Industrial Minerals Association — North America

July 13, 2022

Filed via the Federal eRulemaking Portal: http://www.regulations.gov

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Dear Dr. Freedhoff:

The Industrial Minerals Association – North America ("IMA-NA") respectfully provides the following comments on the Environmental Protection Agency's ("EPA" or the "Agency") rule proposal, Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA), 87 Fed. Reg. 21,706 (Apr. 12, 2022) (the "Proposed Rule").

IMA-NA supports risk mitigation measures for chrysotile asbestos to address its known toxicity. Our comments are focused on ensuring that EPA chooses risk mitigation measures which are rational, based on sound science, and crafted in coordination with appropriate stakeholders in the private and public sector in this risk mitigation action and in the future. None of IMA-NA's members mine, process, or import asbestos in or into the United States[1] nor do they make, import, or use asbestos containing membranes, gaskets, or brake blocks covered by the Proposed Rule. Rather, IMA-NA's comments address the broad and important policy considerations of this rulemaking. We begin with a discussion of the particular importance of transparency and

[1] Asbestos is mined primarily in Russia and Kazakhstan, and to a lesser degree in China, Brazil, and Zimbabwe. See U.S.G.S. Mineral Commodity Summary for Asbestos, 2021.

*IMA-NA is a non-profit trade organization representing essential minerals' producers throughout North America. IMA-NA represents a diverse set of member companies engaged in mining and processing of ball clay, barite, bentonite, borates, calcium carbonate, diatomite, feldspar, industrial sand, kaolin, lithium, mica, perlite, phosphates, potash, salt, soda ash, sodium bicarbonate, talc, uintaite, and wollastonite.*

clear communication of EPA's decision-making processes, particularly as this is EPA's first mitigation rule implementing the updated Section 6 of TSCA. IMA-NA then sets forth its specific concerns with the Proposed Rule, most centrally EPA's ability to use less disruptive mitigation options, particularly in the face of the agency-admitted impacts of the proposed ban (*i.e.*, its high cost, potential impacts on the supply chain for critical products and resources like pharmaceuticals, paper, and public drinking water), and the potential for EPA's preferred alternative to result in increased releases of PFAS chemicals. Finally, IMA-NA commends EPA's interest in developing occupational exposure-based approaches and in establishing a non-zero de minimis content threshold for the products being regulated by this rule. We think that it is very important to include a de minimis content threshold as part of this rule.

## A. Introduction and Summary of Key Points in These Comments.

The Proposed Rule is EPA's first risk management rule developed pursuant to the significantly updated statutory framework for risk management created by the 2016 Lautenberg Amendments to TSCA. Because the Proposed Rule is a pathbreaking exercise for the risk mitigation process envisioned by those amendments, and EPA presently lacks a procedural rule governing the risk management process, it is all the more critical that EPA consider and respond to all stakeholder comments, proceed in a transparent manner, and create a workable system that regulates chemicals "to the extent necessary" to address unreasonable risks without creating unnecessary regulatory burdens while doing so.[2] The need for a transparent and thoughtful approach (and clear communication of that approach) is amplified by the number of potential risk management approaches that are within EPA's authority to use. It is important for EPA to establish as part of this rule an understanding of the criteria EPA will use to select among them.

In this first proposed risk management rule post-Lautenberg, EPA is proposing to prohibit manufacture (including import), processing, distribution in commerce and commercial use of chrysotile asbestos for diaphragms used in the chlor-alkali industry, chrysotile asbestos-containing sheet gaskets used in chemical production, chrysotile asbestos-containing brake blocks used in the oil industry, aftermarket automotive chrysotile asbestos-containing brakes/linings, other chrysotile asbestos-containing vehicle friction products, and other chrysotile asbestos-containing gaskets. EPA also is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of aftermarket automotive chrysotile asbestos-containing brakes/linings for *consumer* use and chrysotile asbestos-containing gaskets for consumer use. Finally, EPA is proposing disposal and recordkeeping requirements for these conditions of use of chrysotile asbestos.[3]

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[2] 15 U.S.C. § 2605(a).

[3] IMA-NA does not support EPA's ad hoc general definition of "chrysotile asbestos" for purposes of risk management as "the asbestiform variety of a hydrated magnesium silicate mineral, with relatively long and flexible crystalline fibers that are capable of being woven." The term "hydrated magnesium silicate mineral" is too broad

IMA-NA would like to highlight the following recommendations in the comments that follow:

- IMA-NA urges EPA to re-evaluate its proposal to impose immense costs on industry, which will result in serious supply chain disruptions, as well as create significant potential public health impacts.
- EPA should invoke TSCA Section 9 to engage deferentially with the Occupational Safety and Health Administration ("OSHA") on consideration of a workplace exposure limit. While IMA-NA does not endorse any specific elements of the proposed Existing Chemical Exposure Limit ("ECEL"), we applaud EPA for considering an occupational exposure limit approach and encourage EPA to coordinate rather than avoid interfacing with OSHA in this area. In the two attachments to IMA-NA's comments (discussed in more detail in Section C, below), a number of flaws in EPA's approach to selecting an Inhalation Unit Risk (IUR) factor are described that raise concerns that the agency is not applying best available scientific principles. EPA's proposed IUR and ECEL present measurement challenges, are misleading to the public, and would create a patchwork approach of federal compliance standards for the same chemical.
- IMA-NA strongly supports EPA's intent to include a de minimis content threshold. Unfortunately, EPA has not provided the public with enough information to meaningfully participate in the process of identifying an appropriate de minimis threshold. We think EPA must consider applying the longstanding one percent threshold in TSCA (in the Asbestos Rule at 40 C.F.R. § 763.163 and in Title II, Section 202 of TSCA). This threshold is recognized by other EPA programs and other federal programs. IMA-NA is concerned that a "zero" threshold is not scientifically defensible in view of background concentrations and is not technologically feasible.
- Federal Register proposals on risk management should be more transparent in detailing why risk mitigation options less restrictive than a total ban are not able to eliminate the unreasonable risk EPA has identified for a condition of use. It appears that such options were available here but were inexplicably discounted. Given the size of the dockets in these rules, EPA should point the public to not just the key underlying agency analyses but also point out specific sections that support the conclusions of a proposed risk management rule published in the Federal Register.

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because it could be used to describe other mineral types. IMA-NA suggests that EPA solely identify the chemical being regulated by CASRN: 12001-29-5 ("Chrysotile"). IMA-NA rejects the use of CASRN 132207-32-0 because it is not the generally recognized CASRN for this commodity as indicated by the Federal government. *See* United States Geological Survey publication located at https://pubs.usgs.gov/of/2002/of02-149/of02-149.pdf.

## B. Reasons Why EPA Should Consider a Regulatory Approach.

IMA-NA encourages EPA to establish a risk management approach that considers all of the regulatory options Section 6 allows and which uses the agency's authority to ban a chemical and/ or its uses as a last resort. In this proposal, EPA's primary proposal is a total ban on the six conditions of use to be regulated based on the agency's findings of unreasonable risk. The sole alternative proposed regulatory approach, which is limited to only one of the conditions of use to be regulated, merely phases in a ban over a slightly longer time frame, despite the inclusion of another regulatory option, namely the proposed Existing Chemical Exposure Limit (ECEL). Limiting regulatory "alternatives" to two durations in which to implement a full ban is particularly puzzling given that EPA "has determined, as a matter of risk management policy" that unreasonable risk is also eliminated if the option of an occupational exposure limit is utilized instead.[4]

Even if true that the 2016 Lautenberg Amendments were intended to "un-paralyze" EPA by removing the mandatory "least burdensome" requirement found in Section 6(a) of TSCA prior to the amendments (Proposed Rule at 21,733) it does not necessary follow that EPA may select the most sweeping mitigation action available to it other than as a last resort if more discrete mitigation actions offered by Congress also eliminate the unreasonable risk. There is a better approach. The statute provides EPA with a list of regulatory requirements ranging from warning requirements, recordkeeping requirements, concentration limits, up through partial and full bans and directs EPA to "apply one or more" of these of requirements "to the extent necessary" so that the chemical substance or mixture no longer presents an unreasonable risk.[5] EPA is also directed to consider, inter alia, the benefits and economic consequences of its actions when selecting from the potential requirements. 15 U.S.C. § 2605(a), (c)(2)(B). Coupled with background requirements arising from Executive Orders,[6] EPA should not simply go straight to a ban without transparently establishing, based on substantial evidence in the administrative record, why other allowable options are not capable of eliminating unreasonable risk or, if they are capable of doing so, why EPA is choosing to ban the chemical instead. But that is precisely what EPA has done here; the record does not suggest that EPA seriously entertained anything short of a full ban.

EPA purports to have considered and rejected respirators as an alternative because it "determined that respirators were not adequate for all conditions of use" for which unreasonable risk determinations had been made. Proposed Rule at 21,718. However, the mere fact that EPA has proposed an ECEL undermines EPA's case that the use of respirators is not adequate and that an outright ban is necessary. EPA clearly expended substantial effort developing the ECEL which

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4 Proposed Rule Ref. 13 at 1.

5 15 U.S.C. § 2605(a).

6 *E.g.*, E.O. 12866, E.O. 13563.

includes not only the inhalation exposure level that EPA has determined no longer presents unreasonable risk, but also respirator requirements (to ensure that human exposure does not exceed the ECEL even if ambient concentrations do) and associated recordkeeping and reporting. IMA-NA cannot understand why EPA would devote so much energy to crafting a fully-formed risk mitigation option (which, by EPA's own determination, is capable of eliminating unreasonable risk) only to effectively discard it by proposing it only as part of a longer phase-out in the primary alternative regulatory action. IMA-NA strongly urges EPA to more fully consider technically feasible options and stakeholder comments in this area.

The agency's authority to ban a chemical from commerce is highly impactful and should be reserved for the most egregious cases in which no other option is sufficient to eliminate the unreasonable risk. Looking forward to this and other risk mitigation exercises, IMA-NA believes that developing mitigation options short of outright bans should be a regulatory priority – even in the case of unpopular chemicals like asbestos – if very limited and controlled use furthers other important public health goals and overall can be managed to eliminate the unreasonable risk. Congress in 2016 did not direct EPA to reduce risk to zero, even if such a Herculean delegation of authority is actually possible to achieve. Even if some regulated entities choose to phase out the affected chemical instead of implementing controls capable of eliminating unreasonable risk, this is still preferable as it preserves choice among regulated entities (and likely in many cases, supply chain robustness).[7]

Given the staggering costs EPA is prepared to accept,[8] and the associated potential supply chain and public health impacts EPA seems to be dismissive of in the Proposed Rule,[9] EPA's preferred regulatory approach sets a dangerous precedent: it is difficult to imagine a chemical for which EPA would not determine that an outright ban was warranted if it found unreasonable risk following the risk evaluation stage.

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[7] EPA should seriously consider that, in general, production capacity from banned conditions of use is likely not to be able to be brought back online quickly, if ever. The infrastructure that serves them will no longer be in place and later issuing an exemption under 15 U.S.C. § 2605(g) for national economy/national security reasons would offer no practical aid in a future emergency. Consider, for example, a future exigency that affects the availability of non-asbestos chlor-alkali production membranes. If asbestos diaphragms have been phased out for several years, equipment associated with the production and use of these diaphragms will not be readily available, as it would be if some plants were continuing to operate using asbestos diaphragms using an ECEL mitigation approach, thereby sustaining associated supply chains.

[8] Proposed Rule at 21,730 ($1.8 billion to convert remaining chlor-alkali processes only).

[9] Proposed Rule at 21,719-20 (acknowledging, but not rebutting, technological feasibility issues with alternatives raised by chlor-alkali producers); 21,721 (noting that "EPA has insufficient information to fully assess the impact of this proposed rule on the cost or availability of water treatment chemicals" and requesting more information on same, despite having potentially not presented a regulatory alternative that would alleviate the concerns). As a matter of public policy, IMA-NA urges EPA to reconsider banning the specific condition of use of chloro-alkali production given the impact it would have on drinking and wastewater systems in addition to industrial sectors dependent on chlorine and the chemical byproducts produced during the chlor-alkali process. Now is a particularly bad time to reduce redundancy in the supply if not absolutely necessary. EPA also appears dismissive of the impact of expanding PFAS use in connection with public water supplies in this Proposed Rule.

## C. EPA Did Not Satisfy its Obligation to Formally Engage with OSHA Under TSCA Section 9 and Cannot Justify the ECEL's 20-Fold Departure from the Current OSHA PEL.

TSCA Section 9(a), 15 U.S.C. § 2608(a), provides that when EPA makes an unreasonable risk finding as it has here, and proceeds to consider risk mitigation, the Administrator should consider whether the "risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by [EPA] … ." If the Administrator believes that another Federal law could address the risk, EPA shall submit a report to the relevant agency describing the unreasonable risk perceived by the Administrator and asking the sister agency to consider whether a law administered by it could address the risk. This initiates a process in which the agencies together determine how to address the risk identified by EPA under TSCA. TSCA Section 9(d) separately charges EPA to consult with other agencies to ensure that EPA enforces TSCA in a manner "imposing the least burdens of duplicative requirements" on regulated entities. Congress kept the main portions of Section 9 in 2016 and aligned it with the new Section 6 provisions, which is a clear signal that EPA should use it.

OSHA is the Federal agency primarily charged with ensuring safe working conditions in industrial settings through the Occupational Safety and Health Act of 1970 ("OSH Act"). In the Proposed Rule, EPA concedes that "the standards for chemical hazards that OSHA promulgates under the OSH Act share a broadly similar purpose with the standards that EPA promulgates under section 6(a) of TSCA." Proposed Rule at 21,711. EPA even refers to the NIOSH/OSHA hierarchy of controls when considering how to mitigate risk in the Proposed Rule and purports to "striv[e] for consistency with applicable OSHA requirements and industry best practices … ." *Id.* at 21,713.

Despite this, EPA determines in the Proposed Rule not to formally engage with OSHA to see if certain identified risks might be best addressed under the OSH Act rather than TSCA. EPA reasons that because TSCA's mandate can be construed more broadly than the OSH Act (either because of the differing risk analysis, or the different groups of potentially exposed populations that a TSCA Section 6 rule can address) the identified risks cannot "be prevented or reduced to a sufficient extent" by an action taken by any sister agency, including OSHA. Proposed Rule at 21,732. EPA asserts that TSCA is the only Federal law that "provides authority to prevent or sufficiently reduce [the identified] cross-cutting exposures" and that "[n]o other Federal regulatory agency can evaluate and address the totality of the risk that EPA is addressing in this proposal."

