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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2019-0038; FRL-XXXX-XX]

Asbestos Reporting Rule Under TSCA Section 8(a); TSCA Section 21 Petition; Reasons for Agency Response

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: This document provides the reasons for EPA's response to a January 31, 2019, petition it received under the Toxic Substances Control Act (TSCA) from the Attorneys General of Massachusetts, California, Connecticut, Hawaii, Maine, Maryland, Minnesota, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and the District of Columbia ("petitioners"). Generally, the petitioners requested that EPA initiate a rulemaking proceeding under section 8(a) of TSCA for the reporting of the manufacture (including import) and processing of asbestos. After careful consideration, EPA denied the petition for the reasons discussed in this document.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Tyler Lloyd, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001; telephone number: (202) 564-4016; email address: *lloyd.tyler@epa.gov.*

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of particular interest to those persons who manufacture or process or may manufacture (which includes import) or process the chemical asbestos (general CAS No. 1332-21-4). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I access information about this petition?

The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0038, is available at *https://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency 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 https://www.epa.gov/dockets.

II. TSCA Section 21

A. What is a TSCA section 21 petition?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a

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rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8, or an order under TSCA sections 4, 5(e), or (f). A TSCA section 21 petition must set forth the facts which it is claimed establish that it is necessary to initiate the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding either within 60 days of either a denial or, if EPA does not issue a decision, within 60 days of the expiration of the 90-day period.

B. What criteria apply to a decision on a TSCA section 21 petition?

TSCA section 21(b)(1) requires that the petition "set forth the facts which it is claimed establish that it is necessary to issue, amend or repeal a rule." 15 U.S.C. 2620(b)(1). TSCA section 8(a)(1) authorizes the EPA Administrator to promulgate rules under which manufacturers (including importers) and processors of chemical substances must maintain such records and submit such information as the EPA Administrator may reasonably require (15 U.S.C. 2607). TSCA section 8(a)(2) outlines the information that the EPA Administrator may require under TSCA section 8(a)(1), insofar as it is known to the person making the report or insofar as reasonably ascertainable. Under TSCA section 8(a), EPA has promulgated several data collection rules, such as the Chemical Data Reporting (CDR) rule at 40 CFR part 711.

III. Summary of the TSCA Section 21 Petition

A. What action was requested?

On January 31, 2019, the Attorneys General of Massachusetts, California, Connecticut, Hawaii, Maine, Maryland, Minnesota, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and the District of Columbia (petitioners) petitioned EPA to initiate a rulemaking proceeding under TSCA section 8(a) for the reporting of the manufacture, import, and processing of asbestos (Ref. 1).

The petitioners requested specific requirements for a section 8(a) reporting rule for asbestos in order to collect information for the ongoing asbestos risk evaluation being conducted under TSCA section 6(b), which is ~~required~~ to be completed by December 22, 2019 (15 U.S.C. 2605(b)(4)(G)(i)~~cite~~) and no later than June 22, 2020 if EPA exercises a six-month extension (15 U.S.C. 2605(b)(4)(G)(ii)~~cite~~), and, if necessary, for any subsequent risk management decisions under TSCA section 6(a). The petitioners specifically requested that EPA:

- eliminate any applicability of the "naturally occurring substance" (NOCS) exemption in the CDR for asbestos reporting;
- apply the CDR reporting requirements to processors of asbestos, as well as manufacturers, including importers, of the chemical substance;

Ex. 5 Deliberative Process (DP)

B. What support do the petitioners offer?

The petitioners request that EPA initiate a rulemaking proceeding under TSCA section 8(a) "to address infirmities in asbestos reporting" under EPA's CDR rule at 40 CFR 711. In support of their request, the petitioners state that "[r]obust reporting of the importation and use of

asbestos in the U.S. is necessary for EPA to satisfy its statutory mandate under TSCA Section 6(a) to establish requirements to ensure that asbestos does not present an unreasonable risk of injury to health or the environment and for states and the public to have access to data necessary to themselves evaluate such risks" (Ref. 1).

The petitioners [redacted] EPA's need for "comprehensive data with respect to the manufacture (including import) and use of asbestos in the U.S." when conducting the asbestos risk evaluation and undertaking any potential subsequent risk management actions. The petitioners conclude that such data are not being collected under the current CDR rule. Several times in their request, the petitioners cite EPA's response to a previous petition filed under TSCA section 21 by the Asbestos Disease Awareness Organization (ADAO) and five other non-governmental organizations. In that petition, which EPA received on September 27, 2018, ADAO and others requested that EPA initiate rulemaking under section 8(a) of TSCA to amend the CDR rule to increase reporting of asbestos to CDR (Ref. 2). EPA denied the petition on December 21, 2018, on the grounds that the petitioners did not demonstrate that it is necessary to amend the CDR rule (84 FR 3396, February 12, 2019) (FRL–9988–56). The petition from ADAO et al. and EPA's response are in Docket EPA-HQ-OPPT-2018-0682 at *https://regulations.gov*.

The CDR rule, which is one of several reporting rules promulgated under TSCA section 8(a), requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals in commerce, generally 25,000 pounds or more of a chemical substance at any single site, with a reduced reporting threshold (2,500 pounds) applying to

chemical substances subject to certain TSCA actions, including, as applicable here, TSCA section 6.

While asbestos is already required to be reported under the CDR rule by manufacturers (including importers) meeting certain criteria, the petitioners point out that CDR exempts from reporting chemicals that are naturally occuring chemical substances, present as an impurity, or incorporated into an article. Additionally, the petitioners note that CDR does not require reporting from processors of chemical substances.

The petitioners assert that "[a]ny TSCA risk evaluation that EPA conducts without access to accurate and complete asbestos data cannot satisfy TSCA's risk evaluation criteria, including TSCA's requirement that EPA use the 'best available science' in carrying out TSCA's mandate to eliminate unreasonable risk of injury to health or the environment presented by the manufacture (including importation), processing, distribution in commerce, use, or disposal of a toxic chemical substance" (Ref. 1).

Petitioners contend that the requested action under section 8(a) "would enable EPA to present and rely on a complete set of domestic data about the amount, and uses, of asbestos, is consistent with those goals and with the statute's requirements" (Ref. 1).

In their request, the petitioners state that "[a]sbestos is a known human carcinogen and there is no safe level of exposure to this highly toxic material ubiquitous in our built environment" (Ref. 1). The petitioners cite research finding dangers from asbestos and provide a review of asbestos assessments and regulations under federal and state law.

In their petition, they state that in 1989, EPA concluded that "asbestos is a highly potent

129 carcinogen regardless of the type of asbestos or the size of the fiber" and assert that "EPA has
130 long possessed an abundance of information that supports aggressive regulatory actions to
131 protect the public from asbestos disease risks" (Ref. 1).

132 The petitioners restate their belief that EPA has "chos[en] to put on blinders and ignore
133 some of the most meaningful data with respect to risks of exposure to the chemical substance"
134 (Ref. 1), a supposition which many of the petitioning Attorneys General first stated in comments
135 on EPA's Problem Formulation of the Risk Evaluation for Asbestos (83 FR 26998, June 11,
136 2018) (FRL-9978–40). Moreover, the petitioners cite language in the Problem Formulation that
137 states that "import volumes of products containing asbestos is [sic] unknown" (Ref 1). The
138 petitioners assert that EPA's response to the ADAO Petition directly contradicts what EPA stated
139 in the Problem Formulation.

140 **IV. Background Considerations: Review of EPA Actions, Activities, and Regulations**

141 To understand EPA's reasons for denying the petitioners' requests, it is important to first
142 review the details of EPA's ongoing risk evaluation of asbestos, section 8(a) rules including the
143 CDR rule, general exemptions for section 8(a) rules, and past reporting of asbestos under section
144 8(a). These details are explained in the following sections.

145 *A. Risk evaluation of asbestos.*

146 On June 22, 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st
147 Century Act (P.L. 114-182), which amended TSCA (15 U.S.C. 2601 et seq.). The new law
148 includes statutory requirements mandating that EPA Ex. 5 Deliberative Process (DP) conduct risk evaluations for
149 existing chemicals. On December 19, 2016, in the **Federal Register**, EPA designated asbestos as

one of the first 10 chemical substances subject to the Agency's initial chemical risk evaluations (81 FR 91927) (FRL-9956-47) pursuant to TSCA section 6(b)(2)(A) (15 U.S.C. 2605(b)(2)(A)), which required EPA to identify the first 10 chemicals to be evaluated no later than 180 days after the date of enactment of the Act.

EPA is currently evaluating the risks of asbestos under its conditions of use, pursuant to TSCA section 6(b)(4)(A). Through scoping and subsequent research for the asbestos risk evaluation, EPA identified the conditions of use of asbestos, including imported raw bulk chrysotile asbestos for the fabrication of diaphragms for use in chlorine and sodium hydroxide production; several imported chrysotile asbestos-containing materials, including sheet gaskets in chemical manufacturing where extremely high temperatures are needed; brake blocks for oil drilling; aftermarket automotive brakes/linings; other vehicle friction products; and other gaskets (Ref. 3). In identifying the conditions of use for asbestos and the rest of the first 10 chemicals undergoing risk evaluation under amended TSCA, EPA included use information reported under the CDR rule. In addition to using CDR data to identify the current conditions of use of asbestos, EPA conducted extensive research and outreach. This included EPA's review of published literature and online databases including Safety Data Sheets (SDSs), the United States Geological Survey's Mineral Commodities Summary and Minerals Yearbook, the U.S. International Trade Commission's Dataweb, and government and commercial trade databases. (See Docket EPA-HQ-OPPT-2016-0736). EPA's review of these data sources served as the basis for the conditions of use of asbestos. Additionally, EPA worked with its Federal partners, such as Customs and Border Protection, to enhance its understanding of import information on asbestos-

containing products in support of the risk evaluation.

EPA also reviewed company websites of potential manufacturers, importers, distributors, retailers, or other users of asbestos and received public comments (1) during the February 2017 public meeting on the scoping efforts for the risk evaluations for the first ten chemicals, (2) when EPA published the Scope of the Risk Evaluation for Asbestos in June 2017, and (3) when EPA published the Problem Formulation of the Risk Evaluation for Asbestos in June 2018 , all of which were used to identify the conditions of use. (See Docket EPA-HQ-OPPT-2016-0736). In addition, to inform EPA's understanding of the universe of conditions of use for asbestos for the scope document published in June 2017, EPA convened meetings with companies, industry groups, chemical users, and other stakeholders (Ref. 3). Lastly, on June 11, 2018, EPA proposed a significant new use rule (SNUR) under TSCA section 5, in an administrative proposal separate and apart from the ongoing risk evaluation process under TSCA section 6, for certain uses of asbestos (including asbestos-containing products) (83 FR 26922; FRL-9978-76) and specifically asked for public comment or information on ongoing uses of asbestos. In the public comments submitted on the SNUR, EPA received no new information on any ongoing uses. (See Docket EPA-HQ-OPPT-2018-0159).

In the Asbestos Problem Formulation document, based on the aforementioned outreach and research, EPA did not identify any conditions of use of asbestos as an impurity. In EPA's Asbestos Problem Formulation for the Risk Evaluation (Ref. 3), the Agency identified the conditions of use as imported raw bulk chrysotile asbestos for the fabrication of diaphragms for use in chlorine and sodium hydroxide production; and several imported chrysotile asbestos-

containing materials, including sheet gaskets; brake blocks for oil drilling, aftermarket automotive brakes, linings, and other vehicle friction products; and other gaskets.

The purpose of EPA's risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation (15 U.S.C. 2605(b)(4)(A)). As part of this process, EPA must evaluate both hazard and exposure, excluding consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence. EPA intends to finalize the risk evaluation for asbestos by December 2019, Ex. 5 AC/DP

Ex. 5 Deliberative Process (DP)

B. Section 5(a) SNUR and asbestos

On April XX, 2019, EPA finalized the SNUR for asbestos and asbestos-containing products (XX FR XXXX; FRL-9991-33). Section 5(a)(2) of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, authorizes EPA to determine that a use of a chemical substance is a "significant new use." Ex. 5 Deliberative Process (DP)

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Ex. 5 AC/DP

Ex. 5 Deliberative Process (DP)

Ex. 5 AC/DP

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Ex. 5 Deliberative Process (DP)

Commented [LT6R1]: Thank you for the added clarity.

Ex. 5 AC/DP

Commented [DA8R7]: Concur.

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Ex. 5 AC/DP

Ex. 5 Deliberative Process (DP)

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For this SNUR, the significant new use of asbestos is manufacturing (including importing) or processing for uses that are neither ongoing nor already prohibited under TSCA. The following uses are subject to the SNUR: adhesives, sealants, and roof and non-roof coatings; arc chutes; beater-add gaskets; cement products; extruded sealant tape and other tape; filler for acetylene cylinders; friction materials (with certain exceptions); high-grade electrical paper; millboard; missile liner; packings; pipeline wrap; reinforced plastics; roofing felt; separators in fuel cells and batteries; vinyl-asbestos floor tile; woven products Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) any other building material; and any other use of asbestos that is neither ongoing nor already prohibited under TSCA.

The asbestos SNUR prohibits these discontinued uses of asbestos from restarting without EPA having an opportunity to evaluate each intended use (i.e., significant new use) for potential risks to health and the environment and take any necessary regulatory action, which may include a prohibition. Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP) The SNUR ensures that the conditions of use that are in the scope of the risk evaluation and therefore not subject to the SNUR are the only ongoing uses of asbestos and asbestos-containing products in the United States.

C. Section 8(a) rules.

Section 8(a)(1) of TSCA authorizes the EPA Administrator to promulgate rules under which manufacturers and processors of chemical substances must maintain such records and submit such information as the EPA Administrator may "reasonably require." 15 U.S.C. 2607. The Agency is prohibited by TSCA section 8(a)(5)(A) from requiring reporting that is "unnecessary or duplicative" and must apply the reporting obligations under TSCA section 8(a) to those persons who are likely to have the relevant information. 15 U.S.C. 2607(a)(5).

