



July 5, 2022

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Washington, DC 20460

Re: TSCA Section 8(a) Reporting and Recordkeeping Requirements for Asbestos (Docket ID No. EPA-HQ-OPPT-2021-0357)

Dear Administrator Regan:

On May 6, 2022, the Environmental Protection Agency (EPA) published the above-referenced proposed rulemaking on reporting and recordkeeping requirements for asbestos under the Toxic Substance Control Act (TSCA).¹ This proposed rule would impose a one-time requirement to electronically report information regarding quantity of asbestos, types of use, and employee data for entities that manufactured (including imported) or processed asbestos and asbestos-containing articles (including as an impurity) in the four years prior to the date of publication of the final rule. The agency intends to use the reported information to inform its future actions under TSCA,² including the supplemental asbestos risk evaluation³ and associated risk management activities.

The Office of Advocacy (Advocacy) is concerned that the agency has improperly certified that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA). The certification is improper because it does not completely assess impacts for all the affected small businesses.⁴ Advocacy is further concerned with small businesses' ability to comply with the rule due to the uncertainty in the scope and

¹ 87 Fed. Reg. 27060 (May 6, 2022).

² See 15 U.S.C. § 2605.

³ Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-asbestos-part-2-supplemental-evaluation> (last visited June 29, 2022).

⁴ 5 U.S.C. § 601 et seq.

applicability. Finally, Advocacy is concerned about the lack of awareness of and public notice about EPA’s proposed definition for small processors and the required Small Business Administration (SBA) consultation.

EPA must supplement its RFA analysis to support its certification or conduct a small business advocacy review panel⁵ if unable to do so. Advocacy also recommends that the agency provide clarification with regard to the scope of the rule and consider burden-reducing compliance flexibilities for the affected small businesses. Lastly, Advocacy requests that EPA reopen the docket to allow small entities to provide feedback on its consultation with SBA for its proposed definition for small processors. Advocacy supports EPA’s goal to obtain information to better understand the exposures and uses associated with asbestos. Advocacy hopes to work with the agency to identify a more effective and less burdensome means to achieve this goal.

I. Background

A. The Office of Advocacy

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the SBA. As such, the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),⁶ gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.⁷ The agency must include, in any explanation or discussion accompanying the final rule’s publication in the *Federal Register*, the agency’s response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.⁸

Advocacy’s comments are consistent with Congressional intent underlying the RFA, that “[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public.”⁹

B. The Proposed Rule

On May 6, 2022, EPA published proposed reporting and recordkeeping requirements for asbestos under TSCA. The proposed rule is a one-time reporting obligation for certain

⁵ 5 U.S.C. § 609 (d)(2).

⁶ Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

⁷ Small Business Jobs Act of 2010 (PL. 111-240) §1601.

⁸ *Id.*

⁹ 5 U.S.C. § 601 note.

manufacturers (including importers) or processors of asbestos and asbestos-containing articles (including as an impurity). EPA estimates the reporting period to be from 2019 to 2022. The data elements for reporting include the quantity manufactured or processed per asbestos type and use, and employee exposure information. The agency allows nine months to collect and submit the required information. EPA intends to use the reported information for potential federal actions involving asbestos, including EPA's TSCA risk evaluation and risk management activities.

The proposed rule is also subject to a settlement agreement¹⁰ where EPA agreed to address information-gathering deficiencies identified in the U.S. District Court in the Northern District of California's decision in *Asbestos Disease Awareness Org. v. Wheeler*.¹¹ Specifically, the court asked EPA to require reporting of reasonably available information from importers of articles, processors, and for the presence of asbestos as an impurity to inform the agency's risk evaluation for asbestos.¹²

The only reporting EPA anticipates receiving in response to this rule is intentional uses of chrysotile asbestos and instances of the presence of asbestos as an impurity. EPA is not aware of any ongoing, intentional use of the other five asbestos fiber types,¹³ or of Libby Amphibole asbestos. EPA defines impurity as a chemical substance which is unintentionally present with another chemical substance.¹⁴ According to EPA, asbestos subject to this rule may occur naturally as an impurity in other products such as talc, vermiculite, and potentially other substances.¹⁵

In addition, although TSCA Section 8(a) provides an exemption for small manufacturers (including importers) or processors, EPA is imposing these requirements on all small businesses for all forms of asbestos, except for Libby Amphibole. EPA explains it can do so under TSCA because these forms of asbestos are subject to an existing TSCA rulemaking. As a result, only small manufacturers and small processors of Libby Amphibole would be exempt from reporting. While EPA is using its existing definition for small manufacturer, the agency is proposing to establish a definition of small processors in this rulemaking. EPA is consulting with SBA on the new definition,¹⁶ as required by statute.¹⁷

II. EPA Has Improperly Certified the Rule under the Regulatory Flexibility Act.

If, after conducting an analysis for a proposed or final rule, an agency determines that a rule will not have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify. The certification must include a statement

¹⁰ Settlement Agreement, Case Nos. 3:19-CV-00871-EMC; 3:19-CV-03807-EMC. *Asbestos Disease Awareness Organization, et al., Plaintiffs, v. U.S. Environmental Protection Agency, et al., Defendants*. June 7, 2020.

¹¹ 508 F. Supp. 3d 707 (N.D. Cal., December 22, 2020).

¹² *Id.* at 724-731.

¹³ These include crocidolite (riebeckite); amosite (cummingtonite-grunerite); tremolite; anthophyllite; and actinolite. 40 § CFR 763.163.

¹⁴ *Id.* at § 704.3.

¹⁵ 87 Fed. Reg. at 27072.

¹⁶ SBA Consultation Letter, April 22, 2022. Available here: [Regulations.gov \(last visited June 29, 2022\)](#).

¹⁷ 15 U.S.C. § 2607(a)(3)(B).

providing the factual basis for this determination, and the certification must be published in the *Federal Register* at the time the proposed or final rule is published for public comment. Agency certifications of final rules are subject to judicial review.¹⁸ Courts evaluate rules by determining whether the statement of basis and purpose accompanying the rule identifies a “factual basis” to support the certification.¹⁹ However, if an agency covered by Section 609 of the RFA, such as EPA,²⁰ is unable to certify, the agency must conduct a SBREFA panel to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.²¹

Advocacy believes that EPA cannot certify the proposed rule under the RFA because it does not completely assess impacts for all the affected small entities. According to small business representatives, this rule would impose significant compliance costs for many small businesses that are not currently included in the impact analysis for this proposed rule. For these reasons, Advocacy is concerned that the agency has underestimated the impact on small entities.

A. EPA Underestimates the Impact of Compliance Costs Associated with the Proposed Reporting Requirements.

EPA did not include compliance cost information for small businesses who would be required to report asbestos as an impurity under the proposed rule. Although EPA accounts for these cost estimates, this information was not included in the analysis to support its RFA certification. EPA’s estimates included costs for identifying the type of imported article or mixture containing asbestos, identifying suppliers, and collecting data from suppliers. EPA notes that an entity may incur a range of the costs provided depending on the number of articles or mixtures, the complexity of supply chains, frequency of supplier change, and the size of the company. EPA estimated average burden and cost per site ranges from approximately 17 hours and \$1,573 to 40 hours and \$3,334, depending on the type of activities and the information that is known or reasonably ascertainable.

Small business representatives have expressed concerns that EPA has severely underestimated these compliance burdens given the scope of the rule and the retrospective nature of the reporting requirement. The scope of the rule is broad because it includes entities that have not been subject to TSCA reporting requirements previously. The rule imposes reporting requirements on entities that will not necessarily possess first-hand knowledge of the chemical substances in their products and will have to engage in upstream supply chain investigation to obtain the required information to comply. These entities include article importers and processors of asbestos and asbestos-containing materials (including impurities). The reporting for asbestos as an impurity extends beyond identified minerals such as talc and vermiculite to include a category of unnamed “other substances.” In addition, even though it is a one-time reporting rule, it requires reporting for the past four years. The reporting is likely to include mixtures or articles for which there is no reasonably available information regarding their asbestos content, especially for the presence of asbestos as an impurity.

¹⁸ 5 U.S.C. § 611.

¹⁹ *Id.* at § 605(b).

²⁰ *Id.* at § 609(d)(2).

²¹ *Id.*

B. EPA Underestimates the Number of Small Entities Subject to the Rule.

EPA does not include the number of small businesses who would be required to report for asbestos as an impurity to support its RFA certification. EPA only provides estimates for the intentional use of chrysotile asbestos. The agency explains that it was unable to provide information on the number of entities likely to report the presence of asbestos as an impurity due to the lack of information on the extent to which asbestos occurs as an impurity.

