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EWG Comments on the Problem Formulation of the Risk Evaluation for Asbestos

Docket ID No.: EPA-HQ-OPPT-2016-0736

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The Frank R. Lautenberg Chemical Safety Act for the 21st Century (hereinafter “Lautenberg Act”) for the first time requires the Environmental Protection Agency (EPA) to comprehensively review existing chemicals on the TSCA inventory, including asbestos. Prior to the passage of the Lautenberg Act, EPA’s failure to ban asbestos was pointed to as a primary example of the failure TSCA to protect Americans from toxic chemicals and other toxic substance. Many are looking to the EPA’s risk evaluation of asbestos as an important litmus test of the strengths of the new law. As such, EWG is alarmed by EPA’s decision to excluded key exposures, populations, and health effects from its problem formulation.

EWG also has deep concerns with regards to EPA’s approach to the problem formulations for the other nine chemicals undergoing risk evaluation under section 6. EWG is particularly concerned with EPA’s decision to exclude from consideration major sources of exposure to the first nine chemicals from sources regulated under other EPA statutes like the Clean Air Act, Clean Water Act, and the Resources Conservation and Recovery Act (RCRA). EWG has joined the comprehensive comments prepared by Earthjustice on the problem formulations, and strongly supports the arguments in those comments demonstrating how EPA has strayed from its statutory obligations to holistically consider all uses of a chemical during a chemical risk evaluation.

EWG also has significant concerns about any EPA plans to rely on its flawed framework for systematic review when conducting risk evaluations. This is especially true with regards to chemicals that have already completed an EPA IRIS assessment. EWG has joined comments prepared by the National Resources Defense Council identifying particular flaws in the systematic review framework document. The approach proposed in that document should not be applied to the asbestos risk evaluation or the risk evaluations for the other nine chemicals under review.

The following comments are meant to assist EPA to strengthen the proposed problem formulation for asbestos before it moves into the risk evaluation phase of the review process. In particular, EWG comments that the EPA’s problem formulation should be revised to include:

- Other elongated mineral particles in the definition of asbestos, including non-asbestiform EMPs,
- Reasonably foreseeable uses,

- The entire lifecycle of the chemical, including legacy uses and legacy disposal,
- Exposures covered by other agencies and statutes (non-TSCA),
- Exposures from asbestos contamination,
- Exposures for which data is limited,
- Risks from cancer other than lung cancer, as well as non-cancer effects,
- Risks to potentially exposed and susceptible populations, and
- Risks from aggregate and cumulative exposures

EWG also comments that because asbestos is a naturally-occurring toxic mineral, EPA must consider the significant body of science on the health effects of asbestos and similar fibrous minerals. EPA should avoid relying on the same scientific methods used to understand negative human health effects of chemicals where the dose-response relationship is measured in minutes or hours, which may not be applicable to bio-persistent minerals like asbestos. Asbestos fibers inhaled can remain in the body and continue to pose a health hazard for the rest of that person's life.

Elongated Mineral Particles

How to define asbestos has been the subject of great academic, scientific, and legal debate. As EPA recognizes, the definition in the problem formulation is a generic commercial definition, and there is not one uniform scientific standard for the identification of asbestos materials. EPA's proposed definition does not include all of the minerals that potentially form asbestos or asbestos-like fibers and can cause serious health effects, including mesothelioma.

EWG urges EPA to broaden the definition of asbestos beyond the six fiber types included in the problem formulation, which is outdated and unduly narrow in scope. Instead of narrowly focusing on the six listed varieties, EPA should consider other elongated mineral particles (EMPs) that share the same properties and risks. For example, there are around 400 EMPs with similar physical and chemical structures of asbestos that may also be carcinogenic.¹ The National Institute for Occupational Safety and Health (NIOSH) has recognized the limitations and scientific challenges of a narrow definition of "asbestos" and has recommended a broader approach.²

In particular, EPA should not limit its consideration to "asbestiform" varieties of EMPs because asbestiform and non-asbestiform varieties of a mineral can occur matrixed together within a narrow geological formation.³ Although the risks are less well-understood, research suggests that

¹ Salih A. Emri, *The Cappadocia Mesothelioma Epidemic: Its Influence in Turkey and Abroad*, 5 *Annals of Translational Medicine* 239 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5497117/>

² Dep't of Health and Human Serv., Nat'l Inst. for Occupational Safety and Health, *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research* (2011), <https://www.cdc.gov/niosh/docs/2011-159/pdfs/2011-159.pdf>.

³ *Id.* at 6-7.

exposure to non-asbestiform varieties of minerals can also pose health risks. A 2013 study of workers who mine nephrite, a non-asbestiform tremolite mineral, found that destroying non-asbestiform tremolite releases both asbestiform and non-asbestiform fibers.⁴ The study concluded that processing non-asbestiform tremolite increases the risk for pulmonary fibrosis and that workers should undergo medical monitoring.⁵ Another study published just this month found high mesothelioma potency in both tremolite fibers in vermiculite from Libby, Montana and non-asbestiform EMPs from taconite mining.⁶ Taconite is still widely mined in the United States. Another example of an excluded EMP is erionite. Erionite is a fibrous zeolite mineral that shares many physical properties with the six listed forms of asbestos and is believed to be a more potent carcinogen than asbestos. Erionite exposure is tied to a mesothelioma epidemic in Cappadocia, Turkey where fifty percent of deaths in three villages have been caused by mesothelioma.⁷ Fibrous erionite occurrences are also common in the western United States, and can potentially be found on hundreds of miles worth of gravel rounds where it easily can become airborne and pose an inhalation risk.⁸ The EPA, United States Geological Survey, and the State of North Dakota and throughout the western United States and have conducted research sampling erionite levels on in graveling operations, on school bus routes, and in auto body shops along gravel roads in North Dakota and found potentially unsafe levels of erionite in the air.⁹ EPA's definition would also exclude some of the amphibole varieties of asbestos found in Libby, Montana, including winchite and richterite, despite the well-documented risks from Libby amphiboles. Vermiculite from Libby, Montana can be found in millions of aging homes across the United States.¹⁰

⁴ Hsiao-Yu, Yang et al., *Pulmonary Fibrosis in Workers Exposed to Non-asbestiform Tremolite Asbestos Minerals*, 24 J. Epidemiology 143 (2013),

https://journals.lww.com/epidem/Fulltext/2013/01000/Pulmonary_Fibrosis_in_Workers_Exposed_to.22.aspx

⁵ *Id.*

⁶ David H. Garabrant & Susan T. Pastula, *A Comparison of Asbestos Fiber Potency and Elongate Mineral Particle (EMP) Potency for Mesothelioma in Humans*, Toxicology & Applied Pharmacology (Online August 2018),

<https://www.sciencedirect.com/science/article/pii/S0041008X18303144?via%3Dihub>

⁷ Salih A. Emri, *The Cappadocia Mesothelioma Epidemic: Its Influence in Turkey and Abroad*, 5 Annals of Translational Medicine 239 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5497117/>; see also Dep't of Health and Human Serv., Nat'l Inst. for Occupational Safety and Health, *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research* 38 (2011),

<https://www.cdc.gov/niosh/docs/2011-159/pdfs/2011-159.pdf>.

⁸ Van Gosen, B.S., Blitz, T.A., Plumlee, G.S. et al. *Geologic Occurrences of Erionite in the United States: An Emerging National Public Health Concern for Respiratory Disease*, 35 Env't'l Geochem Health 419 (2013),

<https://link.springer.com/article/10.1007%2Fs10653-012-9504-9> - page-1

⁹ See, e.g., Michele Carbone et. al., *Erionite Exposure in North Dakota and Turkish villages With Mesothelioma*, 108 Proceedings of the Nat'l. Acad. of Sciences 13618 (2011),

https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/2325156; North Dakota Dep't of Health, *Erionite Fact Sheet*, https://deq.nd.gov/Erionite/General/Erionite_Fact_Sheet.pdf (last accessed August 2018).

¹⁰ Ed Cahill, EMSL Analytical Inc, *Asbestos Analysis of Vermiculite and Vermiculite Containing Materials*, October 2014,

https://www.aiha.org/getinvolved/LocalSections/NewEngland/Resources/Presentations/NEAIHA_EMSL_Vermiculite-2.pdf.

EPA should include EMPs associated with asbestos-related diseases in the scope of the asbestos risk evaluation, including non-asbestiform EMPs. EPA should collect data on biopersistence, toxicity, and the health effects of elongate mineral particles that share the same dimensional and mineralogical characteristics as the six varieties of asbestos defined in the problem formulation. At a minimum this data should be used to better understand the cumulative risks from exposure to asbestos and other EMPs.

Reasonably Foreseeable Uses

EPA must take steps to ensure that all reasonably foreseeable uses and associated life cycles of asbestos are included in the problem formulation. Pursuant to the definitions in TSCA, a chemical's conditions of use include intended, known, and reasonably foreseeable uses and disposals.¹¹ Reasonably foreseeable uses include accidents like chemical spills and leaks that can contaminate air, water, and soil. Although these are not intended uses, they are known to happen, and it is foreseeable that they could happen again. For example, the terrorist attacks on the World Trade Center contaminated most of lower Manhattan with high levels of asbestos. In July, a pipe containing asbestos burst in the Flatiron district of Manhattan, raising fears about health-risks from asbestos exposure in the surrounding community.¹² The problem formulation should include the potential risks from these kinds of incidents and accidents.

Unintentional uses should also be included in the risk evaluation as conditions of use. In the statute, Congress expressly included "storage near significant sources of drinking water" as a consideration when EPA evaluates chemical substances.¹³ Given the heightened risk from unintentional releases near drinking water, Congress clearly intended unintentional uses, such as accidents and misuses, to be included in EPA's determinations. Asbestos contamination in products is an unintended but clearly foreseeable use that EPA should take under consideration. Significant amounts of vermiculite insulation and gardening materials were found to be contaminated with asbestos from Libby, Montana.¹⁴ Libby vermiculite remains as a dangerous exposure for millions of aging homes throughout the United States.¹⁵ Like vermiculite, talc often forms in the earth from and with the asbestos-forming minerals. Because of this close geologic association, these mineral resources are often found to contain substantial asbestos, most commonly amphibole asbestos, e.g., tremolite, actinolite, anthophyllite, winchite, richterite, and

¹¹ 15 U.S.C. § 2602(4)

¹² Matthew Haag & Melissa Gomez, *Asbestos Confirmed in Steam Pipe That Exploded in Manhattan*, N.Y. Times, July 19, 2018, <https://www.nytimes.com/2018/07/19/nyregion/steam-explosion-pipe-flatiron-nyc.html>

¹³ 15 U.S.C. § 2605(b)(1)(A)

¹⁴ See U.S. Env't Prot. Agency, *Protect Your Family from Asbestos-Contaminated Vermiculite Insulation*, <https://www.epa.gov/asbestos/protect-your-family-asbestos-contaminated-vermiculite-insulation> (last accessed August 2018).

¹⁵ *Id.*

can also co-mineralize with serpentine, including fibrous antigorite and chrysotile.¹⁶ This month, asbestos was found in a popular brand of crayons.¹⁷ On several occasions, asbestos has been found in contaminated talc in cosmetics, some of which are marketed to teens.¹⁸

EPA should also include misuses in the scope of chemical risk evaluations if the misuses are known or reasonably foreseeable. For asbestos, consumers may not follow proper guidelines for handling or removing asbestos or asbestos-containing materials from their homes. This is particularly true with the increasing popularity of do-it-yourself home renovation projects. Even professional asbestos abatement companies often fail to adequately protect workers and bystanders during asbestos removal.¹⁹ These types of misuses are reasonably foreseeable and should be included in this and future risk evaluations.

Exposure from so-called legacy uses, as further discussed below, is also reasonably foreseeable. For example, the release of friable asbestos dust from asbestos-containing building materials when disturbed or as the result of normal wear is a reasonably foreseeable exposure to asbestos. EPA has also identified several uses of asbestos in a proposed significant new use rule that the agency believes are no longer ongoing.²⁰ Because the uses identified in the SNUR and other legacy uses are still legal, it is foreseeable that these uses could be resumed or that people could be exposed to old products still containing asbestos. These products may also still be imported without EPA's knowledge. Without adequate public health regulation of such legacy uses, the rate of asbestos associated disease is expected to continue to rise because such exposure through legacy uses are inevitable.

Lifecycle of the Chemical, Including Legacy Uses

¹⁶ International Agency for Cancer Research, *Asbestos (chrysotile, amosite, crocidolite, tremolite, actinolite and anthophyllite)* (2012), <https://www.ncbi.nlm.nih.gov/books/NBK304374/> (last accessed August 2018).

¹⁷ See, e.g., Abha Bhattarai, *Playskool crayons found to contain asbestos, advocacy group say*, Wash. Post, August 6, 2018, <https://www.washingtonpost.com/business/2018/08/06/playskool-crayons-found-contain-asbestos-advocacy-group-says/>

¹⁸ See, e.g., *Study finds asbestos in Claire's makeup products marketed to teens*, CBS News, March 13, 2018, <https://www.cbsnews.com/news/study-asbestos-claires-makeup-products-marketed-to-teens/>; Diane Wilson, *Justice recalls kids makeup containing asbestos*, ABC Eyewitness News, January 31, 2018, <https://abc7chicago.com/shopping/justice-recalls-kids-makeup-containing-asbestos/3012584/>.

¹⁹ See, e.g., Press Release, Wash. State, Office of the Attorney Gen., *Ag Files Criminal Charges Against Hotel Owner Over Asbestos Removal* (May 11, 2016), <https://www.atg.wa.gov/news/news-releases/ag-files-criminal-charges-against-hotel-owner-over-asbestos-removal>; *Asbestos removal company that worked on Mansfield school must pay restitution for wages*, The Sun Chronicle, February 2, 2017, http://www.thesunchronicle.com/news/local_news/asbestos-removal-company-that-worked-on-mansfield-school-must-pay/article_37c73adc-e981-11e6-9815-db0dca72c9a1.html; Press Release, Massachusetts State, Office of the Attorney Gen., *AG Healey Announces New Initiative to Better Protect the Public from Dangers of Asbestos Exposure*, March 01, 2017, <http://www.mass.gov/ago/news-and-updates/press-releases/2017/ag-announces-new-initiative-to-protect-from-asbestos.html>

²⁰ Asbestos; Significant New Use Rule, 83 Fed. Reg. 26922 (June 11, 2018).

EWG is concerned with EPA’s exclusion of so-called “legacy uses” from conditions of use. Section 6(a) requires EPA to regulate when an unreasonable risk is posed by the “manufacture, processing, distribution in commerce, use, or disposal” of a chemical or “any combination of such activities.”²¹ This accounts for the entire lifecycle of the chemical, from when it is produced to when it is disposed of. EPA must account for the risks during manufacturing, processing, distribution, use, and disposal of each chemical for which it does a risk evaluation. The scope of EPA’s risk evaluations should include all uses and disposals.

EPA’s stated intention is to focus on “uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal.”²² This interpretation undermines the design of TSCA as a cradle-to-grave statute and is at odds with EPA’s clear mandate to evaluate and regulate risks at the end of a chemical’s lifecycle. Excluding legacy uses is also at odds with EPA’s requirement to “take into account, where relevant, the likely duration, intensity, frequency and number of exposures under the conditions of use of the chemical substance.”²³ To fully consider the frequency and number of exposures to a chemical, EPA must consider likely exposure from all sources—regardless of whether the exposure came from an ongoing or a legacy use.

This is particularly important for asbestos. Asbestos is currently in use in a variety of ways in the United States, even though it may no longer be manufactured or produced for those uses. It can be found in insulation and other building materials in homes, offices, schools, and other buildings. It is present in aftermarket automobile parts and various textiles. These materials can degrade and the asbestos fibers can become airborne and enter people’s airways long after the products are purchased or installed. The risks associated with asbestos do not end when its production does. For example, although insulation made from contaminated Libby vermiculite is no longer produced, the Libby mine accounted for 80 percent of the world production of vermiculite for 70 years and an estimated 15.6 billion pounds of asbestos-contaminated Zonolite insulation was shipped and distributed around North America.²⁴ An estimated 10-30 million homes contain vermiculite, putting potentially millions of Americans at risk of exposure.²⁵ “Legacy uses” of asbestos-containing building materials also put scores of residents and workers

²¹ 15 U.S.C. § 2605(a)

²² Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017).

²³ 15 U.S.C. § 2605(b)(4)(F)(iv).

²⁴ Ed Cahill, EMSL Analytical Inc, *Asbestos Analysis of Vermiculite and Vermiculite Containing Materials*, October 2014,

https://www.aiha.org/getinvolved/LocalSections/NewEngland/Resources/Presentations/NEAIHA_EMSL_Vermiculite-2.pdf

²⁵ *Id.*

at risk, as underscored by multiple comments filed by asbestos abatement professionals on the scoping docket. According to those experts:

We truly consider that our work relates to our clients' "use" of these legacy materials. Our clients do not benefit from the exposure protections we do as asbestos professionals. Installed legacy asbestos containing materials create potential unprotected exposure to citizens as these materials age and deteriorate. With release of deadly asbestos fibers as a risk assessment criterion, it should be acknowledged that every day citizens "use" the flooring, ceilings, walls, insulations and fireproofings that are in our buildings. The "use" of the material does not end at the time of installation. For many of these materials, the "use" only begins at installation. Most certainly, building "users" are at risk of asbestos exposure from installed legacy asbestos-containing materials caused by vibration, air erosion, water damage and inadvertent or accidental physical contact by citizens and tradesmen.²⁶

In the problem formulation, EPA uses the language "*current* conditions of use"²⁷ to distinguish EPA's recognized uses from "legacy uses." This type of limiting language is not present in the statute, and EPA's decision to arbitrarily limit the scope of the conditions of use is contrary to the language and purpose of the statute. Since EPA distinguishes that there exist current conditions of use, it follows that EPA acknowledges that there are non-current or historical uses that are nonetheless conditions of use under the statutory definition.

Exposures Covered by Other Agencies and Statutes

There is no textual basis in the statute for EPA's conclusion that it may ignore exposures assessed by other statutes. EPA's interpretation of TSCA 6(b)(4)(D) is incorrect. EPA interprets this section of TSCA to grant EPA discretion to exclude exposure pathways that fall under the jurisdiction of other EPA-administered statutes. However, this section does not grant EPA that discretion. The phrase "expects to consider," understood in its ordinary meaning, does not provide discretion to pick and choose among the conditions of use. To the contrary, the term indicates only that EPA must describe the conditions of use it has identified through its fact-gathering.²⁸ TSCA mandates that EPA must describe what exposure pathways it is considering, including pathways that fall under other statutes, but TSCA does not give EPA the power to exclude them from the risk evaluation. Instead, TSCA was enacted with the intention that EPA

²⁶ See, e.g. Accurate Insulation, LLC; Block and Clark Environmental, LLC; Eagle Environmental, LLC; Environmental Testing and Consulting, LLC; Future Environment Designs, Inc.; Michael R Mader Company, Inc.; Payne Environmental, LLC; Sitecon Corporation; Strauss Consulting Services, LLC; Talevi Enterprises, Inc.; and Tighe and Bond, Comments on the Scope of the Risk Evaluation for Asbestos, Docket ID EPA-HQ-OPPT-2016-0736.

²⁷ Env'tl. Prot. Agency, Problem Formulation of the Risk Evaluation for Asbestos, at 18 (May 2018)(emphasis added).

²⁸ Opening Brief of Petitioners at pg. 34, Safer Chemicals, Healthy Families v. U.S. Environmental Protection Agency, No. 17-72260 (9th Cir. Apr. 16, 2018)

would “look *comprehensively* at the hazards associated with [a] chemical”²⁹ and consider “the full extent of human or environmental exposure.”³⁰

EWG is concerned by EPA’s assertion that “During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.”³¹ Even if another agency has taken steps to manage risk from a particular use, that doesn’t mean the use does not contribute to exposure or that the risk has been eliminated. For example, many of the first ten chemicals pose occupational risks that may be regulated by OSHA. However, oftentimes OSHA’s regulations need to be updated or do not go far enough. For example, OSHA has a permissible exposure limit (PEL) for trichloroethylene, or TCE, but it is already 20 years old.³² Even OSHA admits that many of its PELs are outdated and do not adequately protect workers from chemicals.³³ As such, action taken by OSHA should not be a basis for excluding occupational uses from a risk evaluation scope.

EWG is troubled by EPA’s assumption that all exposure risks covered by other agencies and environmental statutes are effectively managed. For example, EPA states in the problem formulation that it will not include stationary source releases of asbestos to ambient air because they “are adequately assessed and any risks effectively managed” under the Clean Air Act.³⁴ A decision of no risk seems out of place when it occurs before the risk evaluation. EPA should only declare exposures to be effectively managed under other agencies and statutes after those exposures have been adequately assessed in a comprehensive risk evaluation. Doing otherwise excludes well-understood exposures of concern and risks skewing EPA’s risk assessment. One of EPA’s own risk assessment handbooks states that “to achieve effective risk assessment and risk management decisions, all media and routes of exposure should be assessed.”³⁵

Contaminants and Impurities

EWG is concerned by EPA’s stated intent to generally exclude impurities and other “de minimis” exposures from risk evaluations. Unintended impurities and contaminants can lead to exposures and risks to human health. They should not be regarded as de minimis before the risk

²⁹ S. Rep. No. 94-698, at 2 (1976).

³⁰ H.R. Rep. No. 94-1341, at 6 (1976).

³¹ Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017)

³² Env’tl. Prot. Agency, Scope of the Risk Evaluation for Trichloroethylene, at 32 (June 22, 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf

³³ U.S. Dep’t of Labor, Occupational Safety and Health Admin., Permissible Exposure Limits—Annotated Tables, <https://www.osha.gov/dsg/annotated-pels/> (last accessed Aug. 15, 2018).

³⁴ Env’tl. Prot. Agency, Problem Formulation of the Risk Evaluation for Asbestos, at 42 (May 2018).

³⁵ Env’tl. Prot. Agency, Nat’l Ctr. for Env’tl. Assessment, *Exposure Factors Handbook: 2011 Edition* at 1-18, (Sept. 2011),

evaluation takes place; the purpose of the risk evaluation is to determine the hazard from the chemical as a whole, taking into consideration hazards that contaminants and impurities create. As before, EPA relies on a faulty interpretation of TSCA 6(b)(4)(D) to exclude de minimis exposures from risk evaluations. The language in 6(b)(4)(D) mandates that EPA must describe what exposure it is considering, including exposures due to impurities or contamination, but TSCA does not give EPA the power to exclude them from the risk evaluation.

Additionally, EPA's exclusion falsely equates de minimis exposure with little or no risk. It disregards the significant body of evidence that hormone disruptors and developmental toxicants may cause adverse effects at very low doses and ignores the possibility of non-monotonic dose-response curves. The pharmaceutical literature is rife with examples of non-monotonicity, timing, and age group specific toxicity concerns.³⁶ Furthermore, even de minimis exposures contribute to an individual's aggregate exposure to a chemical. An important example is asbestos contamination of other widely used minerals, such as vermiculite and talc. The term vermiculite and the term talc both refer to a definable mineral as well as a commercial term for a mineable reserve with specific properties.

The mineral vermiculite is a hydrobiotite mineral but is not the dominant mineral in what is considered "vermiculite" from a commercial perspective. Commercially mineable vermiculite is actually dominantly an expanded mica mineral, specifically, hydro-biotite, and those commercial deposits form under the same type of geological processes as asbestos. Because asbestos and commercial vermiculite form under similar conditions, asbestos can be a contaminant in all vermiculite ore. This was the case in Libby, Montana. As EPA notes in the problem formulation, the vermiculite ore mined in Libby was contaminated with winchite, richterite, tremolite, and other asbestiform amphiboles referred to together as Libby Amphibole Asbestos (LAA), as published by the EPA.³⁷ EPA is not considering Libby vermiculite in its risk evaluation because the mine has been closed, and EPA deems the continued use of Libby vermiculite as a "legacy use." However, Libby vermiculite can be found in as many as 30 million homes throughout the United States, where residents are at risk of exposure. EPA has issued nation-wide warnings about the dangers of this material in homes across the country.³⁸ Additionally, there are still two companies mining vermiculite in the United States today, in South Carolina and Virginia,³⁹ which have also been repeatedly proven to contain asbestos, including actinolite, tremolite, and

³⁶ See, e.g., Theo Colborn et al., *Non-Monotonic Dose Response Curves*, in *Our Stolen Future*, <http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm> (last visited Aug. 15, 2018).

³⁷ Env'tl. Prot. Agency, IRIS Toxicological Review Libby Amphibole Asbestos, https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=292394 (last visited Aug. 15, 2018).

³⁸ See Env'tl. Prot. Agency, *Protect Your Family from Asbestos – Contaminated Vermiculite Insulation*, <https://www.epa.gov/asbestos/protect-your-family-asbestos-contaminated-vermiculite-insulation> (last visited Aug. 15, 2018).

³⁹ U.S. Geological Survey, *Mineral Commodity Summaries 2017*, at 184 (Jan. 2017), <https://minerals.usgs.gov/minerals/pubs/mcs/2017/mcs2017.pdf>.

chrysotile.⁴⁰ EPA must evaluate any exposure risk from these mining operations as current uses to determine if there is harmful asbestos contamination.

Additionally, EPA should evaluate talc products to determine the level of asbestos exposure resulting from the current and continued use of these products. Talc is also both a specific mineral as well as a commercial term. Commercially-viable deposits of talc are comprised of as little as 30-40% of the mineral talc itself, with rare pure reserves in the 80-90% range.⁴¹ The other minerals in those talc reserves which are mined, sold, and processed as “talc” include the asbestos-forming minerals, including amphiboles and serpentines in the asbestiform habit. These talc reserves often form under similar conditions to asbestos. In fact, three out of four of the main ways talc forms in the earth involve metamorphism of the asbestos-forming rocks, and talc often is actually a derived product from those same minerals because of this close geologic and mineralogic relationship.⁴² Asbestos fibers have been found in cosmetic talcum powder and linked to mesothelioma.⁴³ These types of contaminations and impurities can be extremely harmful, especially for chemicals and substances like asbestos with no safe threshold of exposure. Excluding contaminations and impurities underestimates the risk of harmful substances and contravenes the purpose of the law.

Exposures for which Data is Limited

EPA should not omit a condition of use from the scope of the risk assessment because data on that particular use is lacking. For example, EPA has insufficient information about the likely exposure of workers and people living in homes that use HBCD insulation. EPA also has limited information about 1,4-dioxane levels in products that contain ethoxylated ingredients. EPA should study exposures rather than make assumptions based on the limited data. NIOSH has noted the need for more data on health risks from elongated mineral particles which pose risk similar to asbestos. After all, the law requires EPA to actively seek “reasonably available information” about conditions of use from stakeholders.⁴⁴

“Reasonably available” is defined broadly in the final risk evaluation rule to include not only information EPA possesses, but also all information EPA can “reasonably generate, obtain, and

⁴⁰ James Millette & Steven Compton, *Analysis of Vermiculite for Asbestos and Screening for Vermiculite from Libby, Montana*, 63 *The Microscope* 59 (2015).

⁴¹ Edward F. McCarthy et al., *Talc* in *Industrial Minerals and Rocks* 972 (Donald Carr ed., 6th ed. 1994).

⁴² *Id.*

⁴³ Ronald E Gordon, Sean Fitzgerald, & James Millette, *Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women*, 20 *Int. J. Occup. Environ. Health* 318 (2014), <https://www.ncbi.nlm.nih.gov/pubmed/25185462>.

⁴⁴ 15 U.S.C. § 2625(k) (“The Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.”); 15 § 2605(b)(4)(F)(i).

synthesize for use in risk evaluations.”⁴⁵ This would include information published in scientific journals and industry studies. It would also include information already collected by state governments or under foreign regulations like the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) in Europe. If EPA knows this information exists and was submitted to other governments, it should take measures to request the same information from the manufacturers or processors responsible for its submission. Additionally, EWG encourages EPA to rely on the appropriate use of defaults, or calculated uncertainty factors when specific information is missing. Finally, EPA has various tools under sections 4, 8(a), 8(c), 11 and 26(a) to order testing or solicit information as needed to fill data gaps.

EPA should not assume PPE or warning labels are an effective means of risk prevention in order to exclude exposures from the risk evaluation. NIOSH recommends various levels of PPE based upon training, availability of medical monitoring for workers, and extent of exposures as determined by on-site monitoring. The effectiveness of PPE should not be assumed, but rather evaluated during the risk evaluation. To determine the effectiveness of PPE and warnings, EPA should gather information on the use, effectiveness, and compliance with PPE and warnings. This information gathering should not rely solely on voluntary reporting by the industry. While industry participation is very valuable in the risk assessment process, EPA should collect and enforce its own data gathering to ensure it has the most accurate information available, especially on topics such as compliance. The exposure to a chemical despite PPE and warning labels should be established through empirical data-gathering during the risk evaluation stage.

Potentially Exposed and Susceptible Populations

EWG encourages EPA to keep in mind that the appropriate processes and procedures to identify susceptible and highly exposed populations may be unique to each substance evaluated. For example, legacy uses of a substance may have disproportionately contaminated particular communities, or exposure to a substance may pose unique health risks for fetal or childhood development. Consequently, EWG urges the agency to seek communities’ and public health experts’ input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. EWG also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment.⁴⁶

When EPA identifies “any potentially exposed or susceptible subpopulations” and “the hazards to health and the environment that EPA plans to evaluate,” the agency should conduct outreach

⁴⁵ Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33748 (July 20, 2017) (to be codified at 40 C.F.R. pt. 702.33).

⁴⁶ Env'tl. Prot. Agency, EJ 2020 Action Agenda: EPA's Environmental Justice Strategy, <https://www.epa.gov/environmentaljustice/ej-2020-action-agenda-epas-environmental-justice-strategy> (last visited Aug. 15, 2018)

to communities likely to be home to potentially exposed or susceptible subpopulations. These communities may possess crucial information about hazards that the agency may itself lack. For example, as highlighted in the comments submitted by Earthjustice et al. in March 2017, such communities are in the best position to inform EPA about nursing homes or schools located near sites that increase the likelihood of their exposures to the chemical.⁴⁷ Additionally, workers may be best able to identify real-world occupational exposures to chemicals, including roles and responsibilities that create highly exposed subgroups within their ranks. Workers are also likely to have the most accurate information about PPE and its actual use or misuse in the workplace. Other federal, state, and local regulatory authorities may also possess information necessary to establishing the proper scope of a risk assessment. For example, the California EPA has developed child-specific risk values for certain chemicals like atrazine and chlorpyrifos. Those values compare children's susceptibility to adults' by specifically examining child-specific routes of exposure.⁴⁸ EPA should review California EPA's approach and adopt its risk values as appropriate and incorporate information from the analysis California EPA has already completed.

EWG is concerned with EPA's decision to exclude firefighters as a potentially exposed group from the asbestos problem formulation. The term "potentially exposed or susceptible subpopulation" is defined in the statute as "a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture."⁴⁹ Firefighters and construction renovation workers (such as plumbers, cable installers, electricians, telephone repair personnel, and insulators) are exposed to asbestos fibers due to the history of widespread asbestos use in construction materials, including cements, bricks, piping, tiles, and insulation. Firefighters are also more likely to be exposed to asbestos during the course of their work fighting against natural disasters that may occur in areas where there is naturally occurring asbestos. Recently, a fire broke out near the site of the former W.R. Grace & Co. vermiculite mine in Libby, Montana, stoking fears of releasing asbestos-laden ash into the air.⁵⁰ First responders to this fire and others like it are at a disproportionate risk of exposure and should be given special consideration. Firefighters contract mesothelioma at rates

⁴⁷ Alaska Community Action on Toxics, et al., Comments on Scope of the Risk Evaluations for the First Ten Chemicals Under the Toxic Substances Control Act (Mar. 15, 2017).

⁴⁸ Cal. EPA, Office of Env'tl. Health Hazard Assessment, Child-Specific Reference Doses Finalized to Date, <http://oehha.ca.gov/risk-assessment/chr/table-all-chrds> (Jun. 22, 2010).

⁴⁹ 15 U.S.C. §2602(12)

⁵⁰ Justin Franz, *Firefighters Aggressively Attack Wildfire Near Libby Vermiculite Mine*, Flathead Beacon (July 20, 2018),

<https://flatheadbeacon.com/2018/07/20/firefighters-aggressively-attack-wildfire-near-libby-vermiculite-mine/>.

significantly higher than the national average.⁵¹ As the International Association of Firefighters noted in their comments to the scoping docket:

“Considering individuals are most likely to be exposed to asbestos by breathing in fibers that are suspended in the air, Fire Fighters face a greater risk of asbestos exposure than the general population, because asbestos becomes airborne when disturbed or damaged by fire. Additionally, the opening of walls and ceilings to check for fire extension exposes fire fighters to asbestos fibers. These fibers can remain on the turnout gear and station clothing and spread to the apparatus cabs and fire stations. Fire fighters can inhale large amounts of these microscopic fibers, and unknowingly increase their risk of developing an asbestos-related disease like Mesothelioma, Lung Cancer, and Asbestosis to name a few.”⁵²

The exclusion of firefighters and construction renovation workers goes against the core purpose of TSCA, and further exposes EPA’s flawed reasoning in regard to “legacy uses.”

EPA should also consider populations living near mining operations and in areas EPA has identified as places where elongated mineral particles naturally form. Because asbestos is a naturally occurring substance, it may be present in many areas where mining operations occur, and populations living close to and around those areas can be exposed to asbestos and other elongated mineral particles. EPA needs to consider these populations as potentially exposed and assess their risk and exposure to asbestos and asbestos-like particles during the risk evaluation. Finally, genetics is an important risk factor for the development of mesothelioma⁵³ and people who are genetically more likely to develop mesothelioma after exposure to asbestos should also be considered a vulnerable population.

Risks from Aggregate and Cumulative Exposures

As part of a risk evaluation, EPA is required to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered.⁵⁴ EWG strongly believes that considering the aggregate exposures will provide a more robust analysis of the total risk posed by a chemical, and that EPA’s risk evaluation documents should reflect consideration of those aggregate exposures.

⁵¹ Robert D. Daniels et al., *Mortality and Cancer Incidence in a Pooled Cohort of US Firefighters from San Francisco, Chicago and Philadelphia (1950-2009)*, 71 *Occupational & Env'tl. Medicine* 388 (2013), <https://oem.bmj.com/content/71/6/388>.

⁵² International Association of Firefighters, *Comments on the Scope of the Asbestos Risk Evaluation* (March 15, 2017).

⁵³ Salih A. Emri, *The Cappadocia Mesothelioma Epidemic: Its Influence in Turkey and Abroad*, 5 *Annals of Translational Medicine* 239 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5497117/>.

⁵⁴ 15 U.S.C. §2605(b)(4)(F)(ii)

To properly assess aggregate exposures, EPA must consider exposures throughout the lifecycle of the chemical from all routes and pathways, including exposures from conditions of use not regulated by TSCA. This includes exposures from food, drinking water, pesticides, and personal care products, even if those uses are not specifically regulated during section 6(a) rulemaking. EWG emphasizes that this approach should include aggregate exposures from trace contaminants, such as asbestos fibers sometimes found in talc products,⁵⁵ or 1,4-dioxane in cleaning and personal care products that contain ethoxylated ingredients.⁵⁶

When possible, EPA should also consider cumulative exposures when scoping a risk evaluation. EPA has explicit authority to order testing and prescribe protocols and methodologies for a number of health and environmental effects, including “cumulative or synergistic effects.”⁵⁷ Considering cumulative exposures is in line with EPA’s priorities and consistent with the best practices for risk evaluations. In its Framework for Cumulative Risk Assessment (2003), EPA states, “[a]ssessing cumulative risk through complex exposures is one of the Agency’s high priorities...and it is germane and of great interest to all program and regional offices.”⁵⁸

Considering cumulative exposures is important because people and vulnerable subpopulations can be exposed to multiple chemicals and stressors that contribute to the same adverse health effects. The National Academy of Sciences (NAS) has noted the need to evaluate the cumulative effects of phthalates and also pointed to the fact that lead and mercury can collectively affect brain development.⁵⁹ Additionally, cumulative exposures to multiple carcinogenic solvents (e.g. TCE, 1,4-dioxane, methylene chloride and perchloroethylene) via air and drinking water may pose unique risks for people living near sites with industrial contamination. Taking such cumulative impacts into consideration would improve current assessments, and to the extent possible should be included in scoping and risk evaluation documents.

EPA may consider collective exposure to groups of similar chemicals, and use the Adverse Outcome Pathway framework and database to identify where cumulative effects may be an issue.

⁶⁰ EPA should follow the cumulative risk assessment process recommended by the National

⁵⁵ Ronald Gordon, et. al., *Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women*, 20 Int’l J. of Occupational and Env’tl Health 318 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883>

⁵⁶ Agency for Toxic Substances & Disease Registry, Pub. Health Statement for 1,4-Dioxane, Toxic Substances Portal, April 2012, <https://www.atsdr.cdc.gov/phs/phs.asp?id=953&tid=199>.

⁵⁷ 15 U.S.C. § 2603(b)(2)(A)

⁵⁸ Env’tl. Prot. Agency, *Framework for Cumulative Risk Assessment* xi (2003), https://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf (last accessed Aug. 15, 2018).

⁵⁹ Nat’l Acad. Sci., *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008), <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508>.

⁶⁰ Adverse Outcome Pathway Knowledge Database, Org. for Econ. Co-Operation & Dev., <http://aopkb.org/> (last visited Aug. 15, 2018).

Academy of Sciences (NAS) in their Phthalates and Cumulative Risk Report.⁶¹ When specific information is not available, EPA may use default values to account for cumulative exposures.

Excluding specific uses from the risk evaluation would negate the purpose of the Lautenberg Act to prevent unreasonable risks from toxic chemicals. From the EPA's own draft rules, "if EPA were free to base its determination of whether a chemical substance, as a whole, presents an unreasonable risk or injury (as the statute requires) on merely a subset of individual uses, it could, for example, determine that a chemical substance with 10 known uses does not present an unreasonable risk of injury based on an evaluation of a single one of those uses" while neglecting to evaluate other uses that may contribute to the chemical's risks.⁶² Excluding uses would also impair EPA's ability to evaluate the impact a chemical has on exposed and susceptible subpopulations if the EPA did not consider the particular use that affects those groups.

In the risk evaluation for asbestos, EPA should consider the aggregate and cumulative risks from asbestiform and nonasbestiform minerals, as well as from other elongated mineral particles.

Cancer and Non-Cancer Effects

Additionally, EWG is concerned by EPA's decision to limit the risk evaluation by only focusing on lung cancer and mesothelioma as negative health outcomes due to asbestos exposure. Other cancer endpoints, including cancer of the larynx and ovaries may be caused by asbestos exposure, as EPA notes in the problem formulation.⁶³ Non-cancer diseases, such as asbestosis and pleural plaques, have been linked to asbestos exposure.⁶⁴ The incidence of chronic obstructive pulmonary disease, or COPD, among non-smokers has been steadily increasing⁶⁵ and has also been associated with asbestos exposure.⁶⁶ Though not as immediately deadly as cancer, these diseases can lead to breathing difficulty, decreased quality of life, and early death. Lung cancer and mesothelioma are not the only negative health impacts of asbestos exposure, and the risk evaluation should not be limited to only two diseases when asbestos has been linked to multiple illnesses.

Conclusion

⁶¹ Nat'l Acad. Sci., *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008), <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=202508>.

⁶² Env'tl. Prot. Agency, Procedures for Chem. Risk Evaluation Under the Amended Toxic Substances Control Act (January 19, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0001>

⁶³ Env'tl. Prot. Agency, Problem Formulation of the Risk Evaluation for Asbestos, at 35 (May 2018).

⁶⁴ Pierre Alain Gevenois et al., *Asbestosis, Pleural Plaques and Diffuse Pleural Thickening: Three Distinct Benign Responses to Asbestos Exposure*, 11 European Respiratory Journal 1021 (1998), <https://www.ncbi.nlm.nih.gov/pubmed/9648950>.

⁶⁵ Bernd Lamprecht et al., *COPD in Never Smokers*, 129 Chest 752 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3168866/>

⁶⁶ [Dennis Wilken](#), *Lung Function in Asbestos-Exposed Workers, a Systematic Review and Meta-Analysis*, 6 J. Occupational Med. Toxicology 21 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3164601/>

EPA's piecemeal approach to asbestos significantly underestimates exposures, and potentially puts Americans in danger. By ignoring other exposures, such as legacy uses or uses regulated by other agencies, EPA is more likely to set standards that put people at risk.

EWG appreciates the opportunity to comment on the problem formulation of the risk evaluation for asbestos. We hope that these comments will help EPA to reevaluate the problem formulation so that it can conduct a stronger and more thorough risk evaluation for asbestos and other chemicals, so that moving forward, risk evaluations address fully the ways in which vulnerable and chemically over-burdened populations around the country are placed at risk by these chemicals. We look forward to continuing to participate in EPA's risk evaluation and risk management efforts under TSCA. Should you have any additional questions, please feel free to reach out to Melanie Benesh, Legislative Attorney at EWG, 202-939-0120, mbenesh@ewg.org.