Even if true that there are blind spots in other agency's regimes (*e.g.*, state and local employees, or DIY'ers for OSHA),[10] EPA's approach here renders TSCA Section 9 a dead letter. Section 9 does not charge EPA to determine whether EPA *alone* can address the "totality" of all

[10] EPA acknowledges that it has other ways to fill such gaps in cooperation with relevant agencies. *See* 87 Fed. Reg. at 21,710 (discussing extension of OSHA standards to state and local government employees through the Asbestos Worker Protection Rule.)

unreasonable risks it identifies; rather, Section 9 is intended to foster cooperation with expert sister agencies and minimize duplicative regulation whenever another Federal law can address any portion of an unreasonable risk identified. EPA may believe (as it does here) that "risks can be addressed in a more coordinated, efficient and effective manner under TSCA than under different laws implemented by different agencies," *id.* at 21,733, but that is not an excuse to disregard the process set out in TSCA Section 9 and deny those agencies the opportunity to formally and transparently engage in the process laid out in TSCA Section 9.

EPA has now proposed an ECEL that is 20-fold lower than the existing OSHA Permissible Exposure Limit ("PEL") for asbestos. While IMA-NA supports rationally calculated industrial exposure ECELs/PELs, the IUR factor EPA is relying on has several scientific flaws as discussed in more detail in the attached technical analysis from Gradient, *see* **Attachment A**. EPA's ECEL calculation relies on compounding conservative and/or wholly unjustified assumptions that trace back to the Risk Evaluation, as discussed in more detail in a 2021 analysis by Dodge et al. that is included as **Attachment B** hereto. These improper assumptions include, but are not limited to, the use of a linear-no-threshold (LNT) model to calculate Inhalation Unit Risk ("IUR") notwithstanding that asbestos's mode of action is not consistent with the use of such a model, and improperly extrapolating from studies involving exposure to types of asbestos other than chrysotile. Additionally, EPA calculates the ECEL based on epidemiological studies while simultaneously discounting other studies with similar methodologies.

The proposed ECEL is so conservative that, in view of a recent study on background exposure levels, it could be interpreted as a conclusion by EPA that the general public is subjected to an excess lifetime cancer risk of $1.5 \times 10^{-4}$ based on background ambient exposures. *See* Attachment A at 2. This kind of public health messaging by a federal agency is obviously flawed and not born out by any real-world observations. We think it is unlikely that EPA intends to convey such an erroneous message to the public in this precedent-setting rule. However, if EPA does not address the technical issues associate with the IUR it should at least explain why its approach does not consider risks in the general population of the United States.

If enacted, the ECEL would also create varying requirements for workers performing tasks covered by the Proposed Rule as compared to workers performing tasks covered only by OSHA's standards. This is precisely the outcome that Section 9 of TSCA was intended to avoid; EPA unnecessarily creating a patchwork of regulation alongside other existing Federal laws intended to address the same activities and doing so without a fulsome and transparent engagement with the expert agencies that administer those laws. EPA should reconsider this approach in connection with this, and future, mitigation proposals under TSCA, and fully engage in the Section 9 process with OSHA and other agencies as appropriate.

## D. EPA's Concession that it Lacks Information to Assess Increases in PFAS Releases

TSCA requires EPA to consider alternatives when "deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use … and in setting an appropriate transition period for such action[.]" 15 U.S.C. § 2605(c)(2)(C). EPA must consider, "to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect." *Id.*

Here, regarding the proposed ban on the use of asbestos containing diaphragms for chlor-alkali production, EPA concedes that the alternative membrane diaphragms have a higher concentration of at least one per- or polyfluorinated ("PFAS") compound than asbestos diaphragms do. EPA further concedes that it presently lacks information to assess whether the transition to the membrane technology will result in additional PFAS releases. Proposed Rule at 21,719. But EPA proposes to move forward with a ban on the asbestos diaphragms "despite … uncertainties about possible greater use and release of PFAS" resulting therefrom. *Id.* EPA's approach would seem to reduce 15 U.S.C. § 2605(c)(2)(C) to a nullity.[11] EPA's cavalier treatment of the "PFAS-in-the-alternative" and $1.8 billion cost to industry contributes to IMA-NA's concern that the Agency should be demonstrating a more careful approach to considering regulatory alternatives than this administrative record reflects.

## E. Support for a De Minimis Content Threshold for Regulation.

EPA requests comment on how to address the identified unreasonable risks while "recognizing that chrysotile asbestos is a natural occurring fiber that may be unintentionally present" in other minerals. Proposed Rule at 21,720. EPA specifically requests comment on a de minimis provision that would restrict the rule's applicability to products: (1) with asbestos concentrations greater than or equal to 0.1% by weight; (2) with any amount of asbestos, if intentionally added; or (3) with asbestos concentrations above some other level.

IMA-NA would again like to express our appreciation to EPA that any of the foregoing options demonstrates agency support for a non-zero threshold in the Proposed Rule. Again, although IMA-NA members do not manufacture sheet gaskets, brakes or chlor-alkali filters, as a general matter, IMA-NA strongly supports a de minimis concentration for regulation (or various appropriate de minimis concentrations for different products). "Zero" cannot be determined

[11] It is also in tension with the Agency's "central directive" of "pursu[ing] a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment." EPA, PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024 at 5.

scientifically or made feasible technologically due to background limitations and method limitations.

However, IMA-NA is concerned that EPA has once again shifted the entire burden to the public to propose a de minimis level for asbestos, an already highly regulated chemical substance, with little background or explanation provided on the selection criteria for an appropriate level. We respectfully remind the agency that EPA's rulemaking authority rests on its capacity to consider the information available, evaluate its significance to the potential regulatory actions it will take, and craft a rule or standard to fit the facts and circumstances. Here, the agency has issued a call for comments – an essential tool for any regulator and a key part of the public participation process – but it has not armed the public with the critical information it needs to make that participation meaningful in this key aspect of the rule. IMA-NA does not know the criteria by which EPA will weigh the input of various commenters, the standards by which our recommendations will be compared or against what standard our information will be judged.

For example, if EPA stated that all positive tests for asbestos in a given product line would be considered a statistically-representative, pro rata indicator of the presence of asbestos on that product line, then IMA-NA would advocate for a standard that focused on the representativeness of those samples. If EPA stated that it intended to compare all results of all microscopy equally, then IMA-NA would propose a de minimis level close to the detection limit of the lowest-resolution microscope, to ensure that such a comparison was truly indicative of what all of those microscopists could reliably perceive. And if EPA stated that its research would presume that any asbestos fibers identified would be presumed harmful, IMA-NA would insist that EPA first conduct the risk assessment necessary to establish a de minimis level in bulk materials that has been proven to be harmful.

All of these scientific factors and more would influence how IMA-NA and any other responsible commenter would respond to a call for proposals. Unfortunately, this information was not contained in the proposed rule itself and is not available in any other form at this time. Without that information, IMA-NA does not believe that any commenter can reasonably propose a de minimis threshold. More importantly, better agency transparency and proactively proposing a de minimis level for public comment would give the public a more meaningful opportunity to raise questions and comment on EPA's proposed approach, rather than expend considerable resources in addressing the question as a matter of first impression.

As a federal agency, EPA must start by considering the applicability of longstanding federal threshold of one percent in the TSCA Title II (added to TSCA in 1986), Section 202 definition of asbestos, which is also recognized in the existing TSCA Section 6 regulation for asbestos and by other federal programs. A regulatory threshold for asbestos is an essential part of other EPA-administered programs and other rational regulatory approach to regulating asbestos. Continuing this practice would ensure consistency and promote the collection of the most equitable and consistent data set.

There are many federal statutory and regulatory precedents for the use of the one percent threshold already available to EPA for consideration. Historically, the majority of these content-driven regulations have consistently used a one percent threshold determination for regulating "asbestos-containing material".[12] As noted above, other sections of TSCA already contain a definition of "asbestos-containing material," for screening purposes, *i.e.*, "any material which contains more than 1 percent asbestos by weight." 15 U.S.C. § 2642(4) (part of the Asbestos Hazard Emergency Response Act or "AHERA," 15 U.S.C. §§ 2641-56). While TSCA Section 6 and AHERA are intended to address risks from asbestos and other chemicals in different ways, it is of some moment that AHERA reflects the considered view of Congress that one percent by weight is a reasonable screening level to determine if further action is needed to protect human health and the environment for bulk materials. This level was selected in recognition of available analytical methods at the time and focusing resources on materials containing higher thresholds.[13] This same threshold is found in the original Section 6 rule on asbestos (*i.e.*, TSCA 40 C.F.R. Subpart I - Prohibition of the Manufacture, Importation, Processing, and Distribution in Commerce of Certain Asbestos-Containing Products; Labeling Requirements; 40 C.F.R. § 763.163: Asbestos-containing product means any product to which asbestos is deliberately added in any concentration or which contains more than 1.0 percent asbestos by weight or area).

The burden is on the agency to justify if a downward departure is needed. OSHA (in its hazard communication standard) has established 0.1% as a general reporting threshold for known carcinogens in its Globally Harmonized System (GHS) for hazard communication.[14] As noted above, OSHA does not apply this level in the more specific context of asbestos. In its

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[12] The one percent threshold appears in the following federal statutes and regulations: *(1)* EPA TSCA 40 C.F.R. Subpart I - Prohibition of the Manufacture, Importation, Processing, and Distribution in Commerce of Certain Asbestos-Containing Products; Labeling Requirements; 40 C.F.R. § 763.163: Asbestos-containing product means any product to which asbestos is deliberately added in any concentration or which contains more than 1.0 percent asbestos by weight or area; *(2)* EPA TSCA Restrictions on Discontinued Uses of Asbestos; Significant New Use Rule (SNUR), 40 C.F.R. § 721.11095(a)(3)(ii): Exemptions cross-reference Part 763; *(3)* Asbestos Hazard Emergency Response Act (AHERA), 1986; TSCA Subchapter II: Asbestos Hazard Emergency Response, 15 U.S.C. § 2642(4); *(4)* Asbestos-Containing Materials in Schools Rule (per AHERA), 40 C.F.R. § 763.83: Asbestos-containing material (ACM) when referring to school buildings means any material or product which contains more than 1 percent asbestos; *(5)* Occupational Safety and Health Administration (OSHA), 29 C.F.R. §§ 1910.1001 and 1926.1101 (b) ACM means any material containing more than 1% asbestos; *(6)* EPA Asbestos Worker Protection (40 C.F.R. § 763.122 instructs state or local government employer whose employees perform certain activities to comply with 29 C.F.R. §§ 1926.1101 or 1910.1001; and *(7)* Clean Air Act, 42 U.S.C. § 7401 et seq., Asbestos National Emission Standard for Hazardous Air Pollutants (NESHAP), 40 C.F.R. § 61.141 definitions include: *Category I nonfriable ACM* means asbestos-containing packings, gaskets, resilient floor covering, and asphalt roofing products containing more than 1 percent asbestos, *Category II nonfriable ACM* means any material, excluding Category I nonfriable ACM, containing more than 1 percent asbestos, *Friable asbestos material* means any material containing more than 1 percent asbestos, *Nonfriable asbestos-containing material* means any material containing more than 1 percent asbestos, and *Resilient floor covering* means asbestos- containing floor tile, including asphalt and vinyl floor tile, and sheet vinyl floor covering containing more than 1 percent asbestos.

[13] EPA. Final Rule. Asbestos NESHAP. 38 Fed. Reg. 8819, 8821-22 (April 6, 1973).

[14] 29 C.F.R. § 1910.1200, Appendix A, § A.6.3, Table 1.

construction industry (29 C.F.R.§ 1926.1101) and general industry (29 C.F.R. § 1910.1001) exposure control regulations, OSHA defines an asbestos-containing material as "…any material containing more than one percent asbestos."[15] OSHA states that "*The provisions for labels and for safety data sheets required by paragraph (j) of this section do not apply where: Asbestos is present in a product in concentrations less than 1.0%.*"[16] OSHA provides similarly within the hazard communication section of the asbestos standard for the construction industry: "*The provisions for labels … do not apply where … asbestos is present in a product in concentrations less than 1.0 percent*.[17]

If, however, EPA were to consider a de minimis level other than the 1% level established by TSCA and other statutes, IMA-NA strongly asserts that the science requires a non-zero level based on method limitations and background considerations. There is an essential need for a non-zero level to make compliance reasonable for industry and to be consistent with scientific principles regarding significance of data. A threshold consistent with current federal regulations on asbestos ensures *consistent* federal regulation and will help to ensure that EPA obtains meaningful information that focuses on bulk materials containing asbestos as an impurity above such a level.

The administrative record of the risk evaluation or this proposed risk management rule is inadequate to establish that regulation at the zero quantity level is either technically feasible or required to eliminate unreasonable risk and meet the 1 in 10 thousand cancer threshold. In contrast, a regulatory threshold for asbestos is an essential part of other EPA-administered programs and any other rational regulatory approach to regulating asbestos. As stated in the Environment Canada publication to which EPA refers in the Proposed Rule (Ref. 4), background levels of asbestos are "omnipresent in the environment, including in both indoor and outdoor air." Information relative to background levels measured in the United States is extensively discussed in the attachments to IMA-NA's comments as well. Finally, as EPA also acknowledges in the Scope of the Asbestos Part 1 Risk Evaluation, background levels that exist in the environment (air and water) relate to background levels that can be detected in sample preparation and bulk analysis. A content threshold would go a long way to address this consideration.

### 1. Measurement Considerations for De Minimis Levels

The selection of a de minimis threshold aimed at an accurate and effective risk management is directly linked to both the microscopy tools and laboratory procedures providing a concentration measurement, and the methodology for determining the statistical level of confidence. Fiber type, habit, dimensions (*i.e.*, length, width, and aspect ratio), elemental composition, surface charge, elemental composition (*i.e.*, iron oxidation state), surface area and other characteristics

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[15] 29 C.F.R. § 1926.1101(b) definitions; and 29 C.F.R. § 1910.1001(b).

[16] 29 C.F.R. § 1910.1001(j)(6)(ii)(Hazard communication).

[17] 29 C.F.R. § 1926.1101(k)(Communication of hazards)(8)(vi)(B)(Labels).

influence asbestos potency. However, some analytical methods are limited in their abilities to distinguish fiber types, or to distinguish asbestos from other fibers, including non-asbestiform minerals. Furthermore, analytical methods differ in their rules for counting fibers and their dimensions, especially between airborne and bulk methods. A key consideration for the selected method is the manner of analysis of fibers (or structures), including both analytical capabilities and counting rules.

In Attachment A to IMA-NA's comments, specific examples are provided to illustrate that although analytical methods have improved with time, each has strengths with significant weaknesses and very few have empirically based, validated detection limits. Technical and cost considerations factor into method selection. EPA should consider the method limitations related to the measurement of chrysotile asbestos (*i.e.*, detection level must include statistical precision for a reproducible result and methods must also provide enough information to unambiguously provide a correct identification).

Without a de minimis value, the rule would fail to account for the inherent statistical uncertainty of analytical measurements at low level concentrations. We would be happy to discuss this point further.

**a. <u>Airborne Sampling Considerations</u>**

Analytical methods used to analyze airborne (as well as bulk) samples should be able to distinguish specific asbestos fiber types, asbestos vs. other types of particles and fibers, and asbestiform vs. non-asbestiform habits. These methods should also be able to characterize fiber dimensions. Several different analytical methods are available for fiber analysis that differ in these abilities, as well as in the counting rules they employ. The relevant metric for airborne asbestos is fibers or structures per cubic centimeter of air [f/cc or s/cc]).

Most airborne asbestos samples are analyzed using either phase contrast microscopy (PCM) or transmission electron microscopy (TEM) techniques, or a combination of the two. PCM is a low magnification optical microscopic technique. It can distinguish fibrous material from non-fibrous material, but it cannot distinguish between mineral fibers and other types of fibers (*e.g.*, fibrous glass, mineral wool, wood and other plant fibers, and synthetic organic fibers). It also cannot distinguish between different forms of amphibole asbestos, nor between chrysotile and amphibole asbestos. Because of limitations in resolution, PCM does not measure all fibers. Only those > 0.25 μm in diameter are visible, and only those > 5 μm in length are counted by protocol. However, PCM analysis provided the exposure basis for many epidemiology studies of asbestos-exposed occupational populations (in environments where asbestos was known to be present).

TEM uses an electron beam rather than a beam of visible light to detect particles or structures. The advantages of TEM over PCM include a higher resolution (*i.e.*, shorter and smaller diameter fibers can be detected) and the ability to identify mineral phases (Barlow et al., 2017b). Compared to PCM, however, TEM is more expensive and requires more in-depth analyst

training and expertise. For practical reasons (including cost-effectiveness) and historical standardization, PCM is often used when many samples are collected, and TEM is used on a subset of the samples to characterize fiber size distribution and fiber type (Barlow et al., 2017b). When TEM is used for its full resolution capabilities, the number of fibers detected may be greater or lesser for a given sample compared to those analyzed via PCM, depending on the degree to which TEM detected the presence of fibers too thin to be detected by PCM, and the degree to which PCM detected fibers that TEM was able to confirm were not chrysotile or amphibole. Also, as stated in ISO 10312:2019, TEM may not be able to discriminate between individual particles of asbestos and non-asbestos analogues of the same amphibole mineral in airborne samples.

To summarize, although limited compared to TEM, PCM is more suitable for atmospheres where asbestos is known to have been purposely used/processed (such as asbestos textile mills and asbestos mines). PCM results can be skewed high by non-asbestos fibers, making measurements made by PCM potentially unreliable in conditions where other types of fibers may be predominant (US EPA, 2001). Therefore, we recommend TEM to confirm the identity of elongate mineral particles, at least in a subset of samples, measured by PCM.

The basic fiber counting rules for most current methods of analysis of airborne fibers are to include fibers with a length longer than 5 μm, a width narrower than 3 μm, and an aspect ratio greater than 3:1 (NIOSH, 2017). While this proposed rule only concerns chrysotile (serpentine asbestos) it is generally important that these dimensions are not necessarily indicative of asbestos in environments that could include both asbestos and non-asbestiform analogs of the same *amphibole* species. Exposure measurements are most certain when taken in environments with known asbestos sources. Otherwise, additional criteria should be used to help distinguish between asbestos and non-asbestiform particles (Chatfield, 2018).

National Institute for Occupational Safety and Health (NIOSH) Method 7400 is the most accepted method for estimating concentrations of fibers by PCM (Perry, 2004) in the United States. It is used mainly for personal samples and occupational exposures to meet OSHA requirements (*i.e.*, 0.1 f/cc). It counts any fiber longer than 5 μm with an aspect ratio of at least 3:1 (NIOSH, 2019). NIOSH Method 7402 is a method for estimating concentrations of airborne fibers by TEM (NIOSH, 1994), where mineral species can be identified. It is intended to be the TEM equivalent of NIOSH 7400, as it uses the guideline of counting fibers that would have been counted by PCM (*i.e.*, any fiber with a diameter greater than 0.25 μm that meets the definition of a fiber as being longer than 5 μm with an aspect ratio of at least 3:1). In addition, only chrysotile and amphibole fibers are counted, and the fraction of these fibers relative to all fibers on the sample filter is calculated. Chrysotile has a unique electron diffraction pattern and can easily be identified as asbestos by TEM. However, as noted above, TEM data may not be indicative of asbestos for individual amphibole fibers in a mixed (asbestos/non-asbestos) environment.

Exceptions to the 5 μm length threshold for airborne asbestos methods are Asbestos Hazard Emergency Response Act (AHERA) TEM (US EPA, 2016) and International Organization for

Standardization (ISO) 10312 (ISO, 2019) which call for counting fibers or structures (bundles, clusters, and matrices) with a minimum length of 0.5 μm and no minimum width. The AHERA TEM method was developed for analysis of air samples for clearance purposes after removal, encapsulation, or enclosure projects involving asbestos-containing building materials in elementary and secondary schools. The ISO method 10312 was published for ambient air monitoring. The AHERA TEM and ISO 10312 methods are similar, but differ in the manner in which fibers and fiber bundles are counted and measured. The ISO method counts the components of the primary structures individually, while the AHERA TEM method counts only the primary structures (US EPA, 2008a). Both methods report details of fiber type, structure type, and dimensions to allow flexibility in counting, including the ability to count PCM equivalent (PCMe) concentrations.

**b. <u>Bulk Sample Considerations</u>**

It is important to recognize that the quantity of asbestos (such as in a brake pad, gasket, or chloroalkyl manufacturing diaphragms) cannot be directly correlated to human health risks. Such risk are a result of exposure to airborne asbestos fibers, which can only be ascertained by evaluating how a given asbestos-containing product is used (and whether such use may liberate airborne asbestos fibers). IMA-NA would like to emphasize that content determinations in bulk methods (as well as numbers of particles which are altered during preparation) have no known relationship to exposure and are therefore relevant only when methods of use are also contemplated. A meaningful risk assessment cannot be completed without an in-depth study simulating various activities at different concentrations in bulk materials (which is outside the scope of this rule). With respect to health-based considerations, the most relevant data to collect would be air monitoring data.

IMA-NA urges EPA to focus information collection on structures ≥ 5 μm in length and with an aspect ratio of ≥ 20:1 – 100:1. Consideration of fiber lengths between 0.5 and 5 μm obscure, rather than shed light on, potential adverse health effects. Mean aspect ratios for asbestiform fibers > 5 μm can be greater than 3:1, ranging from 20:1 to 100:1 (US Dept. of Commerce and NIST, 2003, 2007). US EPA (1993) has stated, "If a sample contains a fibrous component of which most of the fibers have aspect ratios of < 20:1 and do not display the additional asbestiform characteristics, by definition the component should not be considered asbestos."

Because of ambiguity in determining the asbestiform morphology of a single fiber by TEM, we recommend polarized light microscopy (PLM) for bulk source material to remove, in most cases, any remaining ambiguity. When bulk samples are being analyzed, the relevant metric is based on content (*e.g.*, μg/g or parts per million), as numbers of fibers (or structures) are altered during sample preparation and cannot be replicated or empirically validated. PLM is commonly used to determine the percent asbestos in bulk building materials, as well as other bulk materials such as mineral powders. With proper training, PLM can be used to identify fiber type with reasonable certainty by employing several techniques to determine fiber refractive index and other crystalline properties (NIOSH, 2017). TEM analyses of bulk samples can be ambiguous with

regard to asbestiform vs. non-asbestiform amphiboles (ISO 10312; Verkouteren and Wylie, 2002). PLM used for bulk samples is reasonably representative of the source of airborne fibers and can provide more diagnostic information for interpretation.

## F. Conclusion

In conclusion, IMA-NA has serious concerns regarding how EPA is performing risk management under TSCA in the Proposed Rule, specifically EPA's non-transparent and rapid resort to an outright ban without due consideration of other statutorily available mitigation options. IMA-NA would like to emphasize the following aspects of the foregoing comments:

- IMA-NA urges EPA to re-evaluate imposing immense costs on industry and potentially causing serious supply chain and public health impacts.
- We commend EPA for considering alternatives such as an occupational exposure limit and a de minimis threshold for regulation. With respect to the former, we think Congress intended for EPA to invoke TSCA Section 9 to engage with OSHA on a reasonable workplace exposure limit. EPA should not propose an occupational exposure limit unilaterally that significantly departs from OSHA requirements and creates a patchwork approach to federal regulation of industrial exposures to asbestos. EPA's derivation of the IUR raises the concern that the agency is not applying best available scientific principles and the resulting ECEL presents measurement challenges that make it unworkable.
- IMA-NA strongly supports EPA's expression of interest in a de minimis content threshold in this rule. Unfortunately, EPA has not provided the public with enough information to meaningfully participate in the process of identifying an appropriate de minimis threshold. We think EPA must consider applying the longstanding one percent threshold in TSCA (in the Asbestos Rule at 40 C.F.R. § 763.163 and in Title II, Section 202 of TSCA). This threshold is recognized by many other EPA (including TSCA) and other federal programs. IMA-NA is concerned that a "zero" threshold cannot be determined scientifically or made feasible technologically.
- Overall, risk management proposed rules should be more transparent in explaining why risk mitigation options less restrictive than a total ban do not eliminate the unreasonable risk; it appears that options are available that are inexplicably discounted. Given the size of the docket for this rule, EPA should bring the key underlying agency analyses forward into the Federal Register itself rather than provide general references that the public tmust search for and through to understand the conclusions of a proposed risk management rule published in the Federal Register.

IMA-NA is available at EPA's convenience to discuss these issues, or any of its other comments concerning appropriate de minimis levels and measurements techniques set forth above. Thank you for taking time to consider and act upon these comments.

Sincerely,

Christopher K. Greissing
President

Attachments (2)

# Attachment A

# Comments on the Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA) Proposed Rule

## 40 CFR Part 751
## [EPA–HQ–OPPT–2021–0057; FRL–8332–02–OCSPP]

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July 13, 2022

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# 1 Overview

The amended Toxic Substances Control Act (TSCA) addresses the production, importation, use, and disposal of specific chemicals and certain substances. In December 2020, the United States Environmental Protection Agency (US EPA) released a "Final Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos" (Risk Evaluation) under TSCA Section 6(a), 15 U.S.C. §2605 (US EPA, 2020). The evaluation focuses on chrysotile asbestos and concludes that there are several occupational conditions, consumer uses, and disposal practices that present unreasonable risks to health. US EPA calculated risks by estimating exposures associated with several conditions of use and then applying an inhalation unit risk (IUR) for chrysotile asbestos. The IUR was derived following an evaluation of a subset of chrysotile occupational epidemiology studies that evaluated lung cancer and mesothelioma risks in chrysotile textile manufacturing workers.

On April 12, 2022, US EPA released the Proposed Rule, "Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA)" (US EPA, 2022). In the Proposed Rule, US EPA is proposing an 8-hour existing chemical exposure limit (ECEL) for chrysotile asbestos of 0.005 fibers per cubic centimeter (f/cc) for inhalation exposures as an 8-hour time-weighted average (TWA) and for use in workplace settings based on the Risk Evaluation. As noted in a June 8, 2021, memorandum, US EPA "has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of cancer resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk in the Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos (U.S. EPA, 2020)" (Beachum, 2021).

The proposed ECEL is 20-fold lower than the current Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) of 0.1 f/cc. The ECEL is largely based on the chrysotile IUR, which is based on "new" studies of workers at asbestos textile plants in North Carolina and South Carolina. Workers in these studies were exposed to both long chrysotile fibers and amphibole asbestos, while other conditions of use that US EPA evaluated involve shorter chrysotile fibers and the use of personal protective equipment (PPE). As such, the use of textile worker studies is not an appropriate basis of the IUR, even if these studies are new. In addition, the IUR is based on a linear no-threshold (LNT) model, when there is epidemiology, toxicology, and mode-of-action evidence that indicates a threshold for mesothelioma and lung cancer that far exceeds the current OSHA PEL and the proposed ECEL. Moreover, if the chrysotile IUR was applied to the general population, risks would be considered unreasonable even though there is no expectation that the general population, lacking specific asbestos exposure sources, has an increased risk of developing lung cancer or mesothelioma. Finally, US EPA's proposed ECEL of 0.005 f/cc, which is intended to apply specifically to the manufacture of membranes and sheet gaskets in the chlor-alkali and chemical industries, is not consistent with either the Mine Safety and Health Administration's (MSHA) or OSHA's PELs, and there is no justification for having different exposure limits for different industries. More importantly, current methods are not sufficiently sensitive or reliable to ensure compliance with an occupational ECEL of 0.005 f/cc.

Overall, US EPA has not demonstrated that new information justifies an ECEL 20-fold lower than the current PEL.

# 2 Background Exposures

Almost everyone (if not everyone) in the general population has had some amount of exposure to asbestos (Churg and Warnock, 1977, 1980; Churg and Wiggs, 1986). This is supported by several studies that report chrysotile and amphiboles in human lungs (Churg and Warnock, 1977, 1980; Churg and Wiggs, 1986), and by the Agency for Toxic Substances and Disease Registry (ATSDR) (2001) report of ambient outdoor air concentrations for asbestos ranging from 0.000003 to 0.0003 f/cc. Such exposures in the general population are referred to as background exposures. ATSDR (2001) also indicated that ambient levels can reach 0.003 f/cc near local sources, such as naturally occurring asbestos formations or facilities that mine, mill, or manufacture asbestos-containing products.

More recently, Abelmann *et al*. (2015) published a study of ambient airborne asbestos levels that aggregated data from 17 published and unpublished studies and datasets. The aggregated data included 2,058 samples collected throughout the US (from urban, rural, or unknown locations) from the 1960s to the 2000s. After adjusting for different analytical techniques, and including only fibers ≥5 µm in length, Abelmann *et al*. (2015) estimated an overall mean and median ambient asbestos concentration from these data of 0.00093 and 0.00022 f/cc, respectively. This study indicates that asbestos is ubiquitous in the environment in the US and that all US residents have some level of exposure. Cumulative exposure to asbestos over a lifetime (70 years) for the general population, considering the ranges of typical indoor and outdoor asbestos exposures in both rural and urban areas, was estimated by ATSDR (2001) to be 0.002-0.4 f/cc-year. Using the more recent data from Abelmann *et al*. (2015), and assuming a 70-year lifetime of ambient (*i.e*., background) asbestos, background cumulative exposure is within ATSDR's range (0.00093 f/cc * 70 years = 0.065 f/cc-year).

As noted by Dodge *et al*. (2021):

> To put into context how conservative US EPA's chrysotile IUR is, if it was applied to the general population exposed continuously for a lifetime to the mean ambient background concentration of asbestos in the US over the last several decades (0.00093 f/cc; Abelmann *et al*. 2015), the calculated ELCR [excess lifetime cancer risk] in the general population is $1.5 \times 10^{-4}$. Per US EPA, such a risk, which is similar to the central-tendency risks US EPA calculated for the occupational scenarios for mechanics working with asbestos-containing brakes, is considered unreasonable (in fact, they are 150 times greater than US EPA's acceptable risk threshold for DIY [do-it-yourself] consumers working with asbestos-containing brakes), even though there is no expectation that the general population, lacking specific asbestos exposure sources, has an increased risk of developing lung cancer or mesothelioma.

Because the proposed ECEL is based on the IUR, this again indicates that the ECEL is more conservative than necessary to protect against an unreasonable risk of cancer resulting from chronic inhalation exposure to chrysotile asbestos fibers.

# 3 Textile Worker Studies

The ECEL is largely based on the chrysotile IUR developed in US EPA's Risk Evaluation (US EPA, 2020). US EPA based the chrysotile IUR on the results of studies conducted of workers at asbestos textile plants in North Carolina for mesothelioma (Loomis *et al*., 2019) and in North Carolina and South Carolina for lung cancer (Elliott *et al*., 2012). In these studies, workers were likely exposed to amphibole asbestos in addition to chrysotile. US EPA (2020) acknowledged some degree of amphibole asbestos exposure, stating that "[t]he epidemiologic studies available for risk assessment all include populations exposed to commercial chrysotile asbestos, which may contain small, but variable amounts of amphibole asbestos."

As noted by Paustenbach *et al*. (2021):

> In North Carolina, there is no available record that any type of amphibole asbestos was used at Plant 1 (Davidson, North Carolina) or Plant 2 (Charlotte, North Carolina), while only chrysotile asbestos was used (Garabrant 2020). There is evidence that amosite asbestos was carded, twisted, and woven between 1963 and 1976 at Plant 3 (Charlotte, North Carolina) (Loomis *et al*. 2009) and amosite and crocidolite asbestos was used at Plant 4 (Marshville, North Carolina) while UNARCO owned the mill from 1947 to 1963 (UNARCO 1954; UNACRO [*sic*] 2012). This was confirmed by researchers who assayed worker's lungs from these mills and found that amphiboles were present (Roggli *et al*. 1997; Pavlisko *et al*. 2020).

They further noted:

> [F]or the North Carolina textile cohorts, approximately 96% of the person-time accrued was from workers at plants three and four (Garabrant 2020), which also had documented use of amosite and crocidolite asbestos (UNARCO 1954; UNACRO [*sic*] 2012). (Paustenbach *et al*., 2021)

With respect to the South Carolina cohort, US EPA (2020) stated:

> The Charleston plant produced asbestos textiles from raw chrysotile fibers imported from Canada (Québec and British Columbia) and Rhodesia (now Zimbabwe). Purchased crocidolite yarns were also woven in a small separate operation for about 25 years, but crocidolite was never carded or spun on site 5244 (Dement *et al*., 1994). The total amount of crocidolite handled was 0.03% of the amount of asbestos processed annually (Dement *et al*., 1994).

In addition, some members of the study populations had potential historical exposures to primarily amphibole asbestos used to make amosite or crocidolite products (Yarborough 2006; Loomis *et al*., 2009). As such, neither of the "new" studies US EPA selected for the derivation of the chrysotile IUR can be considered studies of chrysotile only, or even commercial chrysotile only. This is an important limitation when considering the general consensus within the scientific community that amphibole asbestos fibers are far more potent than chrysotile fibers at inducing asbestos-related diseases (*e.g*., Hodgson and Darnton, 2000; Lippmann, 2014; Bernstein, 2014; Pierce *et al*., 2016; Moolgavkar *et al*., 2017).

Finally, workers in these textile cohorts were exposed to long, unbound chrysotile fibers (Dement *et al*., 2009). Longer fibers are more potent than shorter fibers for the induction of mesothelioma and lung cancer (*e.g*., Lippmann, 2014; Barlow *et al*., 2017). US EPA has not considered whether chrysotile asbestos fiber lengths or PPE associated with the assessed conditions of use are similar to those associated with textile worker exposures when deriving the IUR and ECEL.

A consideration of the textile worker study limitations, fiber length, and PPE makes clear that the ECEL is far more stringent than necessary to protect against an unreasonable risk of cancer resulting from chronic inhalation exposure of chrysotile asbestos.

# 4 Linear No-Threshold Model

As noted by Dodge *et al*. (2021):

> The LNT model, which US EPA used to derive the chrysotile IUR in the Risk Evaluation, likely considerably overestimates the cancer potency of chrysotile asbestos. Regarding DNA-reactive substances, recent scientific evidence indicates that the small increase in DNA damage that might occur from very low exposures to such substances, in addition to the already high levels of endogenous DNA damage, should not overwhelm DNA repair capacities (Cardarelli and Ulsh 2018). This indicates that there is a threshold for effects even for DNA-reactive substances.
>
> For substances that do not directly interact with DNA, an LNT model is even less biologically plausible. Although the specific mechanism of chrysotile asbestos-induced carcinogenesis is not established, the evidence is generally supportive of a mode of action involving chronic inflammation and cellular toxicity and repair that leads to the generation of reactive oxygen species and DNA damage, rather than direct interaction with DNA (Huang *et al*. 2011). This threshold mechanism can only occur at exposure concentrations high enough to overwhelm cellular defense mechanisms.
>
> Pierce *et al*. (2016) derived 'best estimate' chrysotile no observable adverse effect levels (NOAELs) of 208-415 fibers/cc-years for mesothelioma and 89-168 fibers/cc-years for lung cancer that can be applied as thresholds in chrysotile cancer risk assessments. In addition, Glynn *et al*. (2018) reported that the incidence rates of female pleural mesothelioma in urban areas of the US are not significantly higher than in rural areas of the US, even though ambient asbestos concentrations are higher in the former. This is contrary to what would be expected if the LNT model for chrysotile asbestos is accurate. Further, Camus *et al*. (2002) used a linear model for mesothelioma risk developed by US EPA in the 1980s to predict the number of mesothelioma cases in a population with high, non-occupational chrysotile asbestos exposures. They found that the linear model substantially overpredicted the number of cases (*e.g*. the model predicted 150 mesothelioma cases in females in a mining town in which only one female mesothelioma case was observed). US EPA did not discuss any of these studies or acknowledge a possible threshold mode of action for chrysotile.

The NOAELs of 208-415 f/cc-years for mesothelioma and 89-168 f/cc-years for lung cancer result in 8-hour TWA concentrations of 5.2 and 2.2 f/cc, respectively, assuming 40 years of occupational exposure. These values far exceed the current OSHA PEL and indicate that an even lower ECEL would be more stringent than necessary to protect against an unreasonable risk of cancer resulting from chronic inhalation exposure of chrysotile asbestos.

# 5 Toxicology and Mode-of-Action Studies

The scientific literature related to a possible threshold for chrysotile-induced mesothelioma was not reviewed by US EPA (2020). While some earlier animal studies reported pathogenic effects from chrysotile asbestos exposures (Wagner *et al.*, 1974; Davis *et al.*, 1978, 1980, 1986; Davis, 1989), these studies were often characterized by high exposures to predominantly long-fiber chrysotile asbestos, which may have led to lung overload (Huang *et al.*, 2011). More recent studies have evaluated doses that did not cause lung overload but were still much higher than even high-end occupational exposures.

For example, Bernstein *et al.* (2010, 2011) examined the fate of chrysotile and amphibole asbestos fibers in the lung and pleura by exposing rats to chrysotile asbestos and sanded joint compound particles (collectively referred to as "chrysotile asbestos and sanded product," or CSP) or amphibole asbestos (of various fiber lengths) for 6 hours per day for 5 days. The investigators found that long chrysotile asbestos fibers (length >20 μm) cleared rapidly from the lung (half-life of 4.5 days), whereas the half-life of long amphibole asbestos fibers (length >20 μm) was >1,000 days (Bernstein *et al.*, 2010, 2011). No exposure-related histopathological findings, such as indications for an inflammatory response, were observed in the rats exposed to CSP up to 90 days after cessation of exposure. In contrast, inflammatory markers were seen in the rats exposed to amphibole asbestos fibers immediately after cessation of exposure, and by 28 days, interstitial fibrosis was observed (Bernstein *et al.*, 2010). Subgroups of rats exposed to CSP were observed for 1 year following exposure, at which point no cellular or inflammatory response was observed in the lung or pleural cavity (Bernstein *et al.*, 2011).

More recently, Bernstein *et al*. (2020a,b, 2021) evaluated effects in rats exposed by inhalation to brake dust containing approximately 30% chrysotile, as compared to pure chrysotile, crocidolite, and amosite. The rats were exposed for 6 hours per day, 5 days per week, for 13 weeks to brake dust at 0.20, 0.34, or 0.67 mg/m$^3$; chrysotile at 0.27 or 0.64 mg/m$^3$; crocidolite at 1.28 mg/m$^3$; or amosite at 2.32 mg/m$^3$. The rats were observed over their entire lifetimes.

In the lungs of the brake-dust-exposed rats, there were few fibers >20 μm in length at the end of the exposure, and none were observed at 90 days after the end of exposure. By contrast, in the chrysotile-, crocidolite-, and amosite-exposed rat lungs, there were 14,000-55,000, 8,000,000, and 11,600,000 fibers >20 μm in length per lung, respectively, at 180 days (*i.e*., 90 days post-exposure). In addition, the amphibole asbestos-exposed rat lungs had greater inflammatory reactions and increased collagen, whereas the inflammatory reactions in the brake dust- and chrysotile-exposed rat lungs were minimal and there was no increased collagen (*i.e*., no fibrosis). The authors concluded that chrysotile is not biopersistent, as it is more readily cleared by macrophages and by dissolution (Bernstein *et al*., 2020a,b).

These and other studies clearly demonstrate that chrysotile has a threshold, but none of these studies were considered by US EPA (2020) in its Risk Evaluation. Collectively, they demonstrate that the equation on which the ECEL is based is far more conservative than necessary to protect against an unreasonable risk of cancer resulting from chronic inhalation exposure.

# 6 Measurements

In addition to not being supported scientifically, an ECEL of 0.005 f/cc cannot be reliably measured by current methods for monitoring personal occupational exposure. The methods available for determination of airborne fiber concentrations are phase-contrast microscopy (PCM) and transmission electron microscopy (TEM).

## 6.1 Phase-Contrast Microscopy

Since the late 1960s, most investigators have measured asbestos by collecting fibers on a cellulose ester membrane filter and examining them *via* PCM (Bayer *et al*., 1969; Edwards and Lynch, 1968; Walton, 1982). National Institute for Occupational Safety and Health (NIOSH) Method 7400 is the current PCM analytical method used in the US for measuring occupational exposure to asbestos. It is important to recognize that PCM does not distinguish between asbestos fibers and other types of fibers, and a fiber concentration result obtained by PCM is a total fiber count; hence, the method title "Asbestos and Other Fibers by PCM."

Current OSHA guidelines specify that NIOSH Method 7400, or an equivalent, should be used to quantify asbestos fibers in air samples collected to determine occupational exposure to asbestos (OSHA, 2014; NIOSH, 2020). The concentration of fibers is determined by counting the number of fibers greater than 5 μm in length with an aspect ratio greater than or equal to 3:1 (OSHA, 2014).

In addition to its use for determining occupational exposure, PCM can be used for post-abatement clearance of non-school buildings of any size after the removal of asbestos. It can also be used for such clearance after the completion of small asbestos removals in US school buildings, with small removals being defined as ≤160 square feet of area or ≤260 linear feet (*e.g*., pipe insulation). The requirement is that five air samples must be collected and the results must all be below 0.01 f/cc (US EPA, 2007).

The limit of detection (LOD) of NIOSH Method 7400 is specified as 7 fibers/mm$^2$ of filter area. The LOD in terms of air concentration depends on the volume of air sampled, and a 1,000-liter air volume corresponds to approximately 0.0027 f/cc (NIOSH, 2020). If other particulate material limits the air volume that can be collected, the LOD will be higher. However, recommended Method 7400 parameters indicate the LOD should not be used; rather, the operating range is 100-1,300 fibers/mm$^2$ of filter area. For legal and legislative purposes, measurements should be within the operating range. Method 7400 also specifically states that air volumes should be selected so that the fiber density is within this range.

As noted above, the lower limit of the range of the NIOSH 7400 PCM method is specified as 100 fibers/mm$^2$ of filter area (NIOSH, 2019). For a standard filter with an active area of 385 mm$^2$, 3,850 liters of air must be collected to obtain 100 fibers/mm$^2$ of filter area if the air concentration is 0.01 f/cc. The lower limit of the range is normally considered to be the limit of quantification (LOQ). The most recent version of NIOSH Method 7400 states that counts outside of the specified range should be noted as "greater than optimal variability" and "probably biased" (NIOSH, 2019).

Assuming that measurements should be within the specified range of the method to be legally acceptable, then it would be necessary to collect an air volume of 7,700 liters to obtain 100 fibers/mm$^2$ of filter area if the air concentration is 0.005 f/cc. Occupational exposure is measured by collecting personal samples,

using a battery-operated miniature pump, usually at a flow-rate of 2 liters/minute, with the sampling cassette on the lapel of the worker. (For occupational exposure measurements, NIOSH Method 7400 specifies a maximum flow-rate of 2.5 liters/minute for all personal sampling, although flow-rates up to 16 liters/minute are permissible for area sampling). Under these conditions, for an 8-hour continuous measurement, 960 liters would be collected, which is far short of the required 7,700 liters. Even if sampling 7,700 liters could be achieved on a personal sample, particulate material in the air other than asbestos would likely overload the filter so that it could not be analyzed by the method. It should also be noted that because PCM does not differentiate between asbestos and non-asbestos fibers, fiber concentrations reported will be overestimates of any asbestos concentrations that may be present.

## 6.2 Transmission Electron Microscopy

In the 1970s, methods for determination of asbestos fiber concentrations by TEM were developed (Chatfield, 1974; Chatfield *et al*., 1978). TEM can detect fibers of smaller lengths and widths than can be detected by PCM, and using selected area electron diffraction (SAED) and energy dispersive X-ray analysis (EDXA), TEM can distinguish between chrysotile, the different amphibole species, and non-asbestos fibers (ATSDR, 2001; NIOSH, 2020; Baron, 2003). However, as stated in the International Organization for Standardization's ISO 10312, TEM "cannot discriminate between individual fibres of asbestos and non-asbestos analogues of the same amphibole species" (ISO, 2019). For this reason, although TEM is diagnostic for chrysotile, it is not necessarily diagnostic for amphibole asbestos. Regardless, NIOSH Method 7402, for asbestos fiber quantification, was established to complement the results obtained by Method 7400 (NIOSH, 2020). The range of Method 7402 is the same as that of Method 7400 (100-1,300 fibers/mm$^2$), for atmospheres free of interferences (NIOSH, 2020). Because fibers reported by NIOSH Method 7400 are not identified in Method 7402, TEM is used to determine the fraction of the total fibers that are chrysotile or amphibole, and this fraction is then multiplied by the fiber counts obtained by PCM. The final result is an adjusted total fiber count (NIOSH, 2020).

In order that fibers counted in Method 7402 correspond to those that were counted in Method 7400, it is specified that the only fibers to be counted in Method 7402 are those longer than 5 µm, thicker than 0.25 µm, and with aspect ratios ≥3:1. The fibers in this dimensional size range are referred to as phase-contrast microscopy equivalent (PCME) fibers because these fibers are considered to be equivalent to those that would have been identified in the same sample through PCM analysis. Because the results from Method 7402 are used only as an adjustment of a PCM count by Method 7400, the LOQ limitations of Method 7400 are not changed by this adjustment.

TEM by itself is also used for post-abatement asbestos clearance sampling in buildings (US EPA, 2007). This method for post-abatement clearance was originally intended to be a statistical comparison of indoor and outdoor air concentrations to demonstrate that the indoor concentration of asbestos was not higher than the outdoor concentration (Chesson Consulting and Battelle, 1989). Because most outdoor measurements resulted in "none detected" results, eventually the test was changed to five indoor samples that had to have a mean value less than 70 asbestos structures/mm$^2$ of filter area (the upper 95% confidence limit of asbestos contamination found on unused filters). A structure is a fiber, a fiber bundle, a cluster, or a matrix mixed with other particles. The fiber in this method is defined as having a length ≥0.5 µm, with aspect ratio ≥5:1. A simple calculation, using the active filter area of 385 mm$^2$, shows that the clearance value of 70 structures/mm$^2$ is approximately equivalent to 0.02 structure/cc, when the minimum air volume of 1,200 liters is collected. This use of TEM is not applicable to determination of occupational exposure to asbestos.

## 6.3 Conclusion

MSHA's existing health standard for asbestos exposure at metal and non-metal mines, surface coal mines, and surface areas of underground coal mines is an 8-hour TWA full-shift PEL of 0.1 f/cc. This is the same as OSHA's asbestos exposure limit. OSHA concluded that this concentration is "the practical lower limit of feasibility for measuring asbestos levels reliably," and MSHA agrees with this conclusion (US Dept. of Labor, 2008; OSHA, 1994).

US EPA's proposed ECEL of 0.005 f/cc, which is intended to apply specifically to the manufacture of membranes and sheet gaskets in the chlor-alkali and chemical industries, is not consistent with either MSHA's or OSHA's PELs, and there is no justification for having different exposure limits for different industries. More importantly, current methods are not sufficiently sensitive or reliable to ensure compliance with an occupational ECEL of 0.005 f/cc.

# 7 Conclusions

The proposed ECEL is 20-fold lower than the current OSHA PEL of 0.1 f/cc. The ECEL is largely based on the chrysotile IUR, which is based on "new" studies of workers at asbestos textile plants in North Carolina and South Carolina.

- Workers in these studies were exposed to both long chrysotile fibers and amphibole asbestos, while other conditions of use that US EPA evaluated involve shorter chrysotile fibers and the use of PPE, indicating the use of textile worker studies are not an appropriate basis of the IUR, even if they are new.
- The IUR is based on an LNT model, when there is epidemiology, toxicology, and mode-of-action evidence that indicates a threshold for mesothelioma and lung cancer that far exceeds the current OSHA PEL and the proposed ECEL.
- If the chrysotile IUR was applied to the general population, risks would be considered unreasonable even though there is no expectation that the general population, lacking specific asbestos exposure sources, has an increased risk of developing lung cancer or mesothelioma.
- The proposed ECEL of 0.005 f/cc is intended to apply specifically to the manufacture of membranes and sheet gaskets in the chlor-alkali and chemical industries. This is not consistent with either MSHA's or OSHA's PELs, and there is no justification for having different exposure limits for different industries.
- Current methods are not sufficiently sensitive or reliable to ensure compliance with an occupational ECEL of 0.005 f/cc.

Overall, US EPA has not demonstrated that new information justifies an ECEL 20-fold lower than the current PEL.

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# Attachment B

Inhalation Toxicology

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ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/iiht20

# US EPA's TSCA risk assessment approach: a case study of asbestos in automotive brakes

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**To cite this article:** David G. Dodge, Anna M. Engel, Robyn L. Prueitt, Michael K. Peterson & Julie E. Goodman (2021) US EPA's TSCA risk assessment approach: a case study of asbestos in automotive brakes, Inhalation Toxicology, 33:9-14, 295-307, DOI: 10.1080/08958378.2021.1998258

**To link to this article:** https://doi.org/10.1080/08958378.2021.1998258

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INHALATION TOXICOLOGY
2021, VOL. 33, NOS. 9–14, 295–307
https://doi.org/10.1080/08958378.2021.1998258

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REVIEW ARTICLE

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# US EPA's TSCA risk assessment approach: a case study of asbestos in automotive brakes

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**ABSTRACT**

The United States Environmental Protection Agency (US EPA) is currently refining its approach for risk assessments conducted under the amended Toxic Substances Control Act (TSCA), largely based on recommendations from the National Academies of Sciences, Engineering, and Medicine (NASEM). We identified several issues with the current TSCA risk assessment approach that were not addressed by NASEM in its recommendations. Here, we demonstrate these issues with a case study of the 'Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos,' which US EPA released in December 2020. In this evaluation, US EPA found that occupational and some consumer uses of automotive brakes and clutches that contain asbestos result in unreasonable risks. These risks were calculated from estimated exposures during brake work and an inhalation unit risk (IUR) developed for chrysotile asbestos. We found that US EPA overestimated risk as a result of unrealistic inputs to both the exposure and toxicity components of the risk equation, and because the Agency did not fully consider relevant epidemiology and toxicity evidence in its systematic review. Our evaluation demonstrates areas in which the TSCA risk assessment approach could be improved to result in risk evaluations that are supported by the available scientific evidence.

**ARTICLE HISTORY**
Received 12 May 2021
Accepted 22 October 2021

**KEYWORDS**
Asbestos; chrysotile; Toxic Substances Control Act (TSCA); risk assessment; lung cancer; mesothelioma; friction products; brakes; gaskets; automotive

## Introduction

The amended Toxic Substances Control Act (TSCA) addresses the production, importation, use, and disposal of specific chemicals and certain substances. Under TSCA, the United States Environmental Protection Agency (US EPA) is required 'to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the Risk Evaluation' (US EPA 2020a). In the case study presented here, we examine the importance of identifying and relying on the most relevant and appropriate scientific evidence regarding exposure and toxicity, so that realistic risks can be calculated.

In December 2020, US EPA released a 'Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos' (referred to as the Risk Evaluation herein) under the amended TSCA (US EPA 2020a). As noted by US EPA (2020a), asbestos has not been mined or otherwise produced in the US since 2002, and the only form of asbestos currently known to be imported, processed, or distributed for use in the US is chrysotile. Among the asbestos-containing products US EPA identified as being imported and used currently are aftermarket automotive brakes and clutches. It evaluated specific conditions of use (COUs) for these products, including importing, processing, and distribution in commerce; occupational and consumer uses; and disposal. In the Risk Evaluation, the Agency evaluated inhalation exposures to workers and occupational non-users (ONUs) in occupational settings and inhalation exposures to both do-it-yourselfers (DIYers) and bystanders in consumer settings. In addition to considering exposure to asbestos in aftermarket automotive friction products, US EPA considered exposure to asbestos in original manufacturer automotive friction products, primarily in older and vintage vehicles.

As part of its Risk Evaluation, US EPA (2020a) derived an inhalation unit risk (IUR) for chrysotile asbestos using a linear-no-threshold (LNT) model and studies of textile manufacturing workers. As discussed below, US EPA's decision to use the LNT model and studies of textile manufacturing workers (rather than studies more relevant to the automotive industry) contributed to its overestimations of risk for automotive mechanics and DIYers working with brakes and clutches.

Using exposure estimates for the COUs, the new IUR, and excess lifetime cancer risk (ELCR) benchmarks of $1 \times 10^{-4}$ for occupational exposures and $1 \times 10^{-6}$ for consumer exposures, US EPA concluded there are several current COUs of chrysotile asbestos that present unreasonable risks to health (US EPA 2020a). US EPA now must finalize any risk management actions to address these risks within 2 years of completing the final Risk Evaluation (US EPA 2020a). This could include requirements for how chrysotile asbestos is used, or limits or prohibitions on the

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manufacture, processing, distribution in commerce, use, or disposal of chrysotile asbestos. Once finalized, any modifications or adjustments to these risk management actions will become challenging.

US EPA has started planning Part 2 of the asbestos risk evaluation, which will include legacy asbestos uses and associated disposals of asbestos (i.e. COUs for which manufacture [including importation], processing, and distribution in commerce no longer occur, but for which use and disposal are still known, intended, or reasonably foreseen to occur). Yet, in February 2021, US EPA indicated it would no longer use the 'structured and systematic review approach' for identifying quality data to support TSCA risk evaluations (US EPA 2021a). The Agency also stated that it will review the last 10 TSCA risk evaluations it conducted using this approach to ensure that they satisfy the requirements of TSCA, and that they are "guided by the best available science, ensure the integrity of Federal decision-making [based on the evaluations' results], and protect human health and the environment" (US EPA 2021b). In addition, US EPA is refining its risk assessment approach for TSCA evaluations based on recommendations from the National Academies of Sciences, Engineering, and Medicine (NASEM) and the approach used in the Integrated Risk Information System (IRIS) Program developed by the Agency's Office of Research and Development (US EPA 2021a). However, there are also many issues with IRIS's approach (e.g. study quality and relevance evaluations, consideration of mechanistic data, evidence integration; American Chemistry Council (ACC) 2021; Cox et al. 2021), and if these are implemented in TSCA risk evaluations, it could result in risk estimates that are not scientifically supported.

We also identified several issues with the current TSCA risk assessment approach (US EPA 2018) that likely affected the reliability of the evaluations conducted by US EPA. While the TSCA risk assessment framework is being reconsidered, we believe there are some systemic issues with how US EPA is applying systematic review and other risk assessment principles, including not adequately following scoping and initial evaluation documents in the subsequent risk evaluations (US EPA 2017, 2018).

Here, we describe these issues with a case study of US EPA's Risk Evaluation as it pertains to occupational and consumer uses of asbestos-containing aftermarket or original manufacturer automotive brakes (with asbestos-containing linings/shoes or pads) and clutches.[1] As discussed below, we have identified several of US EPA's assumptions regarding exposures to and the toxicity of chrysotile asbestos in brakes (and, with use, brake dust) that have, in our view, led to estimates of risk to current and future automotive mechanics and DIYers that greatly overestimate the actual or plausible risks to these populations and that are not corroborated by mechanistic, toxicology, or epidemiology evidence.

## Brief summary of US EPA's risk evaluation

### *Exposure*

In its Risk Evaluation, US EPA derived exposure estimates for a variety of occupational and consumer exposure scenarios involving automotive brakes. Generally, US EPA assumed that exposure to asbestos contained in the brakes could occur during removal and disposal of used parts, while cleaning the brake assemblies, and during handling and installation of new parts. US EPA acknowledged that asbestos-containing brakes are no longer installed in new vehicles in the US for domestic use (US EPA 2020a). It found, however, that at least one company imports asbestos-containing friction products that are currently used in cars assembled in the US, but exported and sold outside the US. Furthermore, US EPA (2020a) stated that the potential remains for some older vehicles to have asbestos-containing parts, for aftermarket asbestos-containing products to exist in older stockpiles, and for foreign-made aftermarket parts that contain asbestos to be imported into the US and installed in cars when replacing the brakes.

US EPA evaluated both occupational and consumer use scenarios that directly involved the use of asbestos-containing parts (by professional motor vehicle mechanics and DIYers, respectively), as well as those nearby (ONUs and bystanders, respectively). Because those working directly with automotive parts have higher estimated exposures than ONUs and bystanders, we only address the direct occupational and DIY use scenarios for the purposes of this critical assessment. For each scenario, US EPA derived both central tendency and high-end exposure concentrations (Table 1).

For all the occupational use scenarios, US EPA (2020a) utilized occupational exposure assessment assumptions of 240 days per year, 8 hours per day, over 40 years (starting at age 16). The Agency calculated exposure estimates for motor vehicle mechanics repairing and replacing brakes and installing new asbestos-containing brakes on new cars for export. US EPA assumed that the average consumer performs a single brake repair/replacement job once every 3 years for 62 years. The two main consumer scenarios addressed by US EPA are an indoor scenario, occurring in a garage with the door closed, and an outdoor scenario, occurring in a driveway. Both consumer scenarios involve DIYers repairing or replacing automobile brake pads (disk brakes) or brake linings/shoes (drum brakes) that contain asbestos (US EPA 2020a, p. 124).

For all the evaluated scenarios, US EPA derived exposure concentration estimates from data available in the scientific literature that reflect a variety of activities and practices (i.e. use of compressed air or newer methods to clean out brake dust, arc grinding, brake filing, and unpacking and repacking of asbestos-containing brake pads and linings/shoes) (Table 1).

US EPA assumed that consumers will have concomitant exposure to settled asbestos fibers that become re-entrained in the air with 'any changes in air currents or activity within the indoor and outdoor use facilities' (US EPA 2020a, p. 204). This was assumed to occur every day for 1 hour or 8 hours (median and 95th percentile, respectively) in garages and 5 or 30 minutes (median and 95th percentile, respectively) in outdoor locations. Exposure concentrations were assumed to be 30 and 2% of the active COUs over the 3-year period in garages and outdoor locations, respectively,

Table 1. Exposure levels for occupational and consumer brake repair, replacement, and installation.

| Exposure scenario | Exposure levels (f/cc) and source: Central tendency | Exposure levels (f/cc) and source: High end | Frequency and duration | Other parameters |
|---|---|---|---|---|
| Occupational | | | | |
| Repairing or replacing brakes with aftermarket parts (8-hour TWA) | 0.006[a] | 0.094[b] | 8 Hours per day, 240 days per year, for 40 years | No use of compressed air. High-end result from arc grinding sample. |
| Repairing or replacing brakes with aftermarket parts (short-term) | 0.006 (30 minutes)[a]<br>0.006 (8-hour TWA) | 0.836 (30 minutes)[b]<br>0.140 (8-hour TWA)[c] | | No use of compressed air. High-end result from packing/unpacking brake pads and shoes. |
| Installing new brakes on new cars for export (8-hour TWA) | 0.006[a] | 0.094[d] | | Same exposures as for repairing and replacing brakes with aftermarket parts. |
| Installing new brakes on new cars for export (short-term) | 0.006 (30 minutes)[a]<br>0.006 (8-hour TWA) | 0.836 (30 minutes)[b]<br>0.140 (8-hour TWA)[c] | | |
| Consumer | | | | |
| Repairing or replacing brakes with aftermarket parts (inside garage with door closed) | 0.0445[e] | 0.4368[f] | 3 Hours once every 3 Years, for 62 years | Use of compressed air. High-end level assumes arc grinding performed. 30% Concomitant exposure. |
| Repairing or replacing brakes with aftermarket parts (outdoors in driveway) | 0.007[g] | 0.0376[h] | | No use of compressed air. High-end level assumes brake filing performed. 2% Concomitant exposure. |

*Notes*: f/cc: fiber per cubic centimeter; TWA: time-weighted average.
[a]Central tendency short-term median of seven studies (Cooper et al. 1987, 1988; Godbey et al., 1987; Sheehy et al. 1987a, 1987b; Blake et al. 2003; Madl et al. 2008). Exposure concentration assumed to occur for 8 hours.
[b]Highest concentration during unpacking and repacking of boxes of asbestos-containing brake pads and shoes from Madl et al. (2008).
[c]Calculated as follows: ([0.836 f/cc × 0.5 hours] + [0.904 f/cc × 7.5 hours]]/8 hours
[d]Concentration during arc grinding from Blake et al. (2003).
[e]Average of two brake shoe removal/replacement values using compressed air techniques from Blake et al. (2003).
[f]Highest arc-grinding value from Blake et al. (2003).
[g]Average concentration during outdoor brake repair/replacement work from Sheehy et al. (1989).
[h]Concentration during filing of brakes from Blake et al. (2003).

reflecting a greater reduction of fibers each year outdoors relative to indoors.

### *Inhalation unit risk*

US EPA (2020a) derived an IUR for chrysotile asbestos by applying an LNT model from the point of departure (1% benchmark risk) from two occupational epidemiology studies of chrysotile asbestos (i.e. Elliott et al. 2012; Loomis et al. 2019) and exposure-response models with the best fit. US EPA used an absolute risk model for mesothelioma and a relative risk model for lung cancer. The latter assumes a background risk and the former does not (i.e. background risk is assumed to be zero). The final IUR is 0.16 per f/cc and it addresses both lung cancer and mesothelioma (US EPA 2020a).

### *Risk estimates*

A summary of US EPA's (2020a) risk estimates for the exposure scenarios of interest in this critical assessment is presented in Table 2. Table 2 shows that US EPA considered the occupational uses of aftermarket or original manufacturer automotive asbestos-containing brakes to result in unreasonable risks (i.e. $>1 \times 10^{-4}$) in all scenarios, and consumer uses in all indoor garage scenarios and the high-end outdoor driveway scenario to result in unreasonable risks (i.e. $>1 \times 10^{-6}$).

## Critical assessment of US EPA's risk evaluation

In our view, US EPA's Risk Evaluation for chrysotile asbestos, which used the TSCA systematic review approach, has greatly overestimated cancer risks to professional automobile mechanics and DIYers from exposure to chrysotile asbestos in brakes. Although US EPA acknowledges that many of the assumptions it used in the Risk Evaluation are likely to be conservative, the extent to which its risk estimates are implausible is, in our opinion, not fully appreciated in the Risk Evaluation. In this section, we describe the major sources of US EPA's overestimations, including those that pertain to both the exposure and toxicity inputs to its Risk Evaluation. We also explore mechanistic, toxicology, and epidemiology data that US EPA did not rely on but that provide directly relevant evidence and serve as a reality check on US EPA's Risk Evaluation. We have also noted where US EPA's assumptions contradict its stated goals in the TSCA systematic review guidance (US EPA 2018) and the 'Scope of the Risk Evaluation for Asbestos' document (subsequently referred to as the Scoping Document herein; US EPA 2017). Although the discussion below focuses on asbestos, similar issues to those we present may occur in future TSCA risk evaluations if issues with the TSCA review process are not addressed.

### *Exposure*

#### *Frequency and duration of occupational exposure to asbestos in asbestos-containing brakes*

In order for automobile mechanics and DIYers to be exposed to asbestos in the COUs that US EPA evaluated,

Table 2. US EPA's estimates of excess lifetime cancer risks following exposures to asbestos aftermarket or original manufacturer automotive brakes.

| Mechanic/DIYer exposure scenario | Other parameters | ELCR | |
|---|---|---|---|
| | | Central tendency | High end |
| Occupational | | | |
| Repairing or replacing brakes | 8-Hour TWA | **$1.2 \times 10^{-4}$** | **$1.9 \times 10^{-3}$** |
| | Short-term | **$1.2 \times 10^{-4}$** | **$2.8 \times 10^{-3}$** |
| Installing new brakes on new cars for import | 8-Hour TWA | **$1.2 \times 10^{-4}$** | **$1.9 \times 10^{-3}$** |
| | Short-term | **$1.2 \times 10^{-4}$** | **$2.8 \times 10^{-3}$** |
| Consumer | | | |
| Repairing or replacing brakes | 30% Concomitant exposure 1 hour/day in garage | **$3.6 \times 10^{-5}$** | **$3.5 \times 10^{-4}$** |
| | 30% Concomitant exposure 8 hours/day in garage | **$2.9 \times 10^{-4}$** | **$2.8 \times 10^{-3}$** |
| Brake/clutch maintenance outdoors | 2% Concomitant exposure 5 minutes/day in driveway | $8.2 \times 10^{-8}$ | $4.4 \times 10^{-7}$ |
| | 2% Concomitant exposure 30 minutes/day in driveway | $2.4 \times 10^{-7}$ | **$1.3 \times 10^{-6}$** |

*Notes*: DIY: do it yourself; ELCR: excess lifetime cancer risk; TWA: time-weighted average; US EPA: United States Environmental Protection Agency. Bold = Unreasonable risk per US EPA.
*Source*: US EPA (2020a).

asbestos-containing used brakes and/or new aftermarket brakes must be sufficiently available and in demand. US EPA in the Risk Evaluation stated that older vehicles still in operation may have various asbestos-containing parts, that older stockpiles of previously manufactured asbestos-containing products may still exist, and that foreign-made aftermarket asbestos-containing automotive parts can be purchased from online retailers (US EPA 2020a, pp. 102–106, 125). By assuming that automobile mechanics are exposed to asbestos from asbestos-containing brakes continuously during a working lifetime of 40 years, US EPA also assumed that a large enough supply of asbestos-containing brakes exists and is readily accessible. In our view, this is the greatest source of exposure overestimation for the occupational use scenarios.

As acknowledged by US EPA in the Risk Evaluation, asbestos-containing automobile parts were all but eliminated decades ago (citing Paustenbach et al. 2004; Jiang et al. 2008; Cohen and Van Orden 2008). Although it is not disputed that vintage cars from the era of asbestos-containing parts still exist and are in operation today, many would have likely had such parts replaced with non-asbestos-containing parts by now. Furthermore, it seems reasonable that stockpiles of new asbestos-containing automotive parts that existed decades ago would be rare today, as any demand for such products would have depleted them by now.

US EPA cited two exposure simulation studies in the Risk Evaluation in which the authors of the respective studies were able to purchase asbestos-containing brakes from a vintage auto parts facility (Madl et al. 2008) and asbestos-containing clutch disks that had been stockpiled at a parts warehouse (Jiang et al. 2008). However, in comments on the draft Risk Evaluation, one of the coauthors of both studies stated that such parts are scarce, and that, with a few exceptions, he and his former colleagues failed to identify new or used asbestos-containing automotive parts despite considerable effort in canvasing parts stores, salvage sites, and the Internet (Paustenbach et al. 2020). Although anecdotal, this evidence does not support asbestos-containing brakes being readily available and accessible. Furthermore, US EPA did not identify a single current source for aftermarket asbestos-containing automotive parts.

Based on importation and market data for aftermarket automotive brakes, US EPA estimated that approximately 0.05% of aftermarket automotive brakes contain asbestos (US EPA 2020a). Applied to the estimated 749,900 automotive technicians and mechanics in the US, US EPA estimated that the number of those potentially exposed to asbestos from asbestos-containing aftermarket automotive brakes is 375 (US EPA 2020a, pp. 108, 224–225). In our view, it is implausible that any one worker would work exclusively with a tiny and shrinking market of asbestos-containing brakes for a working lifetime.

Lastly, even if a reliable supply of asbestos-containing brakes is and will continue to be available to automobile mechanics who wish to use them, continuous occupational use for 40 years is an unlikely amount of time for any mechanic to work on brakes exclusively. Finley et al. (2007) reported that the median and mean occupational tenure for automobile mechanics in the US were 6.3 and 11.0 years, respectively. Furthermore, automobile mechanics who perform brake jobs do not necessarily do so exclusively (Nicholson et al. 1984). Many additional mechanic services besides brake repair would not involve asbestos-containing products, if such products are even available.

US EPA's misrepresentation of the availability of asbestos-containing brakes in the Risk Evaluation means that the frequency and duration which mechanics and DIYers could be expected to work with such brakes are likely highly overestimated, to the point of being implausible. Even when calculating risks with the intention of being conservative, it is misleading to do so to this extent. Future TSCA risk evaluations for other substances will need to use more realistic assumptions.

### Exposure concentration data

The central-tendency exposure concentrations for occupational (8-hour time-weighted average [TWA]) and outdoor DIY consumer users of asbestos-containing brakes that US EPA used in the Risk Evaluation are plausible in that they are rooted in data that reflect brake dust control measures implemented largely in the 1980s (Sheehy et al. 1989; Paustenbach et al. 2003). US EPA's exposure concentrations for other scenarios are also rooted in existing data, but mostly reflect practices that are now obsolete or are otherwise conservative as applied in the Risk Evaluation.

US EPA's high-end exposure concentrations for occupational (8-hour TWA) and indoor and outdoor DIY consumer exposure scenarios rely on data from the conduct of brake practices – arc grinding and hand filing – that have not been common since the 1960s (NIOSH, Sheehy et al. 1989). In fact, the study from which US EPA selected data for arc grinding and hand filing was designed to replicate work on drum brake automobiles using methods and tools typical of the 1960s (Blake et al. 2003). The use of disk brakes, which do not require manipulation before installation, in automobiles increased in the 1970s and 1980s (Richter et al. 2009). US EPA considered arc grinding of brakes to be uncommon, but still relevant to its Risk Evaluation (US EPA, 2020a, pp. 109–110, 112, 126). Even if still used today, but uncommonly, US EPA's assumption that this practice occurs during every occupational and consumer brake job performed by any particular individual is implausible, even as a high-end estimate.

US EPA's central-tendency short-term exposure concentration for the indoor DIY consumer scenario is the average of the two exposure concentrations during brake shoe removal/replacement provided in Blake et al. (2003). These data are from samples in which compressed air was used to blow out residual dust after a brake drum was knocked against the ground, to remove loose material. Improved brake dust control practices largely replaced the use of compressed air as a dust control practice starting in the 1980s (Sheehy et al. 1989; Paustenbach et al. 2003). US EPA (US EPA 2020a) assumed that exposures to asbestos would be higher for consumers than for professional mechanics, partly because it assumed that consumers would be more likely to use the outdated compressed air cleaning technique.

US EPA's high-end short-term exposure concentration for the occupational scenario is 0.836 f/cc (US EPA 2020a). This is the highest short-term personal breathing zone concentration measured in Madl et al. (2008), in which airborne asbestos concentrations were measured during unpacking and repacking of asbestos-containing brake pads and shoes (Table 2). The selected result was from a 15-minute sample, but for the purposes of US EPA's Risk Evaluation, this exposure concentration is assumed to occur for 30 minutes, with exposure for the remaining 7.5 hours of the workday occurring at the high-end TWA concentration (0.094 f/cc) (US EPA 2020a). During the 15-minute sample, 16 boxes of brake pads were handled (Madl et al. 2008). Daily handling of this quantity of boxes of asbestos-containing brake pads and shoes by a professional automobile mechanic in current times is, in our view, implausible.

For the installation of new asbestos-containing brakes in new cars for export in an occupational setting, US EPA used the same central tendency and high-end exposure estimates as it used for the repair and replacement of brakes scenario (Table 2). However, installing new brakes in new cars does not involve the removal of existing asbestos-containing brakes, which is the main potential source of asbestos exposure for automobile mechanics (Sheehy et al. 1989). Furthermore, there is no need to grind or file a new disk brake prior to installation on a modern car. Thus, the potential for exposure to asbestos from installing new asbestos-containing brakes is minimal, if not zero.

Similar to its estimates for frequency and duration, US EPA's asbestos exposure estimates in the Risk Evaluation overestimate risk for automobile mechanics and DIYers working with asbestos-containing brakes by relying on data collected during outdated practices, which is inappropriate for a risk assessment that is intended to estimate risks to current and future populations.

### *Consumer concomitant exposure*

In our view, US EPA's assumption of daily concomitant exposures to re-entrained asbestos is the greatest source of exposure overestimation for the consumer use scenarios. This exposure assumption dominates the cancer risk estimates for DIY consumers working in a garage. The exposure estimates from this exposure source account for 99.1 and 99.9% of the total consumer ELCRs for the 1 hour working in a garage per day and 8 hours working in a garage per day scenarios, respectively (Table 3). Thus, only 0.9 and 0.1% of the total consumer ELCRs for the 1 hour per day and 8 hour per day scenarios, respectively, come from exposures during active brake work.

To reiterate, US EPA assumes that DIYers working in a garage will be exposed every day (for either 1 or 8 hours) to 30% of the asbestos concentration they are expected to experience during active brake work, with active brake work only expected to be done by DIYers once every 3 years. This is based on an unsupported assumption that 50% of the asbestos fibers that are generated in a garage during active work with asbestos-containing brakes would be removed each year following that work (i.e. 50, 25, and 12.5% remaining after years 1, 2, and 3, respectively), for an average of 30% of the fibers remaining present in the garage for the three years after the single day of brake work. Inherent in this assumption is that all of the remaining asbestos fibers in the garage are airborne when the DIYer is in the garage. However, existing evidence indicates that US EPA's assumptions regarding concomitant exposures result in massive overestimates of consumer exposures to asbestos.

The exposure concentrations of asbestos during active brake work that US EPA (2020a) relies upon are from breathing zone samples. Asbestos concentrations collected during an activity like arc grinding would be much higher in the small breathing zone of the DIYer sampled than in the rest of the garage. Yet, US EPA assumes that 30% of those breathing zone asbestos concentrations represent concentrations that a DIYer would experience anywhere in the garage on all days when no arc grinding (or other brake work) is performed. However, any localized airborne asbestos fibers generated during arc grinding (or other brake work activities) would settle to the floor or, to the extent they remain airborne, would become diluted in the greater air space of the garage. This makes US EPA's concomitant exposure assumptions implausible even without consideration of the re-entrainment evidence discussed below.

Table 3. Contributions to ELCRs for indoor DIY scenarios.

| Daily time in garage (hours) | Estimate type | Type of exposure | EPC (f/cc) | TWF | ELCR | % Contribution of concomitant exposure to total ELCR |
|---|---|---|---|---|---|---|
| 1 | Central tendency | Active | 0.0445 | 0.0001142 | $3.3 \times 10^{-7}$ | 99.1 |
| | | Concomitant | 0.01335 | 0.04167 | $3.6 \times 10^{-5}$ | |
| | | Total: | | | $3.6 \times 10^{-5}$ | |
| | High end | Active | 0.4368 | 0.0001142 | $3.2 \times 10^{-6}$ | 99.1 |
| | | Concomitant | 0.13104 | 0.04167 | $3.5 \times 10^{-4}$ | |
| | | Total: | | | $3.5 \times 10^{-4}$ | |
| 8 | Central tendency | Active | 0.0445 | 0.0001142 | $3.3 \times 10^{-7}$ | 99.9 |
| | | Concomitant | 0.01335 | 0.3333 | $2.9 \times 10^{-4}$ | |
| | | Total: | | | $2.9 \times 10^{-4}$ | |
| | High end | Active | 0.4368 | 0.0001142 | $3.2 \times 10^{-6}$ | 99.9 |
| | | Concomitant | 0.13104 | 0.3333 | $2.8 \times 10^{-3}$ | |
| | | Total: | | | $2.8 \times 10^{-3}$ | |

*Notes*: DIY: do it yourself; ELCR: excess lifetime cancer risk; f/cc: fiber per cubic centimeter; EPC: exposure point concentration; TWF: time weighting factor.
*Source*: US EPA (2020a).

Re-entrainment of asbestos settled on surfaces is a complex subject (Fowler and Chatfield 1997; Lee et al. 1999; US EPA 2008, US EPA 2015; Dyken and [Agency for Toxic Substances and Disease Registry (ATSDR)] 2014; Galassi 2015). Normal vibration and air currents in buildings are thought to be insufficient to resuspend dust particles (Health Effects Institute - Asbestos Research (HEI-AR)) 1991). Surface dust may contain asbestos structures of different sizes, matrix materials that bind asbestos structures, and other non-asbestos particles. Larger components of surface dust are incapable of being resuspended into air (Chatfield 1999). Smaller components, like individual asbestos fibers, would have greater potential to be resuspended, but are subject to cohesive forces with other surface dust components and adhesive forces with the surface they are settled on, and thus require large air velocities or other disturbances to overcome those forces (Health Effects Institute - Asbestos Research (HEI-AR) 1991; Millette and Hays 1994; Chatfield 1999; Kominsky et al. 2011). In its 'Framework for Investigating Asbestos-Contaminated Superfund Sites,' developed for investigating and characterizing the potential for human exposure from asbestos contamination in, among other media, indoor dust, US EPA did not consider asbestos in indoor dust to be 'inherently hazardous, unless the asbestos is released from the source material into air where it can be inhaled' (US EPA. 2008). Empirical data suggest that indoor airborne concentrations of asbestos are low even with significant surface contamination (Crankshaw et al. 1999; Dyken and [Agency for Toxic Substances and Disease Registry (ATSDR)] 2014).

When disturbed, some re-entrainment of asbestos from settled dust into the air is expected (US EPA 2008). This is why activity-based sampling has been recommended to simulate activities in an occupied building that would be expected to suspend fibers from indoor surface dust and result in an air concentration at the high end of what could reasonably occur in a building (US EPA 2008, US EPA 2015). This may include, for example, sweeping, dusting, and vacuuming, or more aggressive air sampling methods, which use leaf blowers or fans to dislodge dust (US EPA 2016a, 2016b). It is implausible, in our view, that a DIYer would engage in these types of dust-disturbing activities in a garage on a daily basis. Even with dust disturbing activities, experience-based resuspension factors indicate that re-entrainment concentrations in a garage would be nowhere near 30% of the original airborne concentrations (Millette and Hays 1994), especially when the original airborne concentrations were not uniform, but rather, localized near the asbestos source.

US EPA provides little support for its assumption that DIYers working in a garage will be exposed every day (for either 1 or 8 hours) to 30% of the asbestos concentration they are expected to experience during active brake work, with active brake work only assumed to be done by DIYers only once every 3 years. US EPA's concomitant exposure assumptions dominate the cancer risk estimates for DIY consumers working in a garage, and yet are not supported, and are even contradicted, by available science. Such an overestimation of exposure results in overestimation of risks, and future TSCA risk evaluations for other substances should not include such implausible exposure assumptions.

### *Discordance between TSCA guidance and the asbestos exposure evaluation*

Under TSCA, US EPA is tasked with using the best available science in its risk evaluations (US EPA 2018). Under the definition of 'best available science,' US EPA specified in the TSCA guidance that it 'will consider, as applicable: The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are *reasonable* for, and consistent with the intended use of the information [TSCA Section 26(h)(1)]' (US EPA 2021c [emphasis added]). In addition, in the Scoping Document (US EPA 2017), US EPA stated that it would '[d]etermine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.' As discussed above, it is clear that US EPA generated exposure estimates that are not 'reasonable' given the methods and assumptions used. The exposure assessment in the Risk Evaluation assumed that a mechanic would spend their entire career working with products that are difficult to obtain and, in some scenarios, using outdated methods that

are unlikely to be relevant today; this does not meet the definition of 'reasonable.' In addition, as stated in the Scoping Document, US EPA must determine whether there is additional information that might provide context for the methods used in the exposure analysis. The analysis of the active *vs.* concomitant exposure conditions presented here is an example of the sort of contextual analysis that would have alerted US EPA that its exposure models were yielding unreasonable results.

### Inhalation unit risk

The IUR derived by US EPA in its Risk Evaluation is 0.16 per f/cc and is specific to chrysotile asbestos (US EPA 2020a). This value is not much different than the current IUR for asbestos of 0.23 per f/cc developed by US EPA's IRIS program, which was published in 1988 and is applicable to all asbestos fiber types (US EPA 1988), despite the much lower cancer potency of chrysotile asbestos compared to amphibole forms (e.g. Hodgson and Darnton 2000). As derived by US EPA for the Risk Evaluation, the chrysotile IUR overestimates cancer risks from exposure to chrysotile asbestos generally, and more so for the form of chrysotile found in automobile brakes and brake dust. In fact, as described below, this IUR predicts that background exposures to asbestos in the general population result in unreasonable risks based on US EPA's acceptable risk criteria. This is despite evidence that background ambient air asbestos exposures to individuals do not result in a significantly increased incidence of asbestos-related disease (Glynn et al. 2018).

### The LNT model

The LNT model, which US EPA used to derive the chrysotile IUR in the Risk Evaluation, likely considerably overestimates the cancer potency of chrysotile asbestos. Regarding DNA-reactive substances, recent scientific evidence indicates that the small increase in DNA damage that might occur from very low exposures to such substances, in addition to the already high levels of endogenous DNA damage, should not overwhelm DNA repair capacities (Cardarelli and Ulsh 2018). This indicates that there is a threshold for effects even for DNA-reactive substances.

For substances that do not directly interact with DNA, an LNT model is even less biologically plausible. Although the specific mechanism of chrysotile asbestos-induced carcinogenesis is not established, the evidence is generally supportive of a mode of action involving chronic inflammation and cellular toxicity and repair that leads to the generation of reactive oxygen species and DNA damage, rather than direct interaction with DNA (Huang et al. 2011). This threshold mechanism can only occur at exposure concentrations high enough to overwhelm cellular defense mechanisms.

Pierce et al. (2016) derived 'best estimate' chrysotile no observable adverse effect levels (NOAELs) of 208-415 f/cc-years for mesothelioma and 89–168 f/cc-years for lung cancer that can be applied as thresholds in chrysotile cancer risk assessments. In addition, Glynn et al. (2018) reported that the incidence rates of female pleural mesothelioma in urban areas of the US are not significantly higher than in rural areas of the US, even though ambient asbestos concentrations are higher in the former. This is contrary to what would be expected if the LNT model for chrysotile asbestos is accurate. Further, Camus et al. (2002) used a linear model for mesothelioma risk developed by US EPA in the 1980s to predict the number of mesothelioma cases in a population with high, non-occupational chrysotile asbestos exposures. They found that the linear model substantially overpredicted the number of cases (e.g. the model predicted 150 mesothelioma cases in females in a mining town in which only one female mesothelioma case was observed). US EPA did not discuss any of these studies or acknowledge a possible threshold mode of action for chrysotile.

### The absolute risk model for mesothelioma

US EPA's absolute risk model for mesothelioma, unlike its relative risk model for lung cancer, assumes that no background risk of mesothelioma exists. US EPA (2020a) stated in the Risk Evaluation that Thorotrast and external beam radiotherapy are the only other known non-fibrous risk factors for mesothelioma, and that these are unlikely to be confounders because they are not routinely applicable to healthy workers. US EPA acknowledged that exposures to fluoroedenite and erionite are risk factors for mesothelioma, but that these materials are not used in conjunction with chrysotile asbestos in the identified COUs (US EPA 2020a, p. 154).

However, US EPA did not acknowledge evidence that some mesotheliomas occur in the absence of any known exposure to asbestos or other risk factors. Mesothelioma is like any other cancer in that it is caused by an accumulation of mutations, which can occur randomly and spontaneously every time a cell divides (Tomasetti et al. 2017). Thus, a background rate of spontaneously arising cancers exists in the general population, with older age being the most important risk factor. Some proportion of cases have no known or determinable cause (Moolgavkar et al. 2017).

### Chrysotile asbestos textile plant epidemiology studies

US EPA based the chrysotile IUR derived for its Risk Evaluation on the results of two studies conducted at asbestos textile plants in the US – one in North Carolina for mesothelioma (Loomis et al. 2019) and one in South Carolina for lung cancer (Elliott et al. 2012). Both of these studies are problematic in that some workers were likely exposed to primarily amphibole fibers in addition to chrysotile. US EPA (2020a) acknowledged some degree of amphibole fiber exposure, stating that '[t]he epidemiologic studies available for risk assessment all include populations exposed to commercial chrysotile asbestos, which may contain small, but variable amounts of amphibole asbestos.'

However, the issue with these textile worker studies is not small amounts of amphibole contamination of chrysotile

asbestos, but rather, that some members of the study population had potential historical exposures to primarily amphibole fibers used to make amosite or crocidolite products (Yarborough 2006; Loomis et al. 2009). Thus, neither of the studies US EPA selected for the derivation of its chrysotile IUR can be considered studies of chrysotile only, or even commercial chrysotile only. This is an important limitation given the general consensus within the scientific community that amphiboles are far more potent than chrysotile at inducing asbestos-related diseases (e.g. Hodgson and Darnton 2000; Lippmann 2014; Bernstein 2014; Pierce et al. 2016; Moolgavkar et al. 2017).

In addition, workers in these cohorts were exposed to long, unbound chrysotile fibers (Dement et al. 2009). This is in contrast to the short chrysotile fibers found in automotive brake dust (Hatch 1970; Rohl et al. 1976; Johnson et al. 1979; Roberts and Zumwalde 1982; Sheehy et al. 1989). Longer fibers are more potent than shorter fibers for the induction of mesothelioma and lung cancer (Lippmann 2014), and this contributes to the IUR for chrysotile overestimating risks for auto mechanics. Future TSCA risk evaluations for other substances should use studies with the most relevant exposures to the substance being evaluated for the derivation of toxicity criteria.

### Discordance between TSCA guidance and the asbestos hazard/risk evaluation

As with the exposure evaluation, US EPA did not use the best available science or take into account the Initial Analysis Plan's considerations in its evaluation of chrysotile's carcinogenicity. In the Initial Analysis Plan, outlined in the Scoping Document, US EPA (2017) stated that it would '[r]eview reasonably available human health hazard data' and '[e]valuate the weight of the evidence of human health hazard data.' However (as discussed in more detail below), US EPA did not follow this guidance in a number of instances. As noted above, the scientific literature related to a possible threshold for chrysotile-induced mesothelioma was not reviewed, nor was information related to background rates of mesothelioma. In addition, in the draft Risk Evaluation, US EPA did not consider or cite a large number of epidemiology studies that were directly relevant to the inquiry at hand (and reasonably available) (US EPA 2020b).

The omitted epidemiology studies of mechanics and brake workers (in addition to the other omitted studies) clearly would have to be included in any comprehensive and objective analysis of the scientific literature on the carcinogenicity of chrysotile asbestos, particularly when the cancer risks in question are specific to this very population. Even though a subset of those epidemiology studies were provided in a supplemental document to the final Risk Evaluation (US EPA, 2020a), US EPA stated in that document that it 'did not search for additional papers presenting data on cancer risks among automotive mechanics or other workers performing maintenance and repair on automotive brakes.' In a comprehensive and objective weight-of-evidence evaluation (as defined under TSCA), if a category of relevant studies are missed in the initial literature search but identified later, the iterative process would call for a new search to identify all relevant studies of that type.

### Ground truthing US EPA's risk evaluation

Risk assessments for certain exposure scenarios may need to rely on data that are not directly relevant because information on the relevant exposure scenario (i.e. the specific substance and population at issue) is not available. This is not the case for evaluating risks to workers from chrysotile asbestos exposures during brake work, however, as there are studies available that are directly relevant to and informative regarding such risks. Collectively, the evidence from these studies indicates that there are no increased cancer risks from such exposures, as discussed below.

### Motor vehicle mechanic epidemiology studies

Cancer risks in motor vehicle mechanics, including those involved in brake repair, have been evaluated extensively in epidemiology studies (e.g. see meta-analyses by Garabrant et al. [2016] and Goodman et al. [2004]). As a whole, the epidemiology evidence does not indicate that either employment as a vehicle mechanic or brake repair work is associated with an increased risk of mesothelioma when high-risk, unrelated occupational asbestos exposures are accounted for. There is also no indication of a dose-response association among mechanics (e.g. with duration of employment). Similarly, epidemiology evidence does not support there being an increased lung cancer risk among vehicle mechanics, particularly in studies that controlled for smoking. The prevalence of cigarette smoking in motor vehicle mechanics is among the highest of all occupational groups (Bang and Kim 2001), so while an increase in lung cancer incidence among motor vehicle mechanics was reported in some studies that did not adjust for smoking, this is most likely a result of smoking and not occupational exposure to asbestos.

Regarding mesothelioma, US EPA reviewed Garabrant et al. (2016) and most of the studies Garabrant et al. (2016) cited, and a more recent study (Van den Borre and Deboosere 2015), in an addendum to the Risk Evaluation (US EPA 2020c). Interestingly, as mentioned above, US EPA stated it did not search for additional papers on cancer risks among automobile mechanics and other workers performing brake work. US EPA indicated that it did not find the motor vehicle mechanic epidemiology studies useful for consideration in its Risk Evaluation, for three main reasons. First, US EPA considered the studies to have low sensitivity to detect cancer hazards for commercial chrysotile asbestos, because exposure assessments were not conducted for individual workers in these studies and because referent groups used in the studies included other workers exposed to asbestos. Second, US EPA concluded that the studies were not suitable for derivation of an IUR for chrysotile because the studies concerned only mesothelioma and none provided quantitative exposure-response data. Third, US EPA noted that the studies did not provide data on associations of

asbestos fiber concentrations, types, or size distributions with cancer among motor vehicle mechanics. As discussed below, these points are not supported.

Regarding US EPA's first point, it is true that individual exposure assessments were not available in the cited motor vehicle mechanic epidemiology studies. Instead, occupational categories in most of the studies included 'automobile mechanics,' 'vehicle mechanics,' and other occupations not specific to, but likely including, automotive brake work, though there were some studies that evaluated brake workers specifically. Dozens of studies conducted by National Institute for Occupational Safety and Health (NIOSH) and other investigators have measured and reported airborne concentrations of asbestos in association with work with asbestos-containing automotive parts performed by motor vehicle mechanics (see reviews by Paustenbach et al. [2003], Finley et al. [2007], and Richter et al. [2009]), and there is no reason to conclude that brake worker exposures in these epidemiology studies would have been different. It is also notable that the results of analyses of brake workers were consistent with those for motor vehicle mechanics. With regard to the referent groups, the available studies used a variety of populations. There is no evidence that any of these populations had been, on average, subject to more background exposures to asbestos than the general population. Furthermore, many of these same studies reported elevated risks for other occupational groups (e.g. occupations in shipyards, construction, plumbing, and asbestos product manufacturing) using the same referent groups (McDonald and McDonald 1980; Teschke et al. 1997; Agudo et al. 2000; Peto et al. 2009; Rolland et al. 2010; Tomasallo et al. 2018).

Regarding US EPA's second point, for the purposes of assessing a potential association between motor vehicle mechanic work and mesothelioma or lung cancer, it is immaterial whether the motor vehicle mechanic epidemiology studies are suitable to use for the derivation of an IUR for chrysotile. For example, in its draft 'Handbook for Developing IRIS Assessments' (US EPA 2020d), US EPA did not indicate that quantitative exposure-response data that are suitable for IUR development are required for judgments regarding carcinogenic hazard (i.e. causality). In fact, if quantitative exposure-response data from motor vehicle mechanic epidemiology studies existed, they would be a poor choice (i.e. too conservative) to use for estimating cancer risks from exposure to chrysotile generally, as these studies reported no increased risks of cancer.

Regarding US EPA's third point, many of the dozens of studies that have characterized asbestos fiber exposure concentrations for workers performing brake work have also indicated that asbestos-containing brakes contain chrysotile asbestos and not amphibole asbestos, and that the fibers are generally short (e.g. Sheehy et al. 1989). There is no reason to conclude that exposures to workers in these studies, most of which occurred decades in the past, would be dissimilar to exposures to other workers whose exposures have been characterized in other studies, including those discussed in US EPA's Risk Evaluation.

Finally, regarding lung cancer, US EPA also reviewed several studies that investigated this endpoint among automotive mechanics in response to comments on the draft Risk Evaluation (US EPA 2020c). As before, US EPA indicated that it did not find these studies useful for consideration in its Risk Evaluation, for many of the same reasons it dismissed the mesothelioma studies (e.g. no quantitative exposure-response analysis, no quantitative measures of asbestos fiber concentrations or size distributions, likely effects of nondifferential misclassification of asbestos exposure, no basis for deriving an IUR). Thus, the same arguments discussed above for the mesothelioma epidemiology studies apply to these studies as well.

In summary, the epidemiology literature addressing motor vehicle mechanics encompasses several different study designs and research groups, and different populations around the world, spanning decades. Despite these different circumstances, the results of these studies were consistent, with no appreciable heterogeneity (Garabrant et al. 2016). These findings should provide US EPA with a reality check on the findings of its Risk Evaluation, which uses data from studies that are far less relevant to the exposure scenarios at issue than those US EPA dismissed. The more relevant motor vehicle mechanic epidemiology studies, along with several brake work exposure monitoring studies, show that generally low, but measurable, airborne concentrations of chrysotile fibers found in the vicinity of active brake work does not increase the risk of mesothelioma or lung cancer among brake workers. This is supported by evidence from toxicology studies, as discussed below, and demonstrates that it was inappropriate to extrapolate findings from studies with much higher concentrations of chrysotile fibers of different dimensions and with amphibole co-exposures when there are data available for more relevant exposures that indicate no increased risks.

Going forward in future TSCA risk evaluations, it is essential that US EPA consider relevant exposures in relevant populations, rather than attempting to extrapolate from populations that have different exposure conditions. This is particularly true in this case because US EPA excluded an extensive body of epidemiology literature that is the focus of the present Risk Evaluation.

### *Toxicology studies*

Mechanistic and toxicology evidence indicate that an association between chrysotile-containing brake dust and cancer is not biologically plausible (e.g. see Garabrant et al. 2016; Bernstein et al. 2020a, 2020b). For example, consistent with earlier studies, Bernstein et al. (2020a,b) reported that the lungs of rats exposed to chrysotile-containing brake dust for 90 days at doses orders of magnitude higher than human exposures exhibited little to no accumulation of fibers and no pathological response, while the lungs of rats exposed to asbestiform amphiboles showed extensive fiber accumulation and persistent inflammation, microgranulomas, and fibrosis. Consistent with this, other studies have shown that free chrysotile fibers that are present in brake dust do not persist in the lung (Boyles et al. 2019), and that contrary to

amphibole fibers, chrysotile fibers do not cause an inflammatory response in the lungs of mice (Ferro et al. 2014).

Thus, the mechanistic and toxicology evidence is supportive of the findings of the motor vehicle mechanic epidemiology studies that chrysotile asbestos in brake dust is not associated with increased cancer risk.

## Discussion

It is understood that inputs to quantitative risk assessment for regulatory purposes typically err on the side of being conservative, by design, especially when data to support more precise inputs are lacking. This can lead to risk estimates that are more protective than predictive. To be credible, however, inputs to quantitative risk assessment should still be plausible and, where available, supported by relevant evidence. This is something that US EPA should consider in future TSCA risk evaluations. In the present Risk Evaluation, US EPA relied on unrealistic inputs for determining the risk of exposure to chrysotile asbestos in automotive brakes (i.e. overestimated exposure to and toxicity of chrysotile asbestos in brakes and brake dust) when much more plausible, yet still conservative, inputs could have been used. Furthermore, the motor vehicle mechanic epidemiology studies, which found that motor vehicle mechanics and people who worked with chrysotile-containing brake products are not at increased risks of cancer, provide a contrary 'ground truthing' of US EPA's risk estimates. These epidemiology studies are further supported by the mechanistic and toxicology evidence.

As described in detail in Section "Critical Assessment of US EPA's risk evaluation", US EPA's risk estimates were calculated using unrealistic and inappropriate estimates of exposure to, and the toxicity of, chrysotile-containing brakes and brake dust. The exposure estimates used exposure concentrations that are associated, in some cases, with obsolete brake maintenance techniques; assumed frequencies and durations of exposure that are implausible given the effectively decades-long discontinued use of asbestos-containing automotive parts; the probable scarcity of such parts available currently and in the future; and assumed re-entrainment of asbestos that is not supported even under highly implausible dust-disturbance activities. The cancer potency of chrysotile was calculated by applying an IUR that was derived using an LNT model and studies of textile manufacturing workers, who not only had much higher exposures to chrysotile asbestos than brake mechanics, but were also exposed to long, unbound fibers, unlike those found in brakes, and likely to amphibole asbestos as well. Epidemiology studies of motor vehicle mechanics do not support there being increased cancer risks, nor do toxicity studies of chrysotile or chrysotile-containing brake dust. All of these studies are directly relevant to US EPA's Risk Evaluation and provide strong evidence that US EPA overestimated risks in its evaluation, but were not given due consideration by US EPA.

To put into context how conservative US EPA's chrysotile IUR is, if it was applied to the general population, exposed continuously for a lifetime to the mean ambient background concentration of asbestos in the US over the last several decades (0.00093 f/cc; Abelmann et al. 2015), the calculated ELCR in the general population is $1.5 \times 10^{-4}$.[2] Per US EPA, such a risk, which is similar to the central-tendency risks US EPA calculated for the occupational scenarios for mechanics working with asbestos-containing brakes, is considered unreasonable (in fact, they are 150 times greater than US EPA's acceptable risk threshold for DIY consumers working with asbestos-containing brakes), even though there is no expectation that the general population, lacking specific asbestos exposure sources, has an increased risk of developing lung cancer or mesothelioma.

While many of the issues above are specific to the asbestos Risk Evaluation, they also represent a systemic issue with both the TSCA guidance for risk evaluations and the various chemical-specific documents produced under that guidance, including those for trichlorothyele, perchlorethylene, and Pigment Violet 29 (US EPA 2021d, 2020e, 2020f). A variety of reasonably available documents directly pertinent to the question at hand were either not reviewed or only given a cursory review after being referred to in public comments on the draft Risk Evaluation (US EPA 2020c). Analyses that could provide contextual information for the exposure and risk models employed by US EPA were not undertaken.

As can be seen from this case study, the use of unrealistic and inappropriate exposure and toxicity estimates and the exclusion of relevant studies can result in risks that are not only overestimated, but also implausible. These issues result from inconsistencies with following the guidance prescribed under TSCA, and with the TSCA risk assessment process itself. Similar procedural or methodological issues were also identified in other TSCA risk evaluations (i.e. trichlorothyele, perchlorethylene, and Pigment Violet 29; US EPA 2021d, 2020e, 2020f). Now that US EPA has decided to discontinue its previous TSCA systematic review process, we believe it would be prudent for the Agency to develop more proscriptive, peer-reviewed guidance for the conduct of future TSCA risk evaluations. This new guidance should take advantage of the lessons learned during the initial TSCA risk evaluations, and also lean on current peer-reviewed methodologies. This will help ensure that these documents truly meet the goal of the statute, to use a weight-of-evidence evaluation 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' (US EPA. 2021c), and to calculate risks using the most scientifically robust methodology.

## Notes

1. Although the Risk Evaluation includes asbestos-containing brakes and clutches, its focus is on brakes, which we will use as a collective term herein.

2. ELCR = Exposure Point Concentration (EPC) (f/cc) × Time Weighting Factor (TWF) × IUR (per f/cc) = 0.00093 f/cc × 1 × 0.16 per f/cc = $1.5 \times 10^{-4}$. See Section 4.2.1 of US EPA (2020a, 221-0669).

## Disclosure statement

J. Goodman, D. Dodge, R. Prueitt and M. Peterson have served as experts in asbestos litigation. Some of the underlying research and collection of documents for this article was performed in anticipation of litigation that was funded by law firms for defendants. Neither the law firms nor defendants in these matters asked that this article be written or published. The preparation of this article was supported only by the authors and their employer (Gradient), and its conclusions are exclusively those of the authors. Aside from the authors and internal Gradient reviewers, no one has commented on or revised this article prior to its submission. No potential conflict of interest was reported by the author(s).

## Funding

The author(s) reported there is no funding associated with the work featured in this article.

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