Environmental Defense Fund

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

Docket ID: EPA-HQ-OPPT-2021-0057-0006 (April 12, 2022)

Submitted: July 13, 2022

Introduction

The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the U.S. Environmental Protection Agency (EPA) on the proposed risk management rule for Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA) ("Proposed Asbestos Rule").[1]

EDF commends EPA for proposing a ban on most existing uses of chrysotile asbestos to control risk from the manufacture (including import), processing, distribution in commerce, and use of chrysotile asbestos in the United States. Asbestos is a deadly human carcinogen causing cancer of the lung, larynx, and ovary, as well as pharynx, stomach cancer, and colorectal cancer. It also causes respiratory diseases such as asbestosis. While EDF supports the ban, we believe the ban for diaphragms in the chlor-alkali industry and sheet gaskets in chemical production should go into effect with minimal delay – 180 days after publication of the final rule.

A ban is the most effective and health protective TSCA section 6(a) risk management option to address the unreasonable risks presented by chrysotile asbestos, eliminating exposure to all populations that could come into contact with chrysotile asbestos throughout its lifecycle (e.g., workers in manufacturing as well as disposal, DIY consumers). A ban is also the section 6(a) risk management option that poses the least burden on the general population and "potentially exposed and susceptible populations," particularly workers. If EPA chooses to retain its proposed phase-in period for the ban of greater than 2 years after publication of the final rule[2] rather than the more immediate phase-in we recommend, the agency should require the use of hazard

[1] EPA, "Asbestos Part 1: Chrysotile Asbestos: Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA)" ("Proposed Asbestos Rule"), 87 Fed. Reg. 21706 April 12, 2022, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

[2] Note that EPA proposes that the ban go into effect 2 years after the effective date of the final rule. The rule will not likely be effective until after the publication of the final rule which will likely add another 2 months to the 2 years.

communication and the hierarchy of controls using the existing chemicals exposure limit until the ban goes into effect.

Other proposed requirements associated with the chrysotile asbestos ban

Disposal. EPA proposes to cross-reference existing OSHA and EPA asbestos-containing waste disposal regulations to address unreasonable risk from the disposal of chrysotile asbestos associated with the conditions of use assessed in the Asbestos Part 1 Risk Evaluation. EDF has several concerns with EPA's approach to characterizing and regulating risk from disposal activities, including that EPA has not demonstrated how compliance with the OSHA Asbestos General Industry Standard and the Asbestos NESHAP eliminates the unreasonable risk presented by chrysotile asbestos. EPA should explain how its proposed disposal requirements address the unreasonable risk presented by chrysotile asbestos.

De minimis. Given the well-documented toxicity of chrysotile asbestos, particularly the thousands of fatalities each year resulting from chrysotile asbestos exposure, EPA should not set a *de minimis* level for chrysotile asbestos that would allow the exemption of chrysotile asbestos below this level.

ECEL air sampling and analytical methods requirements. To the extent that EPA promulgates a final rule including an ECEL, EDF supports requiring the use of transmission electron microscopy as proposed for air sampling. EDF also supports EPA's proposed requirements for additional monitoring and encourages EPA to provide clear guidance on the full suite of events it believes warrant additional monitoring. In addition, we recommend that EPA revisit the conditions under which monitoring may be terminated.

Downstream notification. Unless EPA institutes a ban that is effective 180 days after the publication of the final rule, the agency should require downstream notification.

Section 6(c)(2)

EPA properly applies the requirements of TSCA section 6(c)(2). This includes EPA's consideration of the section 6(c)(2)(A) "statement of effects" factors, including reasonably ascertainable costs and benefits and alternatives to the restricted uses, as required by section 6(c)(2)(C). EPA also properly applies section 6(c)(2)(D) in proposing not to exempt replacement parts from regulation and section 6(c)(2)(E) in proposing to regulate articles.

Section 6(g)

EPA has properly declined to grant any exemption for chrysotile asbestos diaphragms used in the chlor-alkali industry or chrysotile asbestos containing sheet gaskets used in chemical production under section 6(g). A ban on the use of chrysotile asbestos would not impact the national economy and would not impact critical uses. Nor, for all the unreasonable risks it poses, is chrysotile asbestos safer than the alternatives.

Section 9

EDF supports EPA's interpretation of section 9 that the agency may not refer or rely on other laws if those laws will not sufficiently address the unreasonable risk. To refer to another agency without authority to reduce identified unreasonable risks or employ other EPA-administered laws

that do not provide people and the environment with the protection that TSCA mandates would result in inadequate risk management actions, or even no risk management actions at all. If EPA did so, it would fail to fulfill its duties under TSCA. In the Proposed Asbestos Rule, EPA has fully supported its correct decision under section 9 to employ TSCA to regulate the unreasonable risk.

Economic analysis

EPA has successfully fulfilled its obligations to consider the costs and benefits of the Proposed Asbestos Rule as required by TSCA section 6(c)(2). However, EPA's Economic Analysis of the TSCA Section 6 Proposed Rule for Asbestos Risk Management, Part 1 ("Economic Analysis") significantly underestimates the direct benefits of the Proposed Asbestos Rule through a number of exclusions and flawed assumptions. While not required to justify the finalization of the Proposed Asbestos Rule, EPA should bolster its analysis for the final rule to more accurately reflect the overall benefits. The agency underestimated the direct benefits from the Proposed Asbestos Rule because it only included a subset of health endpoints, it inappropriately assumed consistent personal protective equipment use in baseline exposure calculations, and it dramatically underestimated the number of individuals who would benefit from the rule.

Cross-cutting issues

This rulemaking provides a model for future risk management rules under TSCA. The assumptions and positions EPA takes in this rulemaking are applicable to other chemicals undergoing risk management. In addition, in the preamble EPA provides notice on risk management considerations it intends to include in its risk evaluations, including voluntary industry practices and existing regulations under statutes other than TSCA, including those that have non-universal applicability and/or different statutory risk findings and standards. Unfortunately, EPA includes non-risk factors and risk management activities in its risk evaluations. The approach is not scientifically supportable and conflicts with sections 6(b)(4) and conflates sections 6(a) and 6(b). Further, EPA inappropriately treats workers differently from the general population by applying a less protective cancer benchmark for workers. EPA should address these cross-cutting issues because they impact the agency's ability to effectively characterize and address unreasonable risks.

In sum, we support EPA's action to ban most uses of chrysotile asbestos and provide recommendations on how to improve this action. We also highlight several cross-cutting issues that should be addressed to protect human health in this action and in subsequent section 6(a) rulemakings.

Table of Contents

1. EDF supports a TSCA section 6(a) ban of chrysotile asbestos.

A. EDF commends EPA for proposing a ban over other risk management alternatives under section 6(a).

EDF commends EPA for proposing a ban on most existing uses of chrysotile asbestos to control risk from the manufacture (including import), processing, distribution in commerce, and use of chrysotile asbestos in the United States. Asbestos is a deadly human carcinogen, as recognized by many authorities starting with the International Agency for Research on Cancer in 1976. Even now, nearly 40,000 Americans die ***every year*** from asbestos-related cancers (e.g., cancer of the lung, larynx, and ovary, as well as pharynx, stomach cancer, and colorectal cancer) and respiratory diseases (e.g., pleural diseases such as asbestosis).[3] These deaths are preventable and must be stopped. EDF supports a ban though believes it should go into effect sooner –180 days after publication of the final rule for all uses.

The U.S. Department of Labor Occupational Health and Safety Administration (OSHA) "is aware of no instance in which exposure to a toxic substance has more clearly demonstrated detrimental health effects on humans than has asbestos exposure."[4] In response to industry claims that current asbestos operations are not putting workers or the general public at risk due to existing workplace safety requirements, OSHA concludes that "there is no 'safe' level of asbestos exposure for any type of asbestos fiber."[5] Thus, continued use of raw or processed chrysotile asbestos, at any level of exposure, threatens the lives of workers and communities.

We are encouraged by EPA's proposed section 6(a) ban on almost all existing uses of chrysotile asbestos, which is consistent with repeated domestic and international calls for the elimination of asbestos. We also applaud EPA for its existing efforts to assess the remaining asbestos fibers in its Part 2 supplemental risk evaluation for asbestos, as potential risk from all types of asbestos fibers, including legacy fibers used in the constructions of homes, schools, and other buildings, must be addressed to effectively reduce risk from the chemical.

i. EPA recognized that a ban is the most appropriate section 6(a) action to address the unreasonable risks posed by chrysotile asbestos.

EPA's assessment of the risks of chrysotile asbestos determined that most conditions of use pose unreasonable risks. After such a determination, TSCA section 6(a) requires that the Administrator shall by rule apply one or more of the section 6(a) requirements to the chemical substance to the extent necessary so that the chemical substance no longer presents such risk.

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[3] APHA, "Eliminating Exposure to Asbestos (Policy Number: 20193)," November 5, 2019, https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2020/01/10/eliminating-exposure-to-asbestos

[4] OSHA, "Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite," 51 Fed. Reg. 119, 22614, June 20, 1986, https://www.grsm.com/Templates/media/files/pdf/51%20fr%2022612.pdf

[5] OHSA, "Asbestos," accessed on June 20, 2022, https://www.osha.gov/asbestos#4

A ban is the most effective and health protective section 6(a) risk management option to address the unreasonable risks presented by chrysotile asbestos, eliminating exposure to all populations that could come into contact with chrysotile asbestos throughout its lifecycle (e.g., workers in manufacturing as well as disposal, DIY consumers). A ban is also the section 6(a) risk management option that poses the least burden on the general population and "potentially exposed and susceptible populations," particularly workers. Furthermore, it is more efficient and cost-effective than an approach such as worker protection programs that may require expensive equipment, worker training, and regular air monitoring – in addition to EPA resources to conduct enforcement – to ensure that unreasonable risk is actually being mitigated. In fact, in 2018 the World Health Organization recognized that "the most efficient way to eliminate asbestos-related diseases is to stop the use of all types of asbestos."[6]

As such, a near-term ban is both more effective and less burdensome than the other section 6(a) alternatives. This includes the primary regulatory alternative of a ban 5 years and 2 months after publication of the final rule and the use of an ECEL in the interim.[7] The ECEL is a performance standard that will result in many workers being required to use respirators[8] to meet the standard. Use of PPE during this interim period would place significant burdens – including the burden imposed by the respirator itself – on workers.

Respirators and other PPE are the least effective workplace controls to address risks for multiple reasons. There may be difficulties associated with the selection, fit, and use of respirators that often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Not all workers can wear a respirator effectively, e.g., workers with facial hair or with medical conditions. Therefore, the effectiveness of the ECEL at mitigating the unreasonable risk is less than a ban. The very low degree of uncertainty in the harm caused by chrysotile asbestos based on the thousands of people who have died after exposure to chrysotile asbestos supports the choice of a risk mitigation regulation that has a high certainty of eliminating the unreasonable risk. Thus, a ban 180 days after publication of the final rule for all uses would be the most effective approach.

The use of an ECEL pursuant to section 6(a)(5) for longer than a very limited time would also shift burdens from companies to workers. Not only is there the physical burden of wearing the respirator, but there can also be physiological burdens associated with the use of certain types of respirators. Job and workplace conditions, such as the length of time a respirator must be worn, the level of physical exertion required of a respirator user, and environmental conditions, can affect worker' physiological burden.[9] Burdens such as these should be considered in choosing

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[6] WHO, "Asbestos: elimination of asbestos-related diseases," February 15, 2018, https://www.who.int/news-room/fact-sheets/detail/asbestos-elimination-of-asbestos-related-diseases

[7] This would also apply to an extreme alternative posed by some in the industry of simply requiring the use of an ECEL under section 6(a)(5) with no long-term ban.

[8] Both EPA's Asbestos Part 1 Risk Evaluation and the Economic Analysis for this rulemaking assume the use of respirators as the primary way to decrease exposure to workers.

among risk management options for section 6(a) rules. Specifically, it should be considered in assessing the appropriateness of a regulatory option and whether it is the most appropriate section 6(a) regulatory approach to address the unreasonable risk.

ii. EPA recognizes in its Proposed Asbestos Rule that risk elimination is preeminent.

Under reformed TSCA, EPA's essential task in risk management is to craft a regulation to ensure at least that the chemical will no longer present an unreasonable risk. In the Proposed Asbestos Rule, EPA properly characterizes this mandate. The agency recognizes that while it will consider other factors where it is practicable to do so, in the end the agency must come back to eliminating the unreasonable risk:

> If EPA determines through risk evaluation that a chemical substance presents an unreasonable risk, TSCA section 6 requires EPA to issue regulations applying one or more control requirements to the extent necessary so that the chemical substance no longer presents such risk. Although EPA must consider, and in some cases factor in, to the extent practicable, non-risk factors as part of TSCA section 6(a) rulemaking (see TSCA section 6(c)(2)), EPA must nonetheless still ensure that the selected regulatory requirements apply "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk." This risk-based requirement is distinguishable from approaches mandated by other laws, including the Occupational Safety and Health Act (OSH Act), which includes both significant risk and feasibility (technical and economic) assessments in its rulemaking.[10]

We commend EPA for centering risk elimination in its risk management analysis.

B. EPA should mandate compliance with its proposed ban without delay, with a six-month transition period.

EPA has requested comment on whether its proposed regulatory timeline for the prohibition of chrysotile asbestos in bulk form, chrysotile asbestos-containing sheet gaskets, and chrysotile asbestos diaphragms used in the chlor-alkali industry (collectively, the "bulk, gasket, and diaphragm ban") is appropriate – specifically, whether the proposed prohibition compliance date is "as soon as practicable," as required under TSCA section 6(d)(1), and also whether the date provides an appropriate transition period. For the reasons described below, the proposed compliance date of more than two years post-final rule does not comport with section 6, and EDF urges EPA to set a compliance date no later than six months after publication of the final rule.

[9] OSHA, "Respiratory Protection," 63 Fed. Reg. 1152, January 8, 1998, https://www.govinfo.gov/app/details/FR-1998-01-08/97-33843

[10] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21711, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

TSCA requires EPA to mandate that its risk management rules take effect, and that compliance occur, "as soon as practicable."[11] EPA has proposed a prohibition compliance date of two years plus sixty days after publication of the final risk management rule. Because TSCA requires the ban to take effect as soon as practicable, the agency must carry the burden to justify any compliance delay beyond an appropriate transition period.

Thus far, the burden is far from being met. The rulemaking record shows that the companies that comprise the chlor-alkali industry, upon which EPA appears to rely in fashioning the proposed compliance date, have not come close to demonstrating a need for a delay of the ban more than two years. Specifically, EPA's notes from its meetings with the companies in which it discussed "the process, time, and costs of transition to chrysotile asbestos-free diaphragms or cell membranes as part of the possible risk management options" under TSCA section 6(a) reveal a notable lack of support for the need for any delay in compliance with a ban:

- EPA met with Olin Corporation in 2021. Olin said "it would like to continue using asbestos-containing diaphragm technology" because it believes it is "safe and effective." But Olin did not provide any reason why it could not transition to non-asbestos technology. In fact, it told EPA that, at three of its facilities in the US, they used only non-asbestos technology, and at its other two facilities, it used both non-asbestos and asbestos technology.[12]

- EPA met with Westlake Corporation in 2021. "Westlake explained that all of its plants, with one exception, use non-asbestos diaphragms. In some instances, Westlake built new cell membranes entirely by using proprietary technology."[13] EPA then told Westlake that it would like information on this technology, which could be adopted by other companies.[14]

- EPA met with OxyChem in 2021. The company told EPA that it has no plans to transition from asbestos chlor-alkali technology, that the return on such a conversion would not be adequate, and "that switching to non-asbestos technology could take many years without even considering potential supply disruption or other impacts to their business." However, EPA did not note that OxyChem offered any support for these assertions, and the agency told the company that details about "cost, timing, volume of

[11] 15 U.S.C. § 2605(d)(1) ("TSCA section 6(d)(1)")

[12] *See* Appendix, 2 (document may also be found at the docket at: EPA-HQ-OPPT-2021-0057-0019)

[13] In a separate, un-dated letter in the rulemaking docket, Westlake informed EPA that its use of asbestos "is limited to production of diaphragms for use in our chlor-alkali facility in Plaquemine, LA … Currently, we have a several year supply on hand and do not plan any further imports. We expect to eventually switch to a non-asbestos technology." *See* Appendix, 4 (document may also be found at the docket at: EPA-HQ-OPPT-2021-0057-0022)

[14] *See* Appendix, 3 (document may also be found at the docket at: EPA-HQ-OPPT-2021-0057-0021)

asbestos consumed per year, and conversion processes would be helpful to support risk management."[15]

- EPA met with Chemours in 2021. The meeting revolved around the company's use of asbestos-containing sheet gaskets and how it employs respirators and other personal protective equipment for its workers. Chemours explained that "their company has an active process in place to evaluate chrysotile asbestos-free alternatives for gaskets." They also said that one of their plants in Taiwan use asbestos-free gaskets, "but claimed there were performance issues using asbestos-free gasket technology in their domestic plants."[16] However, they did not explain the reason for the differential in performance between their Taiwan plant and their domestic plants.

EPA, in what may be viewed as an overly charitable summary of those meetings, points out that industry came up short on details:

> EPA held meetings with several of the processors and industrial users of chrysotile asbestos for these conditions of use. These companies stated to EPA that the transition to asbestos-free technology could take many years, although the companies processing and using chrysotile asbestos for these uses stated that research on asbestos alternatives has been ongoing. Each company did express that conversion to an alternative was possible but would require significant retooling of a facility, testing new processes, and other costly measures. However, these companies did not provide EPA with delineated cost estimates or a detailed timeline for the conversion process.[17]

In light of TSCA's mandate that EPA institute its risk management regulations as soon as practicable – and considering the notable lack of evidence to support the idea that an immediate ban is not practicable – the Proposed Asbestos Rule should go into effect without delay. Further supporting the appropriateness of an immediate ban is the fact that industry has long been aware of the harm caused by chrysotile asbestos and the global push to phase out its use and has been transitioning to non-asbestos technology. Recognizing that TSCA section 6 calls for a "reasonable transition period,"[18] and to harmonize the timeline for the bulk, gasket, and diaphragm ban with EPA's proposed compliance timelines for other uses, we recommend a compliance date of six months maximum from publication of the final rule.

The six-month compliance timeline would be in addition to the many months of notice of the ban that EPA will have provided industry, from April 2022 – when EPA released the Proposed Asbestos Rule – to when the rule is finalized, likely in 2023. And this would be on top of the

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[15] *See* Appendix A, 5 (document may also be found at the docket at: EPA-HQ-OPPT-2021-0057-0020)

[16] *See* Appendix A, 6 (document may also be found at the docket at: EPA-HQ-OPPT-2021-0057-0018)

[17] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21726, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

[18] 15 U.S.C. § 2605(d)(1) ("TSCA section 6(d)(1)")

years of notice companies have been on that EPA was evaluating risk from asbestos.[19]

Our proposed compliance timeframe is supported by factors articulated by EPA itself in its proposal. For example:

> EPA believes an aggressive transition away from chrysotile asbestos will spur adoption of superior technology and that potential supply disruptions could be addressed in the shorter term through increased importing of caustic soda and derivatives of chlorine and caustic soda, and over time with increased production at existing non-asbestos diaphragm or membrane-based chlor-alkali plants.[20]

Similarly, in regard to sheet gaskets, the agency's articulated analysis, although framed as supporting a two-year transition, supports a six-month timeframe:

> Chrysotile asbestos-containing sheet gaskets are used in limited chemical production applications, particularly for the manufacture of titanium dioxide. EPA believes alternative gaskets are available that can meet the high-temperature and pressure conditions for which the chrysotile asbestos-containing gaskets are currently used. At least one manufacturer of titanium dioxide uses only asbestos-free gaskets (Ref. 14) and the two-year transition away from existing use of chrysotile gaskets should be feasible based on the availability of these substitutes.[21]

EPA's proposed protracted timeline seems to be based on an erroneous equation of "achievable" with "as soon as practicable." ("EPA considers the proposed two-year effective date for the prohibition … to be *achievable* by the industry, thus meeting the "as soon as practicable" requirement of TSCA section 6(d)(1)."[22]) In fact, EPA's own analyses in the Proposed Asbestos Rule do not demonstrate that industry cannot meet a tighter timeline, and because TSCA mandates that the ban compliance begin as soon as practicable, our recommendation of six months maximum represents a far more appropriate timeline for the bulk, gasket, and diaphragm ban.

Finally, EDF acknowledges the concern raised regarding water systems' need for chlor-alkali products. However, the information on the possible connection between EPA's proposal and the

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[19] EPA's final risk evaluation for chrysotile asbestos, which indicated which conditions of use present unreasonable risk, was published in December 2020 (https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-asbestos-part-1-chrysotile); additionally, industry stakeholders have been aware of (and advocating against) the potential for restrictions on existing uses of asbestos even prior to EPA's publication of its risk findings in 2020 (*see*, for example, communications between Chemours and EPA regarding asbestos containing gaskets from March 2017, https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0057-0050)

[20] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21721, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

[21] *Id.*

[22] *Id.*

wastewater systems – or, more accurately, a notable lack thereof – does not justify the proposed two-year delay. EPA reports that it "has insufficient information to fully assess the impact of this proposed rule on the cost or availability of water treatment chemicals," and requests comment.[23] Unless and until EPA gathers reliable information that its proposal will significantly impact the availability and cost of water treatment chemicals, TSCA does not permit EPA to invoke speculative concerns to delay for years its restriction of a deadly substance.[24]

C. If EPA imposes any longer than a six-month compliance date, it should also impose an ECEL requirement in the interim period.

As recommended above, EPA should institute its proposed bulk, gasket, and diaphragm ban, and should do so within six months of publication of the final rule. However, if EPA does not institute its ban on this timeline, it should mandate protections for workers in the meantime. EPA has made unreasonable risk determinations for chrysotile asbestos and should not allow workers to continue to face these risks during a prolonged interim period until a ban takes effect. Specifically, EPA should require the use of exposure controls to protect workers.

Substitution of chrysotile asbestos is at the top of the hierarchy of controls and thus preferable. It is the most effective way to eliminate the unreasonable risk and is less burdensome on workers. However, if a ban on chrysotile asbestos does not go into effect within six months of the publication of the final rule, EPA should require the use of hazard communication and the hierarchy of controls using the ECEL until it goes into effect. The regulated community is already familiar with the use of the occupational exposure limits (OELs) required by OSHA – permissible exposure limits (PELs)[25] – and many are currently subject to the PELs. They are also familiar with the hierarchy of controls. The ECELs are analogous to PELs,[26] and EPA's exposure control requirements in the alternative proposal track the approach taken by OSHA. Thus, applying EPA's TSCA section 6 OEL – the ECEL – while not as protective as a ban is a reasonable short-term interim solution.

The use of an OEL is not new to TSCA or the companies subject to TSCA. EPA has also used OELs, exposure controls and hazard communication routinely to meet requirements in the TSCA section 5 new chemicals program. These new chemical OELs – known as new chemical exposure limits (NCEL) – are often an alternative requirement in section 5 consent orders.

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[23] *Id.*

[24] We note that only 5% of the chlorine produced is used for water treatment (*see* https://www.essentialchemicalindustry.org/chemicals/chlorine.html). As discussed in section 2-D of these comments, 5% is within year-to-year production fluctuations (*see* https://www.statista.com/statistics/974614/us-chlorine-production-volume/#:~:text=This%20statistic%20shows%20the%20production,metric%20tons%20produced%20in%201990).

[25] As discussed elsewhere, for various reasons the PELs are not sufficient to address the unreasonable risk.

[26] NCELs, ECELs and PELs are occupational exposure limits. NCELs and ECELs are based on risk, while PELs take into account factors other than risk.

Indeed, EPA's alternative proposal requiring an ECEL as an interim control is very closely modeled on these new chemical requirements. The requirements in the TSCA section 5 consent orders are as detailed and specific as those presented in the regulatory alternative through an ECEL. If EPA believed that the use of OELs and exposure controls were not feasible, they would not have routinely included them in TSCA section 5 consent orders.

Also, in the TSCA new chemicals program, even in the absence of establishing a regulatory NCEL, EPA has routinely specified the combination of engineering controls, administrative controls, work practices, and personal protective equipment necessary to meet a level of concern for the new chemical under the scenarios reviewed for the chemical. These are the requirements that a company must have in place to address an unreasonable risk so that they can commercialize a new chemical. Thus, we question why in the case of chrysotile asbestos EPA would characterize this approach as if it were something so unusual that a company would need a very long time to implement. In fact, EPA implies the regulated community would need much of the two-year period before the ban became effective to meet the ECEL.

> EPA recognizes that an ECEL will require time and resources to prepare for and therefore did not propose to include it for the two-year interim period prior to the proposed prohibition date.[27]

A review of new chemical consent orders and the corresponding notices of commencement for the new chemical would belie this supposition. Further, in EPA's primary alternative regulatory proposal in which the prohibitions on the manufacturing, processing, and use of chrysotile asbestos would be effective five years after the effective date of the rule,[28] EPA would require as interim control an ECEL beginning 180 days after the effective date of the final rule.

We are also concerned about the plausible scenario where EPA finalizes its primary proposal without any provisions for addressing the workplace unreasonable risks in the interim and then subsequently, at the request of industry, delays the effective date of the prohibitions. Of course, this will result in prolonging the workplace unreasonable risks and contribute to the development of asbestos-related health problems. This would not be unexpected given the agency's several extensions of the effective date for the regulation of PIP 3:1.

EPA has provided no substantive or consistent rationale on why workers should continue to be subject to the unreasonable risks from the known carcinogen chrysotile asbestos. Workers are a potentially exposed or susceptible subpopulation and as such TSCA requires that they be given particular consideration, not lesser protection by continuing to be subject to unreasonable risks.

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[27] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21718, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

[28] We note that as proposed, the proposed ban on chrysotile asbestos in bulk, sheet gaskets, and diaphragms would occur 5 years and 2 months after the publication of the final rule.

2. EDF commends EPA for properly applying the requirements of TSCA sections 6(c) and (g).

A. EPA properly considers the TSCA section 6(c)(2)(A) "statement of effects" factors, including reasonably ascertainable costs and benefits and a regulatory alternative.

Congress has directed EPA to "factor in, to the extent practicable," in its rules regulating risk, the factors listed in TSCA's "statement of effects" provision.[29] One of the factors to be considered is the "reasonably ascertainable" costs and benefits of the proposed regulatory action. It is important to note, however, that when Congress enacted the 2016 amendments to TSCA, the lead Senate Democratic negotiators on the bill made clear that EPA should not have to quantitatively determine that benefits outweigh costs.[30] They explained that the list of factors for EPA to consider in the TSCA statement of effects provision (6(c)(2)(A) does *not*:

> require EPA to demonstrate benefits outweigh costs, to definitively determine or select the least-cost alternative, or to select an option that is demonstrably cost-effective or is the least burdensome adequately protective option. Rather, it requires only that EPA take into account the specified considerations in deciding among restrictions to impose, which must be sufficient to ensure that the subject chemical substance no longer presents the unreasonable risk EPA has identified. The Frank R. Lautenberg Chemical Safety for the 21st Century Act clearly rejects the regulatory approach and framework that led to the failed asbestos ban and phase-out rule of 1989 in Corrosion Proof Fittings v. EPA 947 F.2d 1201 (5th Cir. 1991).

Congress did not intend the agency to engage in formal cost-benefit or cost-effectiveness analysis, with a full quantification of costs and benefits. Rather, Congress merely intended that EPA consider the costs and benefits of its proposed requirements, and left to EPA the question of what weight to ascribe to the costs and benefits. Indeed, in last year's *Labor Council for Latin American Advancement v. EPA*, the Second Circuit concluded that EPA's qualitative consideration of costs and benefits, in its rule regulating consumer use of methylene chloride, was sufficient.[31]

In addition, Congress's direction to EPA regarding the TSCA section 6 "statement of effects" factors is for EPA to "consider" those factors, thus providing EPA discretion in how the agency would rely on the information that is reasonably available or ascertainable to the agency.[32] *See New York v. Reilly*, 969 F.2d 1147, 1150 (D.C. Cir. 1992) ("Because Congress did not assign the specific weight the [EPA] Administrator should accord each of these factors, the Administrator is

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[29] 15 U.S.C. § 2605(c)(2)(B) ("TSCA section 6(c)(2)(B)")

[30] *See* 162 Cong. Rec. S3517 (daily ed. June 7, 2016), https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf

[31] 12 F.4th 234, 250-51 (Sept. 2021)

[32] 15 U.S.C. § 2605(c)(2)(A) ("TSCA section 6(c)(2)(A)")

free to exercise his discretion in this area"); *Nat'l Wildlife Federation v. Costle*, 629 F.2d 118, 131-132 (D.C. Cir. 1980) (requirement that EPA "shall consider" listed factors under Ocean Dumping Act does not mean that it must "include" each in permit evaluation criteria if it concludes that it is inapplicable).

Based on the language of TSCA section 6(c), and legal precedent, courts are unlikely to micromanage EPA's analysis of the "statement of effects" economic considerations, particularly in a challenge to a regulation like the Proposed Asbestos Rule in which EPA satisfies its duties to consider the "statement of effects" factors. The agency describes the health and environmental effects of and exposure to chrysotile asbestos, the benefits of its use, the reasonably ascertainable economic consequences, costs, and benefits of its proposal. (However, as we discuss below in section 6 of these comments, EPA has significantly underestimated in its Economic Analysis the direct benefits of the Proposed Asbestos Rule and should reflect the overall benefits in the final rule). EPA also satisfies its section 6(c) mandate to consider the costs and benefits of one or more "primary alternative regulations,"[33] and the cost effectiveness of the proposed and alternative regulations. And throughout the proposal, EPA properly keeps focus on the fact that its duties to consider the "statement of effects" factors is, as observed by the Second Circuit Court of Appeals, "subject to the overall mandate to regulate the chemical to the extent that it 'no longer presents' the identified unreasonable risk."[34]

i. EPA properly considers alternatives to the restricted uses, as required by TSCA section 6(c)(2)(C).

In deciding whether to prohibit or substantially restrict uses of a chemical, EPA is also to consider – to the extent practicable – whether technically and economically feasible alternatives that benefit health and the environment, compared to the use proposed to be prohibited or restricted, will be reasonably available as a substitute.[35]

It is important to recall that, in amending TSCA, Congress chose not to require EPA to identify suitable alternatives before regulating or banning a substance. Proposals to impose such a mandate were rejected in drafting the 2016 amendments.[36] Instead, EPA must only consider the availability of feasible alternative that benefit health or the environment.[37] As with the "statement of effects" factors described above, Congress's direction to "consider" alternatives provides EPA substantial discretion in its analysis.

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[33] 15 U.S.C. § 2605 (c)(2)(A)(iv) ("TSCA section 6 (c)(2)(A)(iv)")

[34] *Labor Council for Latin American Advancement v. EPA*, 12 F.4th at 243 (2nd Cir. Sept. 2021)

[35] 15 U.S.C. § 26056(c)(2)(C) ("TSCA section 6(c)(2)(C)")

[36] *See* H.R.____ [Discussion Draft], Subcomm. on Environment and the Economy, H. Comm. Energy and Commerce, 113th Cong. at 44 (2014) (stating that EPA can only prohibit or substantially prevent specific uses of a chemical "when technically and economically feasible alternatives . . . are available")

[37] 15 U.S.C. § 26056(c)(2)(C) ("TSCA section 6(c)(2)(C)")

In addition, Congress directed that consideration of available substitutes be done as a *comparison* with the proposed restricted use.[38] In the Proposed Asbestos Rule, EPA properly engages in that analysis:

> EPA notes that chrysotile asbestos is not currently the primary substance most commonly used in these conditions of use, nor has it been for the last decade. Chlor-alkali asbestos diaphragms, sheet gaskets for chemical production, aftermarket automotive breaks, oilfield brake blocks, other gaskets and other friction products containing chrysotile asbestos are relatively uncommon in the market space, as described in the risk evaluation. There are a number of alternatives to asbestos in these conditions of use that make up the majority of the market share and have been preferentially used for some time, in part as a result of the known severe and adverse health effects related to asbestos exposure. Based on the information published under TSCA section 6(c)(2)(A), EPA does not expect any adverse impacts to human health and the environment to result from the further reduction of asbestos in these conditions of use *when compared to the continued use of asbestos*.[39]

In coming to its conclusion, EPA considered alternatives and found them economically viable, and – despite uncertainties – preferable to the uses it proposes to restrict of chrysolite asbestos, "a known human carcinogen that causes an aggressive and deadly cancer."[40]

B. EPA properly applies section 6(c)(2)(D) in proposing not to exempt replacement parts from regulation.

Congress directed EPA not to exempt replacement parts for complex consumer and durable goods from its risk management rule if the agency finds that the replacement parts contribute significantly to the risk to the general population or to a potentially exposed or susceptible subpopulation ("vulnerable subpopulation") identified in the Asbestos Part 1 Risk Evaluation.[41] EPA properly applied this direction, declining to exempt the relevant replacement parts (brake blocks in the oil industry, aftermarket brakes and linings, gaskets) because the agency found in its Asbestos Part 1 Risk Evaluation that the parts' use and disposal present unreasonable risk to identified vulnerable subpopulations.[42]

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[38] *Id*.

[39] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21719, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf (emphasis added)

[40] *Id.*

[41] 15 U.S.C. § 26056(c)(2)(D) ("TSCA section 6(c)(2)(D)")

[42] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21728-29, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

C. EPA properly applies section 6(c)(2)(E) in proposing to regulate articles.

Congress contemplated that, in addition to the regulation of chemicals whose uses are determined to pose unreasonable risk, EPA would regulate articles containing those substances, and do so "only to the extent necessary to address the identified risk from exposure to the substance" so that it does not present the unreasonable risk.[43]

In its proposal, EPA explains that numerous articles containing the chrysotile asbestos can change and alter during use, release chrysotile asbestos, cause harmful exposures and unreasonable risk to workers, "occupational non-users," consumers, and bystanders. The agency thus properly applied section 6 in determining that, to properly address these risks from the chrysotile asbestos-containing articles, prohibition of those articles is necessary.

D. EPA properly applies section 6(g) in not granting an exemption from its proposed regulation.

EPA has properly declined to grant any exemption for chrysotile asbestos diaphragms used in the chlor-alkali industry or chrysotile asbestos containing sheet gaskets used in chemical production under section 6(g).

Congress set a high bar for the granting of any exemption from a TSCA section 6 regulation that must eliminate a chemical's unreasonable risk. EPA may not grant an exemption from a risk management rule unless it finds that one or more factors apply:

> (A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;
>
> (B) compliance with the proposed requirement would significantly disrupt the national economy, national security, or critical infrastructure; or
>
> (C) the specific condition of use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.[44]

In the Proposed Asbestos Rule, EPA appropriately does not propose any exemptions. However, the agency queries the public about whether an exemption is warranted. In finalizing the regulation, EPA should keep in mind the high bar imposed by the factors above. As to the first factor, it is important to note that the agency, in determining whether an exemption is warranted, must take into account both the chemical's hazard and exposure, and it must find that the use is critical or essential *and* that no feasible or safer alternative is available.

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[43] 15 U.S.C. § 26056(c)(2)(E) ("TSCA section 6(c)(2)(E)")

[44] 15 U.S.C. § 2605(g) ("TSCA section 6(g)")

Regarding the second factor, EPA would need to find not only that a disruption to our country's economy, national security, or critical infrastructure would occur, but also that it would be significant. Finally, the third factor cannot be satisfied unless the condition of use provides affirmative – *substantial* – benefits.

It is also important to note that EPA's decision to exempt is discretionary, and that if the agency does not grant an exemption, it does not need to produce an "exemption analysis and statement."[45] However, if EPA does decide to grant an exemption from a regulatory requirement, it must take numerous steps: analyze the need for each exemption; prepare a statement describing how the analysis was taken into account; publicize the analysis and the statement; establish a time limit for each exemption; and impose conditions on the exemption that EPA determines are necessary to protect heath and the environment.[46]

Continued use of chrysotile asbestos in the chlor-alkali industry would not meet any of the section 6(g) factors. There are technically and economically feasible safer alternatives to asbestos in the chlor-alkali industry that are being used in the United States and Europe. Banning chrysotile asbestos would not significantly disrupt the national economy, national security, nor critical infrastructure. While chlor-alkali chemicals are used in sectors important to the national economy, as noted there are economically feasible alternatives to the use of asbestos in chlor-alkali facilities. Thus, the presence of chlor-alkali chemicals on the market should not be impeded by a ban on the use of chrysotile asbestos in the chlor-alkali industry.

Further, while chlorine produced by chlor-alkali facilities is used for drinking water treatment, it should be noted that only 5% of the chlorine produced by chlor-alkali facilities goes to this use.[47] This non-significant percentage is clearly within year-to-year market fluctuations.[48] Finally, given the disease and death associated with the mining, processing, use, and disposal of chrysotile asbestos, the third section 6(g) factor – that the use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety – cannot be met.

Nor would a section 6(g) exemption be warranted for the use of chrysotile asbestos in sheet gaskets. As EPA explains:

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[45] 15 U.S.C. § 2605(g)(2) ("TSCA section 6(g)(2)")

[46] 15 U.S.C. § 2605(g)(2) - (g)(4) ("TSCA section 6(g)(2) – (g)(4)")

[47] *See* "Chlorine," The Essential Chemical Industry – Online, Department of Chemistry, University of New York, last updated November 27, 2018, https://www.essentialchemicalindustry.org/chemicals/chlorine.html for more detail. We note that EPA's Economic Analysis estimates 7% of chlorine end use is for water treatment.

[48] Lucía Fernández, "Chlorine production in the United States from 1990 to 2019," Statista, June 14, 2022, https://www.statista.com/statistics/974614/us-chlorine-production-volume/#:~:text=This%20statistic%20shows%20the%20production,metric%20tons%20produced%20in%201990

> Chrysotile asbestos-containing sheet gaskets are used in limited chemical production applications, particularly for the manufacture of titanium dioxide. EPA believes alternative gaskets are available that can meet the high-temperature and pressure conditions for which the chrysotile asbestos-containing gaskets are currently used. At least one manufacturer of titanium dioxide uses only asbestos-free gaskets (Ref. 14).[49]

A ban on the use of chrysotile asbestos would not impact the national economy and would not impact critical uses. Nor, for all the unreasonable risks it poses, is chrysotile asbestos safer than the alternatives.

3. EPA properly applies section 9 in deciding to regulate under TSCA.

i. The Lautenberg Act significantly impacts the analysis that EPA must conduct to determine whether to refer to another agency or rely on other EPA laws to address unreasonable risk.

In the Proposed Asbestos Rule, EPA recognizes that the 2016 Lautenberg Act had a significant impact on section 9 of TSCA. Specifically, section 9 was modified to conform to the Lautenberg Act's removal of non-risk factors from the unreasonable risk standard underlying TSCA. In performing its analysis under section 9, EPA recognizes that the agency may not refer or rely on other laws if those laws will not sufficiently address the unreasonable risk.

Sections 9(a) and 9(b) comprise the principal subsections of section 9. Subsection (a) lays out the relationship of TSCA to legal authorities administered by agencies other than EPA (for example, OSHA), while subsection (b) lays out the relationship of TSCA to other legal authorities administered by EPA itself (for example, the Clean Air Act).

Under section 9(a), there should be no referral to another agency for regulation of an activity related to a substance that EPA has found to present an unreasonable risk of injury to health or the environment unless EPA has affirmatively determined that it should refer that risk to another agency. In turn, the agency should only make that referral if it determines that the other agency may prevent or reduce the unreasonable risk to a "sufficient extent."[50] This means that before EPA can decide to refer, it must assess the other agency's ability to deal with the risk and compare it to the risk reduction or prevention that would occur if EPA used TSCA risk management options to address that risk. Importantly, EPA's determination of whether an unreasonable risk will be addressed to a sufficient extent by the other agency is based on TSCA's unreasonable risk standard as modified by the Lautenberg Act, in which the determination of the unreasonable risk is to be done "without consideration of costs or other nonrisk factors."[51]

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[49] EPA, "Proposed Asbestos Rule, 87 Fed. Reg. 21706, 21721, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

[50] 15 U.S.C. § 2608(a)

[51] 15 U.S.C. § 2605(a) ("TSCA section 6(a)")

By fundamentally changing the nature of TSCA's unreasonable risk standard to exclude cost or other non-risk factors, the Lautenberg Act also reshaped the determination under section 9(a) regarding whether the application of another statute would reduce the risk to a "sufficient extent." While the analysis of unreasonable risk under TSCA before 2016 inherently incorporated economic or cost factors as well as health or environmental risk factors, that analysis no longer includes non-risk factors. Moreover, TSCA section 6(a) requires EPA at least to eliminate the risks it identifies under TSCA; EPA is to act "to the extent necessary so that the chemical substance or mixture no longer presents such risk." Consequently, as TSCA now imposes a more environmentally and health-protective standard on EPA by generally requiring it to eliminate an unreasonable risk that was identified, without reference to costs or other non-risk factors, the Lautenberg Act has changed the nature of the comparison to other statutes that must be made in evaluating whether they prevent or reduce a risk to a "sufficient extent."

Section 9(b) concerns the "coordination" of EPA's TSCA actions with actions taken under other EPA-administered laws. Under the provision, when EPA has identified unreasonable risk from a substance, it must employ TSCA – rather than another law administered by EPA – unless EPA determines that the risk could be "eliminated or reduced to a sufficient extent by actions taken under the authorities contained" in that law.[52] As with section 9(a), this determination must be based on TSCA's unreasonable risk standard, from which non-risk considerations have been eliminated. Even if EPA were to determine that the other law may eliminate unreasonable risk based on that standard, EPA may determine that it serves the public interest to take actions under TSCA, rather than the other EPA-administered law, to protect against the risk.[53] In that case, EPA would regulate under TSCA.

Important considerations for EPA under post-Lautenberg section 9 in comparing TSCA with another law and deciding whether to refer to another agency or rely on another law include:

- whether the other law provides the authority to regulate to sufficiently eliminate the unreasonable risk;
- whether the other law requires the consideration of costs, economic feasibility, or technical feasibility in establishing regulations;
- whether there are jurisdictional limits on the other law that make it insufficient for regulation of the risk;
- whether the law is able to address the precise risk at issue;
- how quickly and efficiently the other law may be able to address the risk;
- whether the law provides authority to establish requirements related to the core regulation (such as associated reporting requirements); and
- the likelihood that the authority provided by the other law would be exercised.

It is also important to note that EPA has discretion in its key section 9 decision making – its determination whether to refer to another agency under 9(a) and its determination under 9(b) to rely on the public interest to regulate under TSCA rather than another statute is "in the

[52] 15 U.S.C. § 2608(b)(1)

[53] *Id.*

Administrator's discretion."

ii. EPA correctly determined that other laws are not adequate to address the unreasonable risk posed by chrysotile asbestos.

In its Proposed Asbestos Rule, EPA correctly recognizes that TSCA is the only statute adequate to address the unreasonable risk posed by chrysotile asbestos, and therefore necessarily declines to employ section 9 to refer to other agencies or employ other laws implemented by EPA to address the risk.

First, EPA declines to refer the chrysolite asbestos uses for regulation by another agency under section 9(a), fully explaining its bases for this decision. The agency correctly observes that TSCA is the only federal law providing authority to prevent or sufficiently reduce the "cross-cutting exposures" from both workplace and consumer settings.[54] In terms of workplace exposure specifically, EPA recognizes that OSHA does not have authority to issue regulations applicable to all workers; under TSCA, EPA does have that authority. In terms of consumer exposure specifically, EPA recognizes that the Consumer Product Safety Commission lacks the authority to regulate the unreasonable risk in all relevant products, such as automobiles; under TSCA, EPA does have that authority.

EPA also recognizes that the changes to TSCA brought by the 2016 Lautenberg Act significantly reduced the chance that it would not regulate unreasonable risk under TSCA, stating that the amendments to TSCA:

> alter both the manner of identifying unreasonable risk under TSCA and EPA's authority to address unreasonable risk under TSCA, such that risk management under TSCA is increasingly distinct from analogous provisions of the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), or the OSH Act. These changes to TSCA reduce the likelihood that an action under the CPSA, FHSA, or the OSH Act would sufficiently prevent or reduce the unreasonable risk of chrysotile asbestos.[55]

EPA points out numerous ways in which other agencies' statutes prove insufficient to address the unreasonable risk at hand. For example, a CPSA consumer product safety rule must find that the benefits bear a relationship to its costs and must impose "the least burdensome requirement" to reduce the risk of injury. This is in significant contrast to reformed TSCA, by which Congress specifically intended to "delete the paralyzing 'least burdensome' requirement."[56] As another example, to set a PEL under OSHA there must be a showing that it is economically and technologically feasible – a marked contrast to TSCA section 6(a)'s unreasonable risk standard, which excludes such consideration. It would be inconceivable that statutory authority based on criteria removed from TSCA in 2016 as part of the effort to enhance the environmental and

[54] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21732, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

[55] *Id.*

[56] 162 Cong. Rec. S3517 (June 7, 2016)

health protectiveness of the law could be found to reduce risk to a sufficient extent when compared with the risk reduction that would result from the application of TSCA today. EPA's analysis more than sufficiently supports EPA's conclusion that, along with the fact that it is the superior statute to efficiently and effectively manage the chrysolite asbestos risk, "TSCA is the only regulatory authority able to prevent or reduce risks of chrysotile asbestos to a sufficient extent across the range of conditions of use, exposures and populations of concern."[57]

Second, EPA has also correctly determined under section 9(b) that the unreasonable risk from chrysolite asbestos could not be eliminated or reduced to a sufficient extent by actions taken under other federal laws administered by EPA. The agency concludes that only TSCA provides it with the authority to fully address chrysotile asbestos exposure to humans. This is in contrast to the Clean Air Act, which focuses is on releases of asbestos to ambient air, and the Resource Conservation and Recovery Act, the focus of which is on asbestos as a non-hazardous solid waste and is unable to address exposure during manufacture, processing, and distribution in commerce of chrysotile-containing products.

In conclusion, to refer to another agency without authority to reduce identified unreasonable risks or employ other EPA-administered laws that do not provide people and the environment with the protection that TSCA mandates would result in inadequate risk management actions, or even no risk management actions at all. If EPA did so, it would fail to fulfill its duties under TSCA. In the Proposed Asbestos Rule, however, EPA has fully supported its correct decision under section 9 to employ TSCA to regulate the unreasonable risk.

4. EPA should make several improvements in promulgating the other requirements of the final chrysotile asbestos ban.

A. EPA must demonstrate that the cross-referenced disposal requirements eliminate unreasonable risk, and if so, implement such requirements immediately.

In the Proposed Asbestos Rule, EPA proposes to cross-reference existing OSHA and EPA asbestos-containing waste disposal regulations to address unreasonable risk from the disposal of chrysotile asbestos associated with the conditions of use assessed in the Asbestos Part 1 Risk Evaluation.

For all conditions of use, EPA proposes to require adherence to OSHA's Asbestos General Industry Standard in 29 CFR 1910.1001, including 1910.1001(k)(6). In addition, for all but one condition of use (sheet gasket processing and use, for which disposal did not present unreasonable risk), EPA also proposes to require adherence to the Asbestos National Emission Standards for Hazardous Air Pollutants (NESHAP) (40 CFR part 61, subpart M) at 40 CFR 61.150.

EDF has several concerns with EPA's approach to characterizing and regulating risk from disposal activities, primarily that EPA has not demonstrated how compliance with the OSHA Asbestos General Industry Standard and the NESHAP eliminates the unreasonable risk presented

[57] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21733, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

by chrysotile asbestos.

i. EPA should clarify under what conditions of use it found disposal to present an unreasonable risk.

EPA should clarify in its final rule under what conditions of use it found disposal presents an unreasonable risk. It is currently unclear, evidenced by discrepancies in the language used in the description of the diaphragm condition of use in Asbestos Part 1 Risk Evaluation and its short name.

For example, in the Asbestos Part 1 Risk Evaluation, EPA identified disposal as a part of the asbestos diaphragm condition of use (Table 4-4 – Table 4-8, Occupational Exposure Scenario, "Producing, handling, and disposing of asbestos diaphragms"); however, the short name for the diaphragm condition of use does not reflect disposal ("Processing and Industrial use of Chrysotile Asbestos Diaphragms in the Chlor-alkali Industry"). EPA should address this discrepancy in its description and short name for the diaphragm condition of use.

EPA should also clarify whether risk from disposal was determined in isolation or in combination with manufacture, processing, and/or distribution in commerce for each condition of use or product category.

This information is needed to properly assess and comment on EPA's decisions regarding the cross-reference of disposal requirements to address unreasonable risk from disposal under TSCA.

ii. EPA must demonstrate that the cross-referenced disposal requirements eliminate unreasonable risk.

EDF is concerned about EPA's proposal to cross-reference existing OSHA and EPA asbestos-containing waste disposal regulations (specifically, OSHA's Asbestos General Industry Standard disposal requirements in 29 CFR 1910.1001(k), and the disposal requirements of Asbestos National Emission Standards for Hazardous Air Pollutants (NESHAP) (40 CFR part 61, subpart M) at 40 CFR 61.150), given the agency has not demonstrated that such requirements eliminate unreasonable risk as required by TSCA section 6(a).

EPA claims that "[b]y following these existing regulations, worker and ONU exposure to chrysotile asbestos during disposal can be prevented."[58] However, the agency has not demonstrated that following these requirements will prevent worker exposure to the extent "*that chrysotile asbestos no longer presents such risk.*"[59]

[58] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21722, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

[59] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21720, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf (emphasis added)

EPA must verify that the proposed cross-referenced waste disposal requirements will protect against the identified unreasonable risk. To the best of our knowledge, EPA has not presented this evidence.

It is not clear that cross-referencing waste disposal requirements from other environmental health laws, including the Occupational Health and Safety (OSH) Act and the Clean Air Act (CAA) will eliminate the unreasonable risk, given the differences in standards. TSCA requires EPA to use a purely risk-based standard when assessing and managing chemical risk. This contrasts with the OSH Act, which requires OSHA to substantially reduce significant risk to the extent feasible, as well as CAA, which requires EPA to issue technology-based emission standards. In both cases, the cross-referenced requirements are not purely risk-based and were not designed to eliminate unreasonable risk as defined under TSCA.

OSHA

EPA has not explained how compliance with OSHA's Asbestos General Industry Standard disposal requirements in 29 CFR 1910.1001(k) addresses the unreasonable risk from asbestos disposal activities.

OSHA waste disposal regulations in 29 CFR 1910.1001(k)(6) state that "Waste, scrap, debris, bags, containers, equipment, and clothing contaminated with asbestos consigned for disposal, shall be collected, recycled and disposed of in sealed impermeable bags, or other closed, impermeable containers."

In its asbestos regulations, OSHA does not indicate the extent to which these waste disposal requirements will reduce exposure. This information is necessary to assess whether exposure would be reduced enough to meet EPA's proposed risk-based ECEL of 0.005 fibers/cm^3. In addition to the lack of evidence in this regard, there is no reason to believe that these requirements would reduce exposures below the OSHA-issued permissible exposure limit (PEL) set at 0.1 f/cm^3 (8-hour TWA), which is much higher than the proposed ECEL under TSCA.

NESHAP

Similarly, EPA has not explained how compliance with NESHAP asbestos disposal regulations at 40 CFR 61.150 addresses the unreasonable risk from asbestos disposal activities. EPA states that "[t]he asbestos NESHAP reduces exposure to airborne asbestos by generally requiring sealing of asbestos containing waste material from regulated activities in a leak-tight container and disposing of it in a landfill permitted to receive asbestos waste."[60] However, this statement is inconsistent with the regulations at 40 CFR 61.150, which specifies the following requirements for regulated entities:

> (a) Discharge no visible emissions to the outside air during the collection, processing (including incineration), packaging, or transporting of any asbestos-containing waste material generated by the source, **or use one** of the emission control and waste treatment methods specified in paragraphs (a) (1) through (4) of this section. (emphasis added)

[60] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21722, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

Further, visual emissions are defined in the NESHAP regulations at 40 CFR 61.141 as "any emissions, which are visually detectable without the aid of instruments, coming from RACM or asbestos-containing waste material, or from any asbestos milling, manufacturing, or fabricating operation. This does not include condensed, uncombined water vapor."

EPA explained in the National Emission Standards for Hazardous Air Pollutants; Asbestos NESHAP Revision final rule (55 Fed. Reg. 48406 November 20, 1990) that visible emissions are used to identify a "serious control devise malfunction."

> While the absence of visible emissions does not mean there are no asbestos fibers being emitted, the presence of visible emissions does indicate a serious control device malfunction. Because visible emissions monitoring is intended primarily to detect serious control device malfunctions, weekly inspections of air cleaning devices are also required.

EPA has not explained how a standard of "no visible emissions" (particularly given EPA's definition of visible emissions at 40 CFR 61.141) would equate with no unreasonable risk. "No visible emissions" is essentially a qualitative measure. EPA has not explained how this measure translates into a quantitative value and how it relates to EPA's proposed ECEL of 0.005 fibers/cm^3, a very low number.[61]

In sum, EPA has failed to demonstrate that following existing regulations from OSHA and EPA (NESHAP) waste disposal requirements will adequately protect workers and the public from unreasonable risk, as defined under TSCA. Moving forward, EPA must demonstrate that the cross-referenced waste disposal regulations would address the unreasonable risk.

iii. If EPA demonstrates that the cross-referenced disposal requirements eliminate unreasonable risk, such requirements should be effective immediately.

If EPA verifies that the cross-referenced waste disposal requirements eliminate the identified unreasonable risk, we argue that any cross-referenced waste disposal and recordkeeping requirements should be effective immediately following the publication of the final rule for all sectors currently subject to OSHA and/or NESHAP regulations, as opposed to the agency's proposed 180-day waiting period. Given that these industries have been subject to the proposed OSHA and NESHAP disposal requirements for over thirty years, there is no need to delay the effective date of these cross-referenced disposal requirements by 180 days; they should be effective immediately.

B. EPA should not set a *de minimis* level for chrysotile asbestos.

Given the well-documented toxicity of chrysotile asbestos, particularly the thousands of fatalities each year resulting from chrysotile asbestos exposure, EPA should not set a *de minimis* level for

[61] While this is a very low number, it is not adequate. It is based on a cancer risk benchmark of 10^{-4}. As we have noted elsewhere in our comments, EPA should use the benchmark of 10^{-6} that it uses for the general population and non-worker potentially exposed or susceptible populations. There is no reason to be less protective of workers.

chrysotile asbestos. In EPA's request for comment on whether a *de minimis* level should be established, the agency notes that "asbestos is a natural (sic) occurring fiber that may be unintentionally present." Actually, EPA is referring to the instances where asbestos, though it is a naturally occurring fiber, has been removed from its natural origin and anthropogenically introduced into manufacturing and processing activities and into products. These activities expose people to asbestos. It is not as if EPA were considering a *de minimis* exemption for exposure to asbestos where naturally found. The fact that asbestos was naturally occurring before it was mined or otherwise disturbed should not be the rationale for establishing a *de minimis* exemption that would apply to its anthropogenic use.

C. EPA should adopt several improvements to its ECEL air sampling and analytical methods requirements.

In the case that EPA finalizes a rule that employs an ECEL in the interim of a ban, we provide the following recommendations on air sampling and analytical method requirements.

To the extent that EPA promulges a final rule including an ECEL, EDF supports requiring the use of transmission electron microscopy (TEM) as proposed for air sampling. Unlike phase contrast microscopy (PCM), TEM allows for the identification of the type of asbestos fibers present and for smaller fibers. EPA's own materials on asbestos sampling point to shortcomings of the PCM approach, including that it "cannot distinguish between asbestos fibers and other kinds of fibers which may be present in the air" and "cannot detect thin asbestos fibers, and does not count short fibers."[62]

We also provide the following comments on EPA's proposed sampling scheme:

- Initial monitoring: EPA appears to be considering allowing two options for companies:

  > Under this alternative action, the initial monitoring would be taken when the operating conditions are representative of the potential exposures of persons in the workplace, *or* of a representative sample of persons in each type of job task during every work shift who are reasonably likely to be exposed to chrysotile asbestos in the workplace.[63]

  We recommend that EPA require the latter option, such that samples collected represent exposure to all job types, including those closest to the source(s) of asbestos because it is more accurate. In contrast, area monitoring may underestimate the true exposures.

[62] EPA, "Monitoring Asbestos-Containing Material (ACM)," last updated April 19, 2022, https://www.epa.gov/asbestos/monitoring-asbestos-containing-material-acm

[63] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21723, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf (emphasis added). We note that other language in the preamble under "Additional exposure monitoring" implies that the regulated industry can determine whether to use area monitoring at any stage ("If the regulated entity is using area monitoring or a representative sampling monitoring…", 21724). To the extent that this is accurate, we recommend requiring a representative sample of persons in each type of job task during every work shift for each monitoring scenario.

Furthermore, to the extent that EPA allows for data collected in the five years preceding the rule to serve as baseline data, EPA should specify detailed criteria to ensure that such data are sufficiently robust and of comparable quality to data newly collected under the rule.

- Termination of monitoring: If all samples taken during initial exposure monitoring or during periodic exposure monitoring reveal concentrations below the ECEL action level, EPA is proposing to allow the regulated entity to terminate monitoring (except as otherwise described). This may allow companies to "test out" of the ECEL prematurely. While the "additional exposure monitoring" requirements somewhat temper this concern, allowing companies to terminate monitoring so quickly places a large burden on EPA to ensure that the initial and periodic exposure monitoring sampling was conducted in a sufficiently robust manner to ensure that there is no unreasonable risk from asbestos in these facilities without ongoing sampling.

- Additional monitoring: EDF supports additional exposure monitoring triggered by events such as changes in production volume, use rate, process, control equipment, and personnel as well as start-up, shutdown, or malfunction that may reasonably be anticipated to result in increased exposure levels. If EPA includes an ECEL in the final rule, it should provide clear guidance on the full suite of events it believes would meet these criteria.

D. Unless EPA institutes a ban that is effective 180 days after the publication of the final rule, the agency should require downstream notification.

Unless EPA institutes a ban that is effective 180 days after publication of the final rule, EPA should require downstream notification during the interim period between the publication of the rule and when the ban takes effect.

EPA's proposed downstream notification approach would require regulated entities to add to sections 1(c) and 15 of the SDS the following language: "This chemical/item is not and cannot be distributed in commerce (as defined in TSCA section 3(5)) or processed (as defined in TSCA section 3(13)) for commercial and consumer use after [prohibition date]."

Unfortunately, EPA did not include a provision for downstream notification in its primary proposal, despite doing so in its proposed primary alternative. Downstream notification is an important tool for companies downstream in the supply chain. It helps ensure that processors, distributors, and other customers and users are aware of chemical restrictions and have the chance to make the necessary preparations to deal with such restrictions, such as the proposed asbestos ban. Downstream notification also streamlines and facilitates compliance and overall enforcement of the risk management actions.

For these reasons, EPA should include a downstream notification requirement in promulgating the final rule for the processing and industrial use of chrysotile asbestos diaphragms in the chlor-alkali industry and chrysotile asbestos-containing sheet gaskets in chemical production so that

those entities that receive chrysotile asbestos will be notified that chrysotile asbestos or an item containing chrysotile asbestos cannot be distributed in commerce after the date of the ban.

Given EPA's assumption that 180 days is a reasonable amount of time to set up the notification system and make the necessary changes to safety data sheets (SDSs),[64] a downstream notification requirement starting 180 days after the rule is published in the Federal Register should be feasible.

5. EPA should bolster its Economic Analysis for the final rule to more accurately reflect the rule's overall benefits.

As described in section 2A of these comments, EPA has successfully fulfilled its obligations to consider the costs and benefits of the Proposed Asbestos Rule as required by TSCA section 6(c)(2). However, EPA's Economic Analysis[65] significantly underestimates the direct benefits of the Proposed Asbestos Rule through a number of exclusions and flawed assumptions. While not required to justify the finalization of the Proposed Asbestos Rule, EPA should bolster its analysis for the final rule to more accurately reflect the overall benefits. The agency's underestimation of direct benefits from the Proposed Asbestos Rule results from the following issues.

A. EPA included only a subset of health endpoints.

In its cost-benefit analysis, EPA assessed only avoided lung cancer, mesothelioma, ovarian cancer, and laryngeal cancer – ignoring benefits of all other avoided health impacts that would result from the Proposed Asbestos Rule. Critically, EPA excluded a number of cancers linked to asbestos exposure (e.g., cancer of the pharynx, colorectum, and stomach) as well as several respiratory illnesses, including asbestosis, all of which are described in the Asbestos Part 1 Risk Evaluation.[66] While EPA may not have the data needed to quantify or monetize the benefits of avoiding such health effects, it should at a minimum describe the qualitative benefits of avoiding these health outcomes.

B. EPA inappropriately assumed consistent PPE use in baseline exposure calculations.

In June 2021, the agency announced a new policy to discontinue its prior assumption that workers are always provided, and use, personal protective equipment (PPE) appropriately when

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[64] *See* EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21727, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf: "The [downstream notification] requirement under the primary alternative regulatory action would take effect 180 days after the effective date of the final rule in order to provide adequate time to undertake the changes to the SDS and ensure that all products in the supply chain include the revised SDS."

[65] EPA, "Economic Analysis of the TSCA Section 6 Proposed Rule for Asbestos Risk Management, Part 1 ("Economic Analysis")," April 2022, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0008/content.pdf

[66] EPA, "Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos" ("Asbestos Part 1 Risk Evaluation"), December 2020, 150-151, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_asbestos_part_1_chrysotile_asbestos.pdf

assessing risk and making risk determinations under TSCA.[67] Consistent with concerns with PPE illustrated by this policy, EPA is appropriately proposing a regulatory approach that eliminates the substance (i.e., a ban) rather than an approach that relies on worker behavior and PPE (e.g., respirators).

Despite this, in its cost-benefit analysis, EPA assumes that baseline asbestos exposure would be considerably reduced by PPE use in the occupational setting – resulting in a range of 10-1,000-fold decrease in estimated baseline exposure.[68] This is particularly troubling for the chlor-alkali industry, where EPA has assumed in its baseline scenario, without appropriate substantiation, that all workers are provided with and appropriately use respirators – half with an assigned protection factor (APF) of 10 and the other half with an APF of 25. While far from transparent in the Economic Analysis, it appears EPA made this assumption based on a comment from the Chlorine Chemistry Division of the American Chemistry Council[69] that describes respirator use for some chlor-alkali industry processes, but not all. In the Asbestos Part 1 Risk Evaluation, EPA itself characterizes the ACC report as describing respirator use "by some chlor-alkali workers."

Furthermore, it does not appear that EPA independently validated industry's claims of PPE use. For all other conditions of use, EPA does incorporate data on PPE usage based on surveys conducted by the Bureau of Labor Statistics and NIOSH in the early 2000s to calculate the baseline percentage of PPE use. However, EPA acknowledges that "[t]he extent to which PPE is properly used in the baseline has an effect on the baseline level of exposures that contribute to health risks"[70] – yet fails to account for improper PPE use in its calculation.

Given the extensive evidence that PPE has major real-world limitations,[71] such assumptions will likely result in an underestimation of baseline workplace exposure to asbestos and a

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[67] EPA, "EPA Announces Path Forward for TSCA Chemical Risk Evaluations," June 30, 2021, https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

[68] EPA, "Economic Analysis," *supra* note **Error! Bookmark not defined.**, ES-5, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0008/content.pdf

[69] *See* Table 4-3 of final Asbestos Part 1 Risk Evaluation references "EPA-HQ-HPPT-2016-0736-0052, Enclosure C." This appears to be referencing https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0736-0052 (Enclosure C). The tables on pp. 5-6 describe the chlor-alkali industry processes for which ACC claims that respirators of APF 10 and 25 are and are not required.

[70] EPA, "Economic Analysis," 4-12, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0008/content.pdf

[71] For example, EPA's 2017 proposed rule, "Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing under TSCA §6(a)" (https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01229.pdf) states: "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-facepiece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable

commensurate underestimate of benefits from avoided exposure and resulting health effects that the rule would afford. In updating the Economic Analysis for the final rule, EPA should calculate the benefits based on more realistic and substantiated assumptions of exposure reductions from PPE use, including actual use in the chlor-alkali industry and factors that may reduce its efficacy even when assumed to be used (e.g., appropriate mask fit). In particular, EPA could conduct a sensitivity analysis assuming no PPE use to better understand the full range of potential benefits from the Proposed Asbestos Rule, including how different PPE assumptions impact the calculated benefits.

C. EPA has dramatically underestimated the number of individuals who would benefit from the Proposed Asbestos Rule.

The Economic Analysis assumes that a mere 144 workers, 276 occupational non-users, and 400 consumers are exposed annually to chrysotile asbestos[72] – a dramatic reduction from the expected number of exposed persons in the final 2020 Asbestos Part 1 Risk Evaluation. In the Asbestos Part 1 Risk Evaluation, for example, EPA estimated that approximately 15,929 consumers are exposed to asbestos through aftermarket automotive breaks, linings, and clutches.[73] EPA revised this value down to 400, apparently based on assertions from importing companies that their brakes do not actually contain asbestos.[74] Aside from industry statements, it appears that EPA made no attempt to independently verify these claims. Furthermore, EPA has not addressed general population exposure to asbestos from these conditions of use, even qualitatively. The result of these inappropriate assumptions is that EPA has vastly underestimated the size of the population that will benefit from the Proposed Asbestos Rule – resulting in artificially low monetized benefits.

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protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good facepiece fit, including those individuals whose beards or sideburns interfere with the facepiece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems and vision problems, increase worker fatigue, and reduce work efficiency (Ref. 37). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health.' (Ref. 37, at 1189-1190)."

[72] EPA, "Economic Analysis," 4-6 (Table 4-3), https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0008/content.pdf

[73] EPA, "Asbestos Part 1 Risk Evaluation," 226 (Table 4-56), https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_asbestos_part_1_chrysotile_asbestos.pdf

[74] EPA, "Economic Analysis," 3-37, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0008/content.pdf

While EPA underestimated the direct benefits of the rule, we applaud EPA for analyzing co-benefits from air quality improvements and greenhouse gas emission reductions as a result of switching to membrane cells. EPA's cost-benefit analysis demonstrates that after just one year, these co-benefits alone would outweigh the costs of the rule. EPA's approach is consistent with both OMB Circular A-4[75] and EPA's Guidelines for Preparing Economic Analyses,[76] which call for the inclusion of indirect (or ancillary) benefits.

The Institute for Policy Integrity at New York University School of Law and Professor Rachel Rothschild have submitted detailed comments on the shortcomings of EPA's Economic Analysis and solutions that can be implemented without delaying the finalization of the rule. EDF supports these comments.

6. EPA should address the following cross-cutting issues that impact its ability to address unreasonable risks.

This rulemaking provides a model for future risk management rules under TSCA. The assumptions and positions EPA takes in this rulemaking are applicable to other chemicals undergoing risk management. In addition, in the preamble EPA provides notice on risk management considerations it intends to include in its risk evaluations, including voluntary industry practices and existing regulations under statutes other than TSCA including those that have non-universal applicability and/or different statutory risk findings and standards. The following comments focus on these cross-cutting issues raised in this action.

A. EPA should not include non-risk factors and risk management activities in its risk evaluations. The approach is not scientifically supportable and conflicts with sections 6(b)(4) and conflates sections 6(a) and 6(b).

In its preamble to the Proposed Asbestos Rule, titled *Risk Evaluation To Inform Risk Management Requirements*, EPA states:

> In addition to the baseline scenario described previously, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the agency.[77]

[75] OMB, "Circular A-4, Regulatory Analysis," September 17, 2003, https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf

[76] EPA, "Guidelines for Preparing Economic Analyses," December 2010, 11-2, https://www.epa.gov/sites/default/files/2017-09/documents/ee-0568-11.pdf

[77] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21713, https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

EPA further states that "In the TSCA Risk Evaluation for Asbestos, Part 1 for chrysotile asbestos, EPA presented risk estimates based on workers' exposures with and without respiratory protection."[78]

The consideration of OSHA requirements that EPA has included in its risk evaluations are *risk management* activities, specifically those that are within the scope of section 6(a)(5): "A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture."

The OSHA requirements referred to by EPA require that companies meet chemical-specific PELs and ancillary provisions that regulate the manner or method of commercial use of the chemical.[79]

EPA's inclusion of risk management considerations in its risk evaluations, including the risk evaluation for chrysotile asbestos, is flawed.

TSCA section 6(b)(4) precludes the consideration of "costs or other nonrisk factors".

> (4) Risk evaluation process and deadlines
> (A) In general
> The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, **without consideration of costs or other nonrisk factors**, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.[80]

The use of PPE or any other mechanism to mitigate exposure and risk is a non-risk factor because it is not part of a baseline risk assessment. Thus, these risk mitigation factors should not be considered in any form as part of the risk evaluation. The risk evaluation is based on the risk assessment paradigm and includes the following steps to determine whether a chemical presents an unreasonable risk: hazard identification; dose-response assessment; exposure assessment; and risk characterization.[81] None of these steps in the risk assessment paradigm include consideration of the use PPE or the assumption of any other risk mitigation actions.

While risk mitigation factors consider risk because they typically lessen the exposure to a chemical or other pollutant they are generally not a part of an exposure assessment (and thus not

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[78] *Id.*

[79] Although, for reasons discussed elsewhere in these comments, these OSHA requirements do not address the TSCA unreasonable risk.

[80] 15 U.S.C. § 2605(b)(4) (emphasis added)

[81] *See* EPA, "Human Health Risk Assessment," last updated June 22, 2022, https://www.epa.gov/risk/human-health-risk-assessment

part of a risk assessment). Neither EPA's "Guidelines for Human Exposure Assessment"[82] nor EPA's Exposure Factors Handbook[83] includes the use of PPE or other risk mitigation factors. The Exposure Factors Handbook considers activity patterns and inhalation rates for workers and consumers but not the use of respirators or other PPE by the worker or the use of a label by a consumer.

Aside from the fact that risk mitigation is not part of the risk assessment paradigm, including risk mitigation factors into the risk evaluation would conflate risk management in section 6(a) – which specifically provides options for risk mitigation – with the risk evaluation of section 6(b).

There are several additional reasons why the risk mitigation factors should not be considered in a risk assessment, particularly a risk assessment that will be the basis for a regulation that will apply to a range of facilities. The use and effectiveness of a specific risk mitigation action will vary and will be dependent upon factors, including cost considerations, associated with the process, the equipment used and attributes of a workplace that may be specific to an industry sector, an individual company or plant. Similarly, for a consumer, the effectiveness of a product label at reducing risk will vary based on factors such as literacy and experience. These are not risk assessment factors.

Even if a risk mitigation action such as use of a respirator were considered, that in itself is not a risk factor the way the specific toxicity presented by a chemical is. A respirator is a tool to reduce the exposure to the person wearing the respirator (provided that the person has been fit-tested and is wearing the respirator in an appropriate manner). The assigned protection factor of the respirator is not specific to the chemical. The appropriate respirator is the respirator both applicable to the type of chemical being used and the level of exposure to the chemical. The level of exposure will depend on the specifics of the workplace. EPA cannot predetermine whether the use of a respirator will lessen exposure sufficiently so that the unreasonable risk is mitigated because EPA does not know what the baseline will be for a particular facility.

Thus, EPA's assumption on the use of specific PPE, e.g., a respirator with a particular APF, or a particular type of engineering control that may be used by some facilities inappropriately applies a site-specific type of assessment to a range of facilities, including those for which it is completely inappropriate. This is an approach that is inconsistent with the risk assessment paradigm and ignores the proven approach of the use of occupational exposure limits and the hierarchy of controls.

B. EPA incorrectly states that compliance with OSHA PELs may protect against unreasonable risks.

In the Proposed Rule, EPA states:

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[82] EPA, "Guidelines for Human Exposure Assessment (EPA/100/B-19/001)," October 2019, https://www.epa.gov/sites/default/files/2020-01/documents/guidelines_for_human_exposure_assessment_final2019.pdf

[83] EPA, "EPA's Exposure Factor Handbook," https://www.epa.gov/expobox/about-exposure-factors-handbook

> For evaluation scenarios which involve OSHA chemical-specific PELs, EPA's risk evaluation in some cases may illustrate that limiting exposure to OSHA's PEL would result in risk levels below the benchmark under the TSCA standard under certain conditions of use.[84]

While there may be some very limited circumstances under which this statement could theoretically be true, this statement is misleading in two significant ways. There is a fundamental difference in the consideration of standards under the OSH Act and under TSCA section 6. In determining risk under TSCA, EPA is directed to not consider cost or other non-risk factors (TSCA section 6(b)). In contrast, in setting a PEL, OSHA must consider technological and economic feasibility. In addition, even without considering technological and economic feasibility, a greater degree of risk is acceptable under the OSH Act (significant risk)[85] than under TSCA (unreasonable risk). Thus, even where the technological and economic feasibility considerations are essentially zero, an unreasonable risk under TSCA would not likely be considered a significant risk under the OSHA Act. Therefore, it is not clear how EPA could envision more than a few isolated scenarios where "EPA's risk evaluation in some cases may illustrate that limiting exposure to OSHA's PEL would result in risk levels below the benchmark under the TSCA standard under certain conditions of use."

It is even more unlikely that this could be the case when one considers that OSHA's Permissible Exposure Limits are antiquated and outdated to such an extent that OSHA includes the following statement on its Permissible Exposure Limits – Annotated Tables web page:

> Industrial experience, new developments in technology, and scientific data clearly indicate that in many instances these adopted limits are not sufficiently protective of worker health. This has been demonstrated by the reduction in allowable exposure limits recommended by many technical, professional, industrial, and government organizations, both inside and outside the United States. Many large industrial organizations have felt obligated to supplement the existing OSHA PELs with their own internal corporate guidelines.[86]

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[84] EPA, "Proposed Asbestos Rule," 87 Fed. Reg. 21706, 21713 (Section II.C.3. *Consideration of OSHA standards in TSCA risk management actions*), https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0057-0006/content.pdf

[85] OSHA, "Chemical Management and Permissible Exposure Limits (PELs); Proposed Rule," 79 Fed. Reg. 61383-61438, October 10, 2014, https://www.osha.gov/laws-regs/federalregister/2014-10-10

[86] OSHA, "Permissible Exposure Limits – Annotated Tables," accessed July 12, 2022, https://www.osha.gov/annotated-pels

Indeed, "more than 90% of current permissible exposure limits date to industry consensus standards set in the 1960s."[87] Of note, the OSHA PEL for asbestos (0.1 fibers/cm^3) is 20x higher than the proposed ECEL of 0.005 fibers/cm^3.

C. EPA should not treat workers differently from the general population by applying a less protective cancer benchmark for workers.

In the Asbestos Part 1 Risk Evaluation, EPA identified unreasonable risks for cancer from chronic inhalation exposure to chrysotile asbestos to workers, occupational non-users (ONUs), consumers and bystanders. These determinations of unreasonable risk were based on different cancer benchmarks depending on the subpopulation. A benchmark of 1 x 10^{-6} was used for consumers and bystanders and a less protective benchmark of 1 x 10^{-4} was used for workers and occupational non-users. In the current rule, the ECEL proposed in the regulatory alternative is also based on the benchmark used for workers and occupational non-users.

EPA should not treat workers differently than the general population when making an unreasonable risk determination under TSCA section 6(b)(4). This differential treatment is based on non-risk factors and is thus prohibited under TSCA section 6(b)(4).

EPA says that it uses a range of 10^{-4} to 10^{-6} for determining acceptable cancer risks under TSCA for everyone, including workers. That is – if the risk falls within this range, EPA will determine on a case-by-case basis if the risk is unreasonable. EPA states in the Asbestos Part 1 Risk Evaluation[88] that this approach is justified because it is consistent with the agency's approach under the Clean Air Act to evaluate residual risk and with the cancer benchmark used by NIOSH.[89] However, because under TSCA EPA categorically uses a benchmark of 10^{-4} for workers and a benchmark of 10^{-6} for everyone else, what is done under TSCA is not actually a range, is not supported by TSCA, and is not consistent with its use of cancer benchmarks under the Clean Air Act.

i. TSCA does not support a higher risk of cancer for workers.

When EPA determines whether a risk is acceptable or unreasonable, it usually does so on a case-by-case basis. However, under TSCA, EPA has not been applying the acceptable risk range on a case-by-case basis. Rather, it takes a categorical approach that bifurcates workers from other people and accepts a higher cancer risk for workers by stating that a cancer risk of less than 10^{-4} is generally acceptable for workers while the more protective cancer risk benchmark of 10^{-6} is

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[87] David Michaels & Jordan Barab, "The Occupational Safety and Health Administration at 50: Protecting Workers in a Changing Economy," *Am J Public Health* 110, no. 5 (April 8, 2020): 631-635. https://doi.org/10.2105/ajph.2020.305597

[88] EPA, "Asbestos Part 1 Risk Evaluation," 230 (Section 5.1.2 *Risks to Human Health*), https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_asbestos_part_1_chrysotile_asbestos.pdf

[89] NIOSH, "Current intelligence bulletin 68: NIOSH chemical carcinogen policy," 2016, https://www.cdc.gov/niosh/docs/2017-100/pdf/2017-100.pdf

generally acceptable for everyone else – consumers, the general population, and non-occupational "potentially exposed or susceptible subpopulations." This means the acceptable cancer risk level for workers is 100 times less protective than for everyone else. By doing this, EPA is putting workers at greater risk.

EPA's rationale for treating workers inequitably under TSCA is in part that a cancer risk of 10^{-4} is the benchmark NIOSH uses as its risk management limit.[90] The agency cites the 2017 NIOSH Bulletin No 68 as a justification for its cancer benchmark for workers. Indeed, the bulletin states that exposures to workers should be kept below a risk level for 1 in 10,000. However, NIOSH also states this risk level is "considered to be a starting point for continually reducing exposures in order to reduce the remaining risk."[91] Thus, it is unclear why EPA did not apply the lower cancer benchmark of 1×10^{-6} to workers as well. Biologically, there is no reason to distinguish between workers and non-workers such as bystanders, consumers, and the general population. The only difference is that the person happens to be a worker exposed to a toxic chemical, often at greater levels than other groups. Workers are equally susceptible to the health effects associated with asbestos exposure, which is confirmed by decades' worth of scientific literature.

The cancer benchmark 10^{-4} for workers was originally established in OSHA regulations in the 1970s, and NIOSH's use of this benchmark reflects this context. The benchmark that OSHA and NIOSH use reflects a consideration of acceptable risk considering costs and the technology of the 1970s. However, technology across our economy has improved since then. Manufacturing equipment is more effective at decreasing exposure to workers. There is also greater availability of and a greater focus on less-toxic substitutes.

While the consideration of costs and related factors may be appropriate given the statutory mandates of the Occupational Safety and Health (OSH) Act and subsequent regulations and related judicial decisions, consideration of costs and other non-risk factors are specifically prohibited in the consideration under TSCA section 6 of:

> whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.[92]

In addition, even if the 1970s-era NIOSH/OSHA benchmarks *were* still appropriate, the fact that NIOSH uses a particular cancer benchmark does not justify the fact that under a single statute – TSCA – EPA takes a differential approach for workers and other people.

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[90] EPA, "Asbestos Part 1 Risk Evaluation," 230, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_asbestos_part_1_chrysotile_asbestos.pdf

[91] NIOSH, "Current intelligence bulletin 68: NIOSH chemical carcinogen policy," 2016, https://www.cdc.gov/niosh/docs/2017-100/pdf/2017-100.pdf

[92] 15 U.S.C. § 2605(b)(4) ("TSCA section 6(b)(4)(A)")

As noted above, in the Asbestos Part 1 Risk Evaluation, EPA also points to the approach taken under the Clean Air Act for cancer benchmarks as support for the approach taken under TSCA section 6. However, the approach EPA takes under TSCA is inconsistent with the approach it takes under the Clean Air Act. Under the Clean Air Act, EPA considers a range of cancer benchmarks.[93] The agency considers a cancer risk of 10^{-6} generally acceptable and a risk of greater than 10^{-4} generally unacceptable. For risks within those bookends, EPA will take in account several factors in determining whether a risk is unacceptable, including among others the distribution of risk within the population and the presence of sensitive subpopulations at various risk levels. Unlike EPA's current approach under TSCA, under the Clean Air Act, EPA has not established one acceptable risk level for one group of people and another for a different group.

It should be noted that Congress defined "potentially exposed or susceptible subpopulation" to include workers, under TSCA section 3(12), and that under the conditions of use for chrysotile asbestos, workers are clearly a relevant subpopulation[94] because they are highly exposed. Thus, TSCA requires that workers be given particular consideration – not lesser protection.

EPA's approach is baffling as well as unsupportable. Treating workers differently is not based on risk factors. Certainly, EPA's risk assessment guidelines do not identify workers or any other subpopulation that would warrant a less protective risk benchmark than the general population nor do the guidelines identify risk factors that would support such an approach.[95] Therefore, for EPA to take this less protective approach to worker risk is inconsistent with the requirement of section 26(h).

EPA's bifurcated approach to workers vs. everyone else for cancer risks is illogical and inconsistent. An example that highlights the absurdity is the situation where a worker is exposed to a chemical in the workplace and to the same chemical from a consumer product. In this case, EPA would apparently use two different acceptable risk levels for the same person.
Perhaps because of its illogic, EPA does not take this bifurcated approach to workers and the rest of the population when it considers the risks for chemicals that are not carcinogens. It should not do so in the case of cancer risk.

Finally, under the 2016 amended TSCA, before the Trump Administration took office, EPA did appropriately use a range of cancer benchmarks for workers, and not the current inequitable approach. Specifically, the agency used this cancer benchmark range for the two proposed rules

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[93] EPA, "Residual Risk Report to Congress (EPA—453/R-99-001)," March 1999, https://www.epa.gov/sites/default/files/2013-08/documents/risk_rep.pdf

[94] 15 U.S.C. § 2602(12)

[95] *See*, for example, Risk Assessment Guidance (https://www.epa.gov/risk/risk-assessment-guidance); Conducting a Human Health Risk Assessment (https://www.epa.gov/risk/conducting-human-health-risk-assessment); Guidelines for Carcinogen Risk Assessment (https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment); Guidelines for Human Exposure Assessment (https://www.epa.gov/risk/guidelines-human-exposure-assessment); EPA's Exposure Factors Handbook (EFH) (https://www.epa.gov/expobox/about-exposure-factors-handbook)

for trichloroethylene and one for methylene chloride.[96] It appears that the current approach, in which workers are less protected, is a problematic hold-over from the Trump Administration.[97]

ii. Workers often face higher risks than the general population, making a less protective standard particularly unjustified.

Another reason that EPA should not use a less protective standard for workers is that Congress explicitly included them in TSCA as a "potentially exposed or susceptible subpopulation," [98] given that they often face higher overall risks. Workers are often exposed to multiple chemicals, some that are probable or known carcinogens, and often at greater levels than the general population. Setting a cancer benchmark of less than one in one million could still lead to cumulative risks of 10^{-4} to 10^{-6} for the combination of the chemicals many workers are exposed to in the workplace and often also at home. This is analogous to the approach EPA has taken under the Superfund program where there is likely increased risk from multiple chemicals.[99]

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In sum, under TSCA, EPA should use the same benchmark approach for everyone. There is no scientific reason to treat workers differently than everyone else. Risks that are considered unreasonable risks for the general population should not be considered reasonable for workers. We encourage EPA to change their approach to cancer benchmarks so that risks faced by workers are considered equitably.

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[96] EPA, "Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a)," 81 Fed. Reg. 91592, December 16, 2016, https://www.govinfo.gov/content/pkg/FR-2016-12-16/pdf/2016-30063.pdf; EPA, "Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a)," 82 Fed. Reg. 7432, January 19, 2017, https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01229.pdf; EPA, "Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a)," 82 Fed. Reg. 7464, January 19, 2017, https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01222.pdf

[97] It should be noted that for at least two (1-bromopropane and 1,4-dioxane) of the first ten TSCA risk evaluations conducted under the Trump EPA, the Scientific Advisory Committee on Chemicals (SACC) expressed concern that EPA's decision to use 1 x 10^{-4} as the cancer risk benchmark for workers "may not be stringent enough" (*see "*1-BP TSCA SACC Meeting Minutes Final Report, "https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0235-0061, 53) and asked for explanation and justification behind its decision (*see* "SACC July 2019 Meeting Minutes and Final Report Docket" pertaining to the draft risk evaluation for 1,4-dioxane, https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0063, 23 and 76).

[98] 15 U.S.C. § 2602(12) ("TSCA section 3(12)")

[99] *See,* for example, the Technical Background Document (https://www.epa.gov/superfund/superfund-soil-screening-guidance#technical) for the Soil Screening Guidance (https://semspub.epa.gov/work/HQ/175238.pdf) used by EPA to help standardize and accelerate the evaluation and cleanup of contaminated soils at sites on the National Priorities List (NPL) with anticipated future residential land use scenarios.

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The Environmental Defense Fund appreciates EPA's consideration of these comments.