EPA has promulgated several data reporting rules under section 8(a); the CDR rule is the largest data collection rule, based on entities subject to reporting. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

The CDR rule requires U.S. manufacturers (including importers) of chemicals on the TSCA Chemical Substance Inventory, with some exceptions, to report to EPA every four years the identity of chemical substances manufactured (including imported) for all years since the last principal reporting year (40 CFR 711.8(a)(2)). Generally, reporting is required for substances with production volumes of 25,000 pounds or more at any single site during any of the calendar years since the last principal reporting year. However, a lower threshold (2,500 pounds) applies for chemical substances that are the subject of certain TSCA actions (see 40 CFR 711.8(b)). The CDR regulation generally exempts several groups of chemical substances from its reporting requirements, e.g., polymers, microorganisms, naturally occurring chemical substances, certain forms of natural gas, and water (see 40 CFR 711.5 and 711. 6). Asbestos is subject to the lower production volume reporting threshold of 2,500 pounds; thus Mmanufacturers and importers of asbestos are required to report asbestos under the CDR rule i Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) unless they qualify for an exemption.

Ex. 5 Deliberative Process (DP)

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D. Exemptions from reporting under the section 8(a) rules.

EPA has specified general reporting and recordkeeping provisions for section 8(a) information gathering rules at 40 CFR 704 and has promulgated general exemptions to reporting at 40 CFR 704.5 using the Agency's broad discretion in section 8(a) to fashion reporting schemes "as the Administrator may reasonably require." (15 U.S.C. 2607(a)(1)(A)). However, also utilizing this discretion, Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

If the chemical substance is imported solely as part of an article, the chemical substance is generally exempt from being reported under section 8(a). An article is defined in 40 CFR 704.3 as "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design."

Impurities are also generally exempt from reporting under rules promulgated pursuant to section 8(a). An impurity is defined as a chemical substance unintentionally present with another chemical substance (40 CFR 704.3). Impurities are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the

substance, mixture, or article of which they are a part.

The exemption from reporting naturally occurring chemical substances under the CDR rule, found at 40 CDR 711.6(b), is one example of an exemption that has been added to a Ex. 5 Deliberative Process (DP) e under EPA's broad discretion to fashion reporting schemes "as the Administrator may reasonably require" Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP)

While section 8(a) provides EPA with the authority to collect information from processors, EPA has used its discretion to not require processors to report under the CDR rule. Processing information is reported by the manufacturers: if a manufacturer reports a chemical under the CDR rule, it must also report processing and use information for the chemical substance unless it is exempted from this reporting by 40 CFR 711.6(b).

E. Recent asbestos reporting under section 8(a).

Two companies, both from the chloro-alkali industry, reported importing raw asbestos during the 2016 CDR reporting cycle (Ref. 4) and did not claim the exemption for naturally occurring chemical substances. Both companies claimed their reports as confidential business information. Because asbestos has not been mined or otherwise produced in the United States since 2002 (Ref. 5), all raw asbestos currently in commerce in the U.S. is imported. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

V. Petition Response

A. What was EPA's response?

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Ex. 5 Deliberative Process (DP)

After careful consideration, EPA has denied the petition. A copy of the Agency's response, which consists of a letter to the signatory petitioner from the Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) (Ref. 6), is available in the docket for this TSCA section 21 petition. In accordance with TSCA section 21, the reasons for the denial are set forth in this **Federal Register** document.

EPA agrees that knowledge of which entities are importing and using asbestos and asbestos-containing products, where and how these activities occur, and the quantities of asbestos involved is important for identifying exposed populations, and characterizing pathways of exposure. EPA already has this information, which it obtained through reporting, voluntary submission, and modeling. EPA has used information currently reported under the CDR rule and other sources of data to identify and characterize the conditions of use for asbestos, and is using this information as part of the ongoing risk evaluation for asbestos.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) to conduct its risk evaluation on asbestos and any potential subsequent risk management. While the petitioners assert that EPA's response to the ADAO Petition directly contradicts what EPA stated in the Problem Formulation regarding EPA's acknowledgement of a lack of certain data, EPA disagrees. EPA believes that the Agency is aware of all ongoing uses of asbestos and already has the essential information that EPA would receive if EPA were to issue a section 8(a) rule. Since asbestos was announced in December 2016 as one of the first ten chemicals for evaluation under TSCA, the Agency has conducted market research, public outreach, voluntary data collection,

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collaborative work with other Federal and State agencies, and stakeholder engagement. Given EPA's understanding of asbestos and reporting under section 8(a), as a result of implementation of the CDR rule and other section 8(a) rules, EPA does not believe that Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) This use of modeled data is in line with EPA's final Risk Evaluation Rule (82 FR 33726, July 20, 2017) and EPA's risk assessment guidelines. Furthermore, EPA will provide opportunity for peer and public review of the draft Asbestos Risk Evaluation, which EPA will use to refine the risk evaluation of asbestos.

Even if EPA believed that the requested rule would collect new and useful information, Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) The petitioners request does not factor in the necessary timeframes for any rulemaking processes that would be required to propose and then finalize such amendments. To allow for the notice and comment period for the public and regulated community required under the Administrative Procedure Act (5 U.S.C. 553) and for appropriate internal deliberation prior to proposal and after the close of the comment period, EPA typically needs at least 18 months to finalize a Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) EPA intends to finalize the risk evaluation for asbestos in December 2019, Ex. 5 Deliberative Process (DP) If EPA finds unreasonable risk for a condition of use, risk management must promptly be initiated with a

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Commented [LT31R30]: Yes. Change made. Thank you.

Ex. 5 Deliberative Process (DP)

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Ex. 5 AC/DP

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Ex. 5 AC/DP

Ex. 5 Deliberative Process (DP)

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Commented [LT45R40]: Language added.

Ex. 5 Deliberative Process (DP)

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proposed rule issued one year after EPA makes such a determination. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Given the statutorily-required timing for finalizing the asbestos risk evaluation and initiating risk management, if unreasonable risk exists for a condition of use, a section 8(a) reporting rule on asbestos would not provide timely or useful information to inform either the ongoing asbestos risk evaluation or any potential subsequent risk management action.

B. What are the details of the petitioners' requests and EPA's decision to deny each of the requests?

This unit provides the reasons for EPA's decision to deny the petition asking EPA to initiate rulemaking under section 8(a) of TSCA for the reporting of the manufacture, import, and processing of asbestos.

i. Eliminate exemption for naturally occurring chemical substances for asbestos.

a. Petitioners' request.

The petitioners ask that the requested section 8(a) reporting Ex. 5 Deliberative Process (DP) an exemption for naturally occurring chemical substances. The petitioners state that the import of raw asbestos represents "pathways of exposure that present risks to health and the environment that EPA must consider in conducting its risk evaluation and regulating asbestos" (Ref. 1). In support of this request, the petitioners question EPA's prior assertion that the Agency has sufficient information about asbestos use and exposure, as obtained through CDR and other

"voluntary disclosures" (Ref. 1). The petitioners believe that EPA contradicted itself when, in the response to the earlier ADAO petition, the Agency stated it has sufficient information for the risk evaluation, while, in the Problem Formulation EPA said "[i]t is important to note that the import volumes of products containing asbestos is [sic] unknown" (Ref. 1).

b. Agency response.

Raw asbestos is the only type of asbestos to which the naturally-occurring substance exemption could apply. As defined by the CDR-specific rules in 40 CFR 711.6(a)(3), a naturally occurring chemical substance is:

> Any naturally occurring chemical substance, as described in 40 CFR 710.4(b). The applicability of this exclusion is determined in each case by the specific activities of the person who manufactures the chemical substance in question. Some chemical substances can be manufactured both as described in 40 CFR 710.4(b) and by means other than those described in 40 CFR 710.4(b). If a person described in § 711.8 manufactures a chemical substance by means other than those described in 40 CFR 710.4(b), the person must report regardless of whether the chemical substance also could have been produced as described in 40 CFR 710.4(b). Any chemical substance that is produced from such a naturally occurring chemical substance described in 40 CFR 710.4(b) is reportable unless otherwise excluded.

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A chemical substance qualifies as naturally occurring only if it is: (1)(i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or (2) extracted from air by any means (40 CFR 710.4(b)). Articles containing asbestos would not be considered a naturally occurring chemical substance, given the processing required to create the article.

EPA does not believe that the requested elimination of the exemption for naturally occurring chemical substances would result in the reporting of any information that is not already known to EPA, for several reasons. EPA Ex. 5 Deliberative Process (D) that the chloro-alkali industry is the only

importer of raw bulk asbestos, and the Agency has sufficient volume, import, use, and hazard data from that industry to conduct the risk evaluation. EPA has no reason to believe there are other importers of raw asbestos. Raw asbestos generally refers to asbestos as a naturally occuring chemical substance. Issuing a section 8(a) asbestos reporting rule for manufacturers (including importers) of asbestos as a naturally occuring chemical substance, therefore, would not provide any additional useful or timely information to EPA on the use of raw asbestos.

Because the purpose of domestic manufacturing or importing of raw asbestos is to make asbestos diaphragms, for which EPA already has use and exposure information, the request to require reporting on naturally occurring substances for asbestos would not provide any additional data to EPA. EPA already has this information obtained through extensive outreach and research (as described in Unit IV A.i), and the Agency is prohibited by TSCA section 8(a)(5)(A) from requiring reporting that is unnecessary or duplicative.

EPA finds that petitioners have failed to set forth sufficient facts to establish that it is necessary for the Agency to use its discretion Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

ii. Apply the CDR reporting requirements to processors of asbestos.

a. Petitioners' request.