Small business representatives expressed concerns that there could be many additional small businesses that would be impacted under this category. The reporting rule requirements only apply to entities who know that their products contain asbestos or the presence of asbestos as an impurity. However, businesses who may not have knowledge that they have imported asbestos (including as an impurity) and therefore do not report under the rule will still have to document its activities to support any claims needed to demonstrate their compliance with the “known to or reasonably ascertainable by” standard.²² EPA acknowledges that it did not provide the number of small business importers of articles who would incur these costs to demonstrate this compliance.

C. Advocacy Recommends EPA Supplement its Threshold Analysis to Support its RFA Certification, Convene a SBREFA Panel, or Provide An Exemption for Small Businesses.

Based on the deficiencies noted above, the agency’s estimate for compliance burden and the number of small businesses impacted cannot be considered to provide a true representation of the small business impacts under this rule. As a result, the agency lacks the factual basis required to support a certification under the RFA.

Advocacy recommends that EPA supplement its RFA analysis to support its certification or conduct a small business advocacy review (SBREFA) panel,²³ if unable to do so. To supplement its RFA analysis, EPA should revise its threshold analysis by including compliance costs for entities required to report for the presence of asbestos as an impurity. As part of this undertaking, EPA should include an adjustment based on feedback from small businesses to address concerns that the current compliance costs provided are underestimated. EPA should also include any estimates regarding the number of entities that would be subject to the rule’s requirement to determine whether reporting is required for asbestos as an impurity, particularly for importers of articles.

If EPA is unable to obtain the information needed to improve the threshold analysis to support its RFA certification or if the information obtained does not allow EPA to certify the rule under the RFA, then the agency is required to convene a SBREFA panel.²⁴ A SBREFA panel will allow the agency to get information on the number of small entities that would be impacted and assess the impacts of the proposed rule on all relevant small entities.

²² “Known to or reasonably ascertainable by” includes “all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.” 40 § CFR 704.3.

²³ 5 U.S.C. § 609 (d)(2).

²⁴ *Id.*

Alternatively, Advocacy recommends EPA provide an exemption for small businesses who would otherwise be required to report for the presence of asbestos as an impurity. Excluding these entities from the scope of the rule will likely allow the agency to certify the rule under the RFA without having to add the missing impact information. Most importantly, it will reduce the compliance burden on small entities who are not likely to provide any responsive information. EPA is limited to requiring information that is reasonably available.²⁵ In addition, under TSCA 8(a)(5), EPA is required, to the extent feasible, to minimize the cost of compliance on small manufacturers and processors and impose reporting obligations on entities who are likely to have the relevant information.²⁶

In *Asbestos Disease Awareness Org.*, the court also alluded to the disparity in number of resources in discussing large businesses' (e.g. Johnson and Johnson) ability to obtain information to report on impurities.²⁷ The court further advised EPA against a one-size-fits-all approach in applying requirements without the consideration of whether the information is reasonably ascertainable by an entity.²⁸ Small business representatives have expressed significant concerns about their ability to report impurities, given their limited resources. This concern is especially important because, in contrast, large businesses often have dedicated in-house resources to collect information and track supply chains.

III. Advocacy Recommends EPA Clarify the Scope of its Rule and Consider Additional Burden-reducing Compliance Flexibilities for Small Businesses.

Advocacy is concerned with small businesses' ability to comply with the rule due to the uncertainty in its scope and applicability. Advocacy recommends that the agency provide clarification with regard to the scope of the rule and consider additional burden-reducing compliance flexibilities for the affected small businesses.

As explained above, the scope of the rule is broad because it includes entities that have not been subject to TSCA reporting requirements such as processors and importers of articles. The rule also requires reporting for the presence of asbestos as an impurity. Compliance obligations are further compounded for these entities under EPA's "known to or reasonably ascertainable by" standard which requires making inquiries for reportable data gathering within and outside the organization.²⁹ Small business representatives have also expressed concerns about the difficulty in determining whether they would be subject to the proposed rule as a processor. EPA does not usually impose reporting on processors for chemical reporting under TSCA. Advocacy recommends that the agency provide tailored compliance guidance, specifically for processors, importers of articles, and those subject to the reporting for the presence of asbestos as an

²⁵ 15 U.S.C. § 2607(a)(1)(A).

²⁶ *Id.* at § 2607(a)(5)(B)-(C).

²⁷ 508 F. Supp. 3d at 728.

²⁸ *Id.*

²⁹ See 86 Fed. Reg. at 27067.

impurity. EPA should also clarify the expectations and obligations for these entities to satisfy the “known to or reasonably ascertainable by” standard for reporting under this rule.

Small business representatives have also expressed concerns that the requirement to report on asbestos impurities could pose substantial burdens due to the retrospective nature of the required reporting and in determining whether their mixtures and/or articles contain the presence of asbestos as an impurity. Entities such as manufacturers and importers of a bulk chemical are in the best position to provide information on potential impurities. Downstream user entities such as processors and importers of articles required to report on impurities will not have ready access to this information. They will have to rely on information from upstream suppliers, including foreign entities. There is no guarantee that these communications requests will produce the required information for reporting. Therefore, in addition to the consideration of an exemption for small entities to report the presence of asbestos as an impurity, Advocacy recommends EPA consider limiting the small businesses’ obligation to report for asbestos impurities to only known information within the organization.

Some small business representatives have also expressed concerns with small businesses’ ability to comply within the provided timeframe. Advocacy recommends that the agency conduct outreach with small entities to determine whether extended compliance timeframes, including tiered or phased-in reporting, will better ensure that the agency is able to receive the information requested from them.

Finally, in requiring reporting for the presences of asbestos as an impurity, EPA references “talc, vermiculite, and potentially other substances.” EPA does not provide any information on what could be included as these “other substances.” This ambiguity further adds to the burden of determining whether an entity is subject to the reporting requirements for this rule because it expands the scope of inquiry to account for the presence of asbestos impurities. Advocacy recommends that the agency strike “potentially other substances” from its required reporting on impurities.

IV. Advocacy Recommends EPA Reopen the Docket to Seek Public Comment on the Proposed Definition of Small Processor.

Advocacy is concerned that EPA did not provide adequate public notice for its required consultation with SBA for the proposed definition of small processor for reporting rules.³⁰ While the consultation letter is provided in the docket,³¹ it is not discussed or mentioned in the preamble of the notice for this proposed rulemaking. In contrast, when EPA consulted with SBA for the small manufacturer definition, the agency provided a detailed account of its obligation to

³⁰ TSCA section 8(a)(3)(B) authorizes the EPA Administrator, after consultation with the Administrator of the Small Business Administration (SBA), to prescribe by rule the standards for determining the manufacturers and processors which qualify as small manufacturers and processors. 15 U.S.C. § 2607(a)(30)(B).

³¹ SBA Consultation Letter, April 22, 2022. Available here: [Regulations.gov \(last visited June 29, 2022\)](#).

consult with SBA, including a consideration of SBA's approach in revising the small manufacturer definition.³²

Moreover, for this proposed action, the consultation letter notes that EPA "may also use this small processor definition for subsequent rulemakings under TSCA section 8(a), without further consultation with SBA."³³ This information is also not provided in the notice for this proposed rule. EPA's failure to include this information in the notice for the proposed rulemaking deprives the public of adequate notice regarding the importance of the proposed definition for small processors for future rulemakings.

Advocacy urges EPA to reopen the docket or consider initiating a separate action. EPA should do so after receiving SBA's written response as part of the consultation. As part of this effort, EPA should inform the public of its consideration of SBA's feedback as the agency did for the small manufacturer definition. This will allow the public to comment meaningfully on EPA's proposal to establish a small processor definition, for the first time, for TSCA 8(a) reporting rules.

V. Conclusion

Advocacy is concerned that the agency has improperly certified that this rule will not have a significant economic impact on a substantial number of small entities under the RFA. Advocacy is also concerned with small businesses' ability to comply with the rule due to its broad scope and applicability. In addition, Advocacy is concerned about the lack of public awareness of EPA's proposed definition for small processors and the required SBA consultation. Therefore, Advocacy believes that EPA must supplement its analysis to assess the impact of the proposed rule on all the affected small entities, and to consider less burdensome alternatives. Lastly, Advocacy requests that EPA reopen the docket to allow small entities to provide feedback on its consultation with SBA on its proposed definition for small processors.

Advocacy urges EPA to give full consideration to the above issues and recommendations. We look forward to working with you to reduce the regulatory burden on small businesses. If you have any questions or require additional information, please contact me or Assistant Chief Counsel Tayyaba Zeb at tayyaba.zeb@sba.gov.

Sincerely,

/s/

Major L. Clark, III
Acting Chief Counsel
Office of Advocacy
U.S. Small Business Administration

³² TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a), 84 Fed. Reg. 17692 (April 25, 2019).

³³ See, SBA Consultation Letter.

/s/

Tayyaba Zeb
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: Dominic Mancini, Deputy Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget