of this rule. For those companies choosing to undertake actions to assess the composition of the articles they import or process, EPA expects that importers and processors would take actions that are commensurate with the company’s perceived likelihood that a chemical substance might be a part of an article, and the resources it has available. Example activities and their costs are provided in the accompanying Economic Analysis of this rule.

C. Export Notification

EPA regulations under TSCA section 12(b) (15 U.S.C. 2611(b)) at 40 CFR part 707, subpart D require that, for chemicals subject to a proposed or final SNUR, a company must notify EPA of the first export or intended export to a particular country of an affected chemical substance. EPA estimated the one-time cost of preparing and submitting an export notification to be \$80. The total costs of export notification would vary per chemical, depending on the number of required notifications (i.e., number of countries to which the chemical is exported).

X. Response to Public Comments

EPA received seven public comments on the proposed SNUR. The comments and EPA’s complete response (Ref. 2) are available in the docket for this final rule (EPA-HQ-OPPT-2011-0489). EPA made two changes to the regulatory text as a result of issues raised in public comments; these changes are explained below in Section A of this unit. A summary of the remaining issues is in Section B of this unit, and the full discussion of these comments is in the docket.

A. Changes to Regulatory Text as a Result of Public Comments

Article exemption. Two commenters indicated that there was some concern regarding the breadth of the lifting of the exemption for persons who import or process chemical substances as part of an article. EPA had proposed to make the exemption at 40 CFR 721.45(f) inapplicable to this rule.

The proposal preamble stated that “EPA is concerned that exempting HBCD as part of articles would render the SNUR less effective because of the possibility that consumer textile articles containing HBCD, the primary concern of EPA associated with this proposed rule, could be imported or processed for uses subject to this proposed SNUR without the submission of a SNUN. This proposed rule would not include the exemption at § 721.45(f).” 77 FR 17386, 17391, March 26, 2012. (Ref. 1) Accordingly, the proposed regulatory text stated that “[t]he provisions of § 721.45(f) do not apply to this section. A person who imports or processes the chemical substances identified in paragraph (a)(1) of this section as part of an article for the significant new use described in paragraph (a)(2) of this section must submit a significant new use notice (SNUN).”

Although the Agency has the authority to lift the exemption for importers and processors of HBCD as part of all articles, such a broad application is not necessary or desirable for this rule. This is because there are ongoing uses of HBCD as part of articles that are unlikely to be diverted to the significant new use.

EPA considered a narrow approach that would have made the exemption inapplicable to importers and processors of HBCD as part of consumer textiles only, not all textiles. EPA is concerned that if the inapplicability of the exemption was limited to consumer textiles, undifferentiated textiles (e.g., the type of textiles that could be for a consumer use or a non-

consumer use), could be imported or processed and distributed in commerce for consumer use without notification to the Agency. The category “consumer textiles” is fully subsumed by the broader category of textiles, so by requiring importers and processors of all textiles containing HBCD to meet the notification requirements at 40 CFR 721.5, EPA is ensuring that the regulatory mechanisms designed to prevent significant new uses without notice to the Agency will apply to import and processing of HBCD-containing articles that have the potential to be used as consumer textiles.

Thus, EPA is making the exemption at 40 CFR 721.45(f) inapplicable for importers and processors of HBCD as part of a textile article, rather than as part of all articles. Accordingly, importers and processors of HBCD as part of textile articles, regardless of whether those textiles are consumer textiles, are subject to this final SNUR. The term “textile” is intended to be read in conjunction with the definition of “consumer textile” and includes, but is not limited to, bolts of cloth and draperies, as well as textiles that are part of upholstered household furniture and mattresses. The definition of “consumer textile” for this rule is in the regulatory text at 40 CFR 721.10281. The Agency’s decision to lift the exemption for importers and processors of HBCD as part of textile articles rather than for importers and processors of all HBCD-containing articles is specific to this SNUR and based on the particular significant new use in this SNUR.

Definition of consumer textile. One of the seven commenters stated that the definition of “consumer textile” in the proposed SNUR is “rather nuanced . . . [and] contains several terms that are not self-evident on their face.” The proposed definition at 77 FR 17386, 17394, March 26, 2012 was:

“*Consumer textile* means any cloth, fabric, or other item produced during the milling process (including spinning, weaving, knitting, felting, or finishing), consisting in whole or as part of a

product that is sold to or made available to a private individual who uses the product in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment. Consumer textiles include but are not limited to draperies and textiles that are part of upholstered household furniture and mattresses” (Ref. 1). The proposal defined “consumer textile” to distinguish consumer textiles from other textiles (e.g., commercial, industrial, institutional, military). While this rule does not use the term “consumer product” as defined in 40 CFR 721.3, some of the terms and phrases used in the consumer textile definition, including those that the commenter claims are “not self-evident on their face,” are the same as those in the consumer product definition.

However, in the course of considering the comments, EPA revisited the definition of consumer textile, and concluded it could be clarified in certain respects. In this final rule, EPA is making minor changes to clarify the definition, as explained below. The changes do not impact the scope of the SNUR, as the final definition of “consumer textile” covers only those textiles that the Agency intended to cover in the proposal. The final definition is:

“Consumer textile means any cloth, fabric, or other item produced during a milling process for textiles (including spinning, weaving, knitting, felting, or finishing), that is sold or made available either as a product or as part of a product, to a private individual who uses it in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment. Consumer textiles can include, but are not limited to, bolts of cloth and draperies, as well as textiles that are part of upholstered household furniture and mattresses.”

Because there are milling processes that do not relate to textiles, the final definition clarifies that only items produced during milling processes for textiles are covered. The final definition also clarifies that the textile itself can be a consumer textile and that the textile need not be part of a

larger product like a mattress. This clarification is made in two places: by changing “consisting in whole or as part of a product” to “as a product or as part of a product” and by adding “bolts of cloth” as an example of a type of textile.

B. Summary of Response to Remaining Public Comments

Some commenters questioned whether EPA has the legal authority to regulate articles under TSCA. EPA’s response is that TSCA section 5 provides EPA with authority to regulate chemical substances, including chemical substances that are part of articles. Commenters also stated that EPA should establish a policy framework by rule for the issuance of article SNURs. EPA’s response is that development of a “policy framework” is not necessary before reaching the conclusion, with respect to HBCD, that persons who import or process this substance as part of consumer textiles (other than for use in motor vehicles) should be subject to the notification provisions of 40 CFR 721.25.

One commenter objected to the wording of the significant new use (“consumer textiles, other than for use in motor vehicles”) because it implies that a motor vehicle is a consumer product as defined by 40 CFR 721.3. EPA’s response is that the HBCD SNUR does not rely on the definition of consumer product as defined by 40 CFR 721.3. Instead, the rule specifically defines “consumer textile” and the definition would ordinarily encompass textiles used in motor vehicles. Another commenter said the proposed exclusion for consumer textiles in motor vehicles is appropriate but that the proposed SNUR appears to be a signal that EPA would like HBCD to be phased out of use in textiles in vehicles. The commenter is concerned that the phasing out of HBCD would leave the automotive industry without a substitute. EPA’s response is that the exclusion from this SNUR for manufacture and import of HBCD as part of textiles in motor vehicles is not a signal that EPA would like this use of HBCD to be phased out. Use of

HBCD in textiles in motor vehicles is unaffected by this SNUR because the use is ongoing. EPA continues to evaluate ongoing uses of HBCD as part of its TSCA Work Plan chemical assessments (see <http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html>). The remaining three commenters supported the proposed SNUR.

XI. References

The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA in developing this rule, including documents that are referenced within the documents that are in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Significant New Use Rule for Hexabromocyclododecane and 1,2,5,6,9,10-Hexabromocyclododecane: Proposed Rule. **Federal Register** (77 FR 17386, March 26, 2012) (FRL-9341-6). Available at

<http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>.

2. EPA. Response to Public Comments on Proposed Significant New Use Rule for Hexabromocyclododecane and 1,2,5,6,9,10-Hexabromocyclododecane, April 24, 2015.

3. EPA. 2012 Chemical Data Reporting (CDR). Chemical Data Access Tool (CDAT). Available at: http://java.epa.gov/oppt_chemical_search/. Accessed May 21, 2013. Last updated April 4, 2013.

4. EPA. Inventory Update Reporting (IUR): Non-Confidential 2006 TSCA Inventory Update Rule (IUR) Records. Available at: <http://cfpub.epa.gov/iursearch>.

5. EPA Environmental Economics and Technology Division (EETD), Economic and Policy Analysis Branch (EPAB). Economic Analysis of the Final Significant New Use Rule for Hexabromocyclododecane (HBCD), Washington, DC. 2015.
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7. ACC. Personal communication with Jackson Morrill, Director of Chemical Products of the American Chemistry Council (ACC). February 16, 2011.
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17. Ronisz, et al. Sublethal effects of the flame retardants hexabromocyclododecane (HBCDD), and tetrabromobisphenol A (TBBPA), on hepatic enzymes and other biomarkers in juvenile rainbow trout and feral eelpout. *Aquatic Toxicology*. August 2004. 69(3), pp. 229-245.
18. Drottar, Hexabromocyclododecane (HBCD): A flow-through life-cycle toxicity test with the cladoceran (*Daphnia magna*). Final Report. 439A-108, *Wildlife International, Ltd.* Easton, Maryland, USA. 1998. pp. 78.
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30. EPA. TSCA Work Plan Chemical Problem Formulation and Initial Assessment, Cyclic Aliphatic Bromides Cluster, Flame Retardants. August 2015. Available at <http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html>.

31. EPA. Significant New Uses of Certain Chemical Substances, Final Rule. **Federal Register** (55 FR 17376, April 24, 1990) (FRL-3658-5).

32. EPA. Modification of Significant New Use Rules for Certain Substances, Final Rule. **Federal Register** (62 FR42690, August 8, 1997) (FRL-5735-4).

XII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This final rule is not a “significant regulatory action” under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563, entitled “Improving Regulation and Regulatory Review” (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved by OMB under OMB control number 2070-0038 (EPA ICR No. 1188), and the information collection activities associated with export notifications are already approved by OMB under OMB control number 2070-0030

(EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for an export notification is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9 and included on the related collection instrument, or form, if applicable. EPA is amending the table in 40 CFR part 9 to list this SNUR. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. Since the existing OMB approval was previously subject to public notice and comment before OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend the table is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)), to amend this table without further notice and comment.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this SNUR will not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

EPA generally finds that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities (See, *e.g.*, Ref. 32). Since this SNUR

will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to engage in such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. During the six year period from 2005-2010, only three submitters self-identified as small in their SNUN submission (Ref. 5). EPA believes the cost of submitting a SNUN is relatively small compared to the cost of developing and marketing a chemical new to a firm and that the requirement to submit a SNUN generally does not have a significant economic impact.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." In the proposed HBCD SNUR (Ref. 1), EPA preliminarily determined, based in part on the Agency's market research, that HBCD is not manufactured or processed for the significant new use (i.e., use in consumer textiles other than in textiles in motor vehicles). EPA received no public comment indicating otherwise. Therefore, EPA is finalizing its determination that use of HBCD in consumer textiles (other than in textiles in motor vehicles) is not ongoing. Thus no small entities presently manufacture or import HBCD for the significant new use. EPA believes that there will be minimal impact to processors and importers of HBCD as part of textile articles from this SNUR. The SNUR does not require processors and importers of textile articles to conduct specific activities to ascertain if they are importing or processing a textile article containing HBCD. EPA expects importers and processors will take actions that are commensurate with their perceived

likelihood of HBCD being part of a textile article, and the resources they have available. EPA has no reason to believe that a firm would voluntarily incur substantial costs to comply with the SNUR, but rather, EPA believes each firm will choose the most efficient route to identify whether it is importing HBCD in textile articles.

Therefore, EPA believes that the potential economic impact of complying with this SNUR is not expected to be significant or adversely impact a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government will be impacted by this rulemaking. As such, EPA has determined that this regulatory action will not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of UMRA (2 U.S.C. 1531-1538).

E. Executive Order 13132: Federalism

This action does not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have Tribal implications because it will not have any effect (i.e., there will be no increase or decrease in authority or jurisdiction) on Tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of

power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 (65 FR 67249, November 9, 2000), does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action is not intended to address environmental health or safety risks for children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

K. Congressional Review Act (CRA)

Pursuant to the CRA, 5 U.S.C. 801 *et seq.*, EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: September 16, 2015.

Wendy C. Hamnett,
Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9--[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following sections in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * *	* *
Significant New Uses of Chemical Substances	
* * *	* *
721.10281	2070-0038
* * *	* *

* * * * *

PART 721--[AMENDED]

3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

4. Add new § 721.10281 to subpart E to read as follows:

§ 721.10281 Hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified as hexabromocyclododecane (CASRN 25637-99-4) and 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6) are subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is use in consumer textiles, other than for use in motor vehicles.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Definitions.* The definitions in § 721.3 apply to this section. In addition, the following definitions apply:

“*Consumer textile*” means any cloth, fabric, or other item produced during a milling process for textiles (including spinning, weaving, knitting, felting, or finishing), that is sold or made available either as a product or as part of a product, to a private individual who uses it in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment. Consumer textiles can include, but are not limited to, bolts of cloth and draperies, as well as textiles that are part of upholstered household furniture and mattresses.

Motor vehicle has the meaning found at 40 C.F.R. § 85.1703.

(2) *Revocation of article exemption.* The provisions of § 721.45(f) do not apply to importers and processors of the chemical substances identified in paragraph (a)(1) of this section as part of a textile.