The petitioners note that EPA has the authority to require that processors report under section 8(a), but EPA does not require processors to report to CDR. The petitioners believe the Ex. 5 Deliberative Process (DP) of the processing of asbestos is needed in order "to enable EPA to carry out its responsibility to impose requirements on processors to eliminate

429 unreasonable risks of injury to health or the environment arising from exposures to asbestos"
430 (Ref. 1). In support of their request, the petitioners cite the U.S. Geological Survey (USGS)
431 Minerals Yearbook for 2016 (Ref. 5) and state that "U.S. firms exported and reexported $35.4
432 million of manufactured asbestos products in 2016, Ex. 5 Deliberative Process (DP)
433 Ex. 5 Deliberative Process (DP)
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435 *b. Agency response.*

436 EPA knows of two ongoing uses of asbestos that constitute processing: (1) the processing
437 of raw asbestos into diaphragms and (2) the fabrication of gaskets from imported asbestos-
438 containing sheets. Information on these uses is well understood by EPA as a result of direct
439 communication with these processors (see Problem Formulation of the Risk Evaluation for
440 Asbestos (Ref. 3, pg 25)).

441 To support a claim that there is ongoing processing of articles that EPA is unaware of, the
442 petitioners cite the export and reexport of articles described in the USGS Minerals Yearbook for
443 2016 (Ref. 5). The petitioners, however, neglect to note that the same report states that these
444 shipments were likely misclassified and that "[s]hipments reported under these categories may
445 have been reexports and (or) exports of products that were similar but did not contain asbestos."
446 In identifying the conditions of use for asbestos during the TSCA risk evaluation process, EPA
447 reviewed the U.S. International Trade Commission's Dataweb and other government and
448 commercial trade databases. EPA was unable to confirm any processing of asbestos beyond
449 processing of raw asbestos into diaphragms and the fabrication of gaskets from imported

asbestos-containing sheets.

Since asbestos is not mined in the United States, raw asbestos is imported solely by the chlor-alkali industry; because sheet gaskets are the only imported asbestos-containing products that may involve processing, EPA does not believe there are additional, unknown processors of asbestos in the United States. Accordingly, EPA does not believe that requiring reporting from processors of asbestos under section 8(a) will provide useful information not already in the Agency's possession. The petitioners have failed to indicate what additional information EPA would collect by requiring asbestos processors to report under a section 8(a) rule and the Agency is prohibited by TSCA section 8(a)(5)(A) from requiring reporting that is unnecessary or duplicative. Therefore, EPA finds that petitioners have failed to set forth sufficient facts to establish that it is necessary for the Agency to use its discretion to issue a section 8(a) reporting rule for asbestos that requires processors of asbestos to report.

iii. [redacted] *reporting of imported articles containing asbestos.*

a. Petitioners' request.

In support of their request to [redacted] of imported articles containing asbestos, the petitioners state that "the Asbestos Problem Formulation provides virtually no information about the amount of asbestos in any of these products, the quantities in which they may be imported, and where they may be used, let alone any information about the extent to which the public may be exposed to these asbestos-containing products" (Ref. 1). Furthermore, the petitioners state that "EPA simply throws up its hands, stating that '[c]onsumer exposures will be difficult to evaluate since the quantities of these products that still might be imported into

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the United States is not known'" (Ref. 1).

b. Agency response.

EPA has relied on extensive outreach and research to determine the conditions of use of asbestos, as described in Unit IV.A.i. The Agency does not believe promulgating a section 8(a) reporting rule for asbestos would be helpful in collecting additional import information on asbestos-containing articles because the Agency has identified the articles that are imported into the United States and promulgated a significant new use rule under TSCA section 5 to require notification to the Agency of any new uses, including different or new articles. The Agency is prohibited by TSCA section 8(a)(5)(A) from requiring reporting that is unnecessary or duplicative. Even if EPA were to promulgate a reporting rule for asbestos, EPA does not believe that potentially useful information for EPA's ongoing asbestos risk evaluation would be "reasonably ascertainable" and thus EPA could not require this information to be reported under section 8(a). Nor would EPA be able to collect new data in time to inform the risk evaluation, which EPA intends to complete in December 2019. **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP) If EPA finds unreasonable risk for a condition of use, risk management must promptly be initiated with a proposed rule issued one year after EPA makes such a determination.

Commented [HM50]: Ditto

Commented [LT51R50]: Added

EPA has sufficient information on imported articles containing asbestos to conduct the risk evaluation and inform any potential risk management decisions based on the risk determination. The only asbestos-containing articles that EPA has identified that are currently imported into the United States are asbestos-containing sheet gaskets, other gaskets, aftermarket

automotive brakes/linings, other vehicle friction products, and brake blocks. Furthermore, the Asbestos SNUR, finalized on April XX, 2019, ensures that no significant new uses of asbestos, including as an article, can begin without EPA first evaluating the significant new use and then, if necessary, taking action to prohibit or limit the activity.

Commented [WJ52]: ###by finalized we mean signed, correct? I'm concerned that it won't publish before this petition response needs to be signed.

Commented [LT53R52]: We can change to the date of signature if needed.

