House Energy and Commerce Committee
Subcommittee on Environment and Climate Change
Hearing on
"Ban Asbestos Now: Taking Action to Save Lives and Livelihoods"
May 8, 2019

The Honorable Alexandra Dunn, Assistant Administrator
U.S. Environmental Protection Agency

The Honorable Frank Pallone, Jr. (D-NJ)

During the hearing, you were asked about EPA's interpretation of the term "impurity." Your response referred to a threshold concentration for impurities. Impurity, as defined in both 40 CFR § 791.3 and 40 CFR § 720.3, is a chemical substance which is unintentionally present with another chemical substance or mixture, with no threshold. It appears that your answer may have been based on the definition of "asbestos-containing material" under asbestos abatement activities as described under TSCA Title II – "any material which contains more than 1 percent asbestos by weight."

1. Please clarify whether you interpret the term "impurity" to include a threshold concentration.

   RESPONSE: The term "impurity," as described in section 2 of H.R. 1603 creating a new TSCA section 6(k)(4)(C), does not include a threshold amount. As such, EPA would have to exercise discretion to determine what counts as an "impurity" in a product.

2. What, if any, risk-based justification can you offer for excluding materials containing just under 1% asbestos by weight from abatement activities? What monitoring is being done to ensure no risk to human health from materials containing just under 1% asbestos by weight?

   RESPONSE: The 1 percent asbestos by weight threshold, incorporated into the definition of asbestos-containing material set by Congress under the Asbestos Hazard Emergency Response Act (AHERA) or TSCA Title II, is not health-based. Rather, the 1 percent threshold, first adopted under the asbestos National Emission Standards for Hazardous Air Pollutants was based in part on the limit of detection for asbestos analytical methods prior to the passage of TSCA Title II in 1986. Under TSCA Title II, bulk materials containing less than 1 percent asbestos by weight would not be considered asbestos-containing building material and therefore would not require any additional monitoring.

The Honorable John Shimkus (R-IL)

1. As part of the exemption provisions in H.R. 1603, the President is required to publish the application for an exemption, as well as any terms and conditions, if granted. In contrast, the existing national defense waiver provisions in section 22 of the Toxic Substances Control Act (TSCA) – the use of which H.R. 1603 prohibits -- allows the Administrator to "omit such publication because the publication itself would be contrary to the interests of national defense."

    a. Could the provisions in H.R. 1603 result in the release of classified national security-related information regarding the exempted use?

    RESPONSE: It is unclear what effect H.R. 1603 could have on classified national security-related information regarding an exempted use. Section 2 of H.R. 1603 creates a new TSCA 6(k)(2)(E) that states that the Administrator may not issue a national defense waiver under TSCA section 22. The TSCA section 22 waiver provision allows the Administrator to "omit such publication because the publication itself would be contrary to the interests of national defense."

    While section 2 of H.R. 1603 includes a process for a national defense exemption, it does not allow for the Agency to omit publication of information related to the exemption. H.R. 1603 section 6(k)(2)(D) requires that an application for national defense exemption, and the terms and conditions of a granted exemption be published in the Federal Register.

    b. Does H.R. 1603 include any other exemption provision for non-national security uses that may be deemed in some way essential?

    RESPONSE: The bill does not include exemption provisions for non-national security uses.

2. The definition of the term "asbestos" in H.R. 1603 is broader than the current statutory definition of asbestos under the Asbestos Emergency Hazard Response Act (TSCA Title II).

    a. Are richterite and winchite appropriate to be grouped together with the other asbestiforms?

    RESPONSE: Mineralogically, the asbestiform varieties of richterite and winchite could be appropriately grouped together with other asbestiform minerals.

    b. Why did EPA omit adding these two forms to its risk evaluation of asbestos?

    RESPONSE: Richterite and winchite are minerals that, along with tremolite and other trace minerals make up the "Libby Amphibole" that contaminated vermiculite originating from a mine in Libby, Montana. That vermiculite mine

ceased operations in 1990. Vermiculite containing Libby Amphibole is no longer manufactured or processed for use in the United States and therefore was not included in the risk evaluation under TSCA. However, the Ninth Circuit Court of Appeals recently issued a decision in which the court found that EPA's interpretation of the term "conditions of use" to exclude legacy uses and associated disposals contradicted TSCA and vacated that provision of EPA's Risk Evaluation Rule. EPA is currently evaluating the Court's decision and its impact on the asbestos risk evaluation.

c. Is it reasonable to expect that without a component percentage or other more specific definition, a single fiber in a commodity may make the item a mixture or article containing asbestos for the purposes of the provisions in H.R. 1603?