The petitioners state that EPA lacks information on the quantity of asbestos contained in articles and assert that the Agency "lack[s] this information despite" communication with Chemours, a company that uses asbestos-containing gaskets, and Branham Corporation, the gasket supplier to Chemours (Ref. 1). Yet, as stated in the Asbestos Problem Formulation, Chemours notified EPA of their current use of imported gaskets from China (Comment ID EPA-HQ-OPPT-2016-0736-0067). Chemours stated that these sheet gaskets are composed of 80% (minimum) chrysotile asbestos, encapsulated in Styrene Butadiene Rubber, and used to create tight chemical containment seals during the production of titanium dioxide. Furthermore, as stated in the Asbestos Problem Formulation, on October 30, 2017, EPA met with Chemours and Branham Corporation, who provided EPA with additional information on the fabrication and use of the gaskets (Ref. 3).

Similarly, the petitioners stated that EPA lacks information on asbestos-containing brake blocks, even though a domestic brake block manufacturer confirmed the continued import of these products (Ref. 1). However, **Ex. 5 Deliberative Process (DP)** **Ex. 5 Deliberative Process (DP)** For the asbestos risk evaluation, in instances where the specific use information on asbestos is unknown, EPA has made use of **Ex. 5 Deliberative Process (DP)** **Ex. 5 Deliberative Process (DP)** EPA's assumptions, uncertainty factors, and models

Ex. 5 AC/DP

Commented [BC55R54]: Agree. Flagged this word earlier in document, may need to explain there too.

Commented [LT56R54]: Removed. Conservative assumptions have not been defined in the RE rule and may be misunderstood. Changed 'information' to 'science' to align with RE rule.

513 or screening methodologies used when assessing risks associated with the conditions of use of
514 asbestos-containing articles will be peer and publicly reviewed. It is standard practice for EPA to
515 make conservative assumptions in the absence of complete information. Considering the
516 extensive outreach and research conducted since December 2016, EPA has no reason to believe
517 there are ongoing imports of articles containing asbestos that are unknown to EPA.

518 Additionally, information reported under section 8(a) is limited to that which is "known
519 to or reasonably ascertainable" by the reporter. Thus, even if EPA were to require the reporting
520 of asbestos-containing articles under a section 8(a) rule, importers would rely on information
521 readily available to them, such as Safety Data Sheets or other documentation provided by their
522 foreign supplier. As a result, EPA does not believe that the requested reporting rule would result
523 in importers reporting articles that are not already known to EPA because the Agency has
524 conducted its own research to analyze Safety Data Sheets and other evidence in order to
525 determine the conditions of use of asbestos for the risk evaluation. Requiring importers of
526 asbestos-containing articles to report under section 8(a), therefore, would not provide any new
527 use information that would inform the ongoing risk evaluation or any subsequent risk
528 management decisions, if needed, and the Agency is prohibited by TSCA section 8(a)(5)(A)
529 from requiring reporting that is unnecessary or duplicative.

530 For these reasons, EPA believes that the petitioners have failed to set forth sufficient facts
531 to establish that it is necessary for the Agency to use its discretion Ex. 5 Deliberative Process (DP)
532 Ex. 5 Deliberative Process (DP)
533 *in impurity exemption for asbestos.*

534 *a. Petitioners' request.*

535 In support of their request for the reporting of asbestos impurities, the petitioners state
536 that "contamination of talc with asbestos is well-known, having been discovered as impurities in
537 cosmetics, baby powder, and crayons" (Ref. 1). As such, the petitioners assert that the "presence
538 of asbestos in such consumer products, whether unintentional "impurities" or as an unintended
539 ingredient in the article, dictates that these exemptions cannot apply with respect to the reporting
540 requirements for asbestos in commerce" (Ref. 1).

541 *b. Agency response.*

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548 **Ex. 5 Deliberative Process (DP)**
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Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) Instead, the standard for all information required to be reported under TSCA section 8(a)(2) is that it be "known or reasonably ascertainable." EPA is aware that testing by a small number of importers of talc or products such as crayons has shown that some of these products are contaminated with asbestos as an impurity. However, EPA cannot compel importers who have not tested their imports to conduct this kind of testing under section 8(a) Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) EPA is not aware of routine testing of imports for impurities of asbestos. Thus, it is unlikely that EPA would receive new information that would change its understanding of the conditions of use for asbestos that can be addressed under TSCA.

EPA does not believe that issuing the requested section 8(a) reporting rule Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) would result in reporting of asbestos as an impurity, to the extent that the presence of asbestos as an impurity in these articles

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generally is not known or reasonably ascertainable to the importer. EPA finds that the petitioners have failed to set forth sufficient facts to establish that it is necessary for the Agency to use its discretion to Ex. 5 Deliberative Process (DP) requires reporting from manufacturers (including importers) of asbestos as an impurity.

v. Enable EPA to Satisfy Requirements for Best Available Science.

a. Petitioners' request.

As overall support for their petition, the petitioners state that EPA must Ex. 5 Deliberative Process (DP) Ex. 5 Deliberative Process (DP) to satisfy its statutory obligation under TSCA section 26 to consider the information "reasonably available" to it. Additionally, since the petitioners believe that if EPA were to require reporting on asbestos as a naturally occurring chemical substance, asbestos-containing articles, asbestos as an impurity, and from asbestos processors, that this data is "reasonably available to the agency" and thus "needed for EPA to be able to make informed technically complex decisions regarding the regulation of asbestos" (Ref. 1).

b. Agency response.

TSCA section 26 requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use scientific standards and base those decisions on the best available science and on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). In the final Risk Evaluation Rule (82 FR 33726, July 20, 2017), EPA defined "best available science" as science that is reliable and unbiased. This involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best

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available methods (if the reliability of the method and the nature of the decision justifies use of the data).

Additionally, in the final Risk Evaluation Rule, EPA defined weight of scientific evidence as a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance (82 FR 33733, July 20, 2017). EPA sees weight of the scientific evidence approach as an interrelated part of systematic review, and further believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA.

TSCA section 26(k) (15 U.S.C. 2625(k)) states that in carrying out risk evaluations, EPA shall consider information that is "reasonably available," but the statute does not further define this phrase. In the final Risk Evaluation Rule (82 FR 33726, July 20, 2017), EPA defined "reasonably available information" to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. While EPA prefers high quality data, where available, EPA recognized in the Risk Evaluation Rule that data is not always necessary to reach a scientifically grounded conclusion on the potential risks of a chemical substance, within the timeframes dictated by the statute (82 FR 33739, July 20, 2017).

As outlined in the previous sections, EPA does not believe that an asbestos reporting rule

618 would collect information that is either new or useful in informing the ongoing asbestos risk
619 evaluation. EPA believes that it already has sufficient information to conduct the risk evaluation.
620 Moreover, even if EPA were to initiate the requested action, EPA would not collect information
621 in a timely manner to inform the ongoing risk evaluation nor any potentially subsequent risk
622 management activities. if unreasonable risk for the asbestos uses being evaluated is determined.
623 EPA intends to finalize the risk evaluation for asbestos no later than December 2019 Ex. 5 Deliberative Process (DP)
624 **Ex. 5 Deliberative Process (DP)** If EPA finds unreasonable risk for a
625 condition of use, risk management must promptly be initiated with a proposed rule issued one
626 year after EPA makes such a determination.

Commented [HM77]: Ditto earlier comment
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627 Thus, EPA finds that the petitioners have failed to set forth sufficient facts to establish
628 that it is necessary to issue a section 8(a) reporting rule for asbestos in order to meet its
629 obligations under TSCA section 26 to make its decision under section 6 based on the weight of
630 the scientific evidence, using reasonably available information, and using the best available
631 science.

632 **VI. References**

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

1. The Attorneys General of Massachusetts, California, Connecticut, Hawaii, Maine, Maryland, Minnesota, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and the District of Columbia to Andrew Wheeler, Acting Administrator, U.S. Environmental Protection Agency. Re: Petition of the Commonwealths of Massachusetts and Pennsylvania, the States of California, Connecticut, Hawaii, Maine, Maryland, Minnesota, New Jersey, New York, Oregon, Rhode Island, Vermont, and Washington, and the District of Columbia under Section 21(a) of TSCA, 15 U.S.C. § 2620(a), for EPA to Issue an Asbestos Reporting Rule to Require Reporting under TSCA Section 8(a), 15 U.S.C. § 2607(a), of Information Necessary for EPA to Administer TSCA as to the Manufacture (including Importation), Processing, Distribution in Commerce, Use, and Disposal of Asbestos. Received January 31, 2019.

2. Asbestos Disease Awareness Organization, American Public Health Association, Center for Environmental Health, Environmental Working Group, Environmental Health Strategy Center, and Safer Chemicals Healthy Families to Andrew Wheeler, Acting Administrator, Environmental Protection Agency. Re: Petition under TSCA Section 21 to Require Reporting on Asbestos Manufacture, Importation and Use under TSCA Section 8(a). Received September 27, 2018.

3. EPA. Problem Formulation of the Risk Evaluation for Asbestos. May 2018. Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. [HYPERLINK "https://www.epa.gov/sites/production/files/2018-06/documents/asbestos_problem_formulation_05-31-18.pdf"].

4. EPA. Public database 2016 chemical data reporting (May 2017 release). Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from [HYPERLINK "https://www.epa.gov/chemical-data-reporting"].

5. Flanagan, DM. (2016). 2015 Minerals yearbook. Asbestos [advance release]. In US Geological Survey 2015 Minerals Yearbook. Reston, VA: U.S. Geological Survey. [HYPERLINK "https://minerals.usgs.gov/minerals/pubs/commodity/asbestos/myb1-2015-asbes.pdf"].

6. EPA. Response to Petition to Initiate Rulemaking Under Section 8(a) of TSCA for the Reporting of the Manufacture, Import, and Processing of Asbestos. Letter. 2019.

List of Subjects in 40 CFR Chapter I

Environmental protection, Asbestos, Flame retardants, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: _____

_____

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.