RESPONSE: Yes, without a component percentage or other more specific definition, EPA would have to exercise discretion to determine whether a single fiber in a product may make the item a mixture or article containing asbestos for the purposes of the provisions in H.R. 1603.

3. H.R. 1603 amends section 6 of TSCA, whose operative definitions are "chemical substance" and "mixture." H.R. 1603 uses the term "mixture" but uses the word "asbestos" without stating that for purposes of the bill it is a "chemical substance."

a. Do you interpret "asbestos" for purposes of the legislation to be a "chemical substance" subject to that meaning in TSCA or something else?

RESPONSE: H.R. 1603 is unclear on this point, but it expressly defines "asbestos" without using or cross-referencing the term "chemical substance." Without additional clarity in the bill, this consideration would be subject to further legal analysis and interpretation.

b. How would the ban apply to uses specifically excluded from the definition of "chemical substance" under TSCA section 3(2)(B), such as pesticides, food, food additives, drugs, cosmetics, or medical devices.

RESPONSE: It is unclear how the ban would apply to uses specifically excluded from the definition of "chemical substance" under TSCA. Without additional clarity in the bill, this consideration would be subject to further legal analysis and interpretation.

The Honorable Cathy McMorris Rodgers (R-WA)

1. Why does the Agency read the Toxic Substances Control Act (TSCA) to prevent consideration of future risks under section 6 risk evaluations and risk management?

   RESPONSE: EPA does not interpret TSCA as preventing consideration of future risks. In a TSCA section 6 risk evaluation, the statute requires that EPA evaluate a chemical under its "conditions of use," defined in the law as the intended, known and reasonably foreseen circumstances of manufacture, processing, distribution in commerce, use and disposal. EPA interprets the mandates under TSCA section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on activities that are intended, known to be occurring, or reasonably foreseen to occur.[1]

2. One of the witnesses on the next panel expressed concerns in her testimony that EPA's risk evaluation does not address exposures in the ambient environment, specifically air, soil or water.

   a. Why did EPA choose not to include those?

   RESPONSE: In EPA's asbestos risk evaluation problem formulation, EPA identified exposure pathways under other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist, e.g., the Clean Air Act, the Safe Drinking Water Act, the Clean Water Act, and the Resource Conservation and Recovery Act.[2] In developing the problem formulation, EPA's Office of Pollution Prevention and Toxics worked closely with the offices within EPA that administer and implement the regulatory programs under these statutes. In some cases, EPA determined that chemicals present in various media pathways, e.g., air, water, and land, fall under the jurisdiction of existing regulatory programs and associated analytical processes carried out under other EPA administered statutes and have been assessed and effectively managed under those programs. EPA believes that the TSCA risk evaluation should focus on those exposure pathways associated with TSCA uses that are not subject to the regulatory regimes discussed above because these pathways are likely to represent the greatest areas of concern to EPA. As a result, EPA does not expect to include in the risk evaluation certain exposure pathways identified in the asbestos problem formulation.

   b. How does TSCA section 9(b) interact with your consideration, including the application of other EPA enforced statutes to address these risks?

   RESPONSE: TSCA section 9(b) states, generally, that where EPA determines that chemical risks to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under the authorities of another federal law administered by EPA, that EPA will use those other authorities to protect against the risk unless EPA determines it is in the public interest to take action under TSCA. Therefore, EPA has

[1] https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0654
[2] https://www.epa.gov/sites/production/files/2018-06/documents/asbestos_problem_formulation_05-31-18.pdf

discretion to use other authorities administered by the Administrator to address such risks under TSCA section 9(b), pursuant to the authority contained therein.

3. This witness also argued that under the Significant New User Rule finalized by the Agency, new uses of asbestos could become commercialized simply if EPA is notified.

    a. Doesn't TSCA section 5 prohibit ANY new substance from going into commercial production and sale without EPA first approving it?

    RESPONSE: TSCA section 5 requires EPA to review notices of new chemical substances and notices of significant new uses of existing chemical substances and to make a determination regarding the risk of the new chemical substance or significant new use before the chemical can be allowed to commercialize. See the answer to question 3.b. below for further details. For EPA to require the review of significant new uses for an existing chemical, such as asbestos, the Agency would need to issue a significant new use rule (SNUR) specific to that existing chemical. EPA issued a SNUR for asbestos on April 25, 2019, which ensures that EPA has an opportunity to evaluate any discontinued use of asbestos before it resumes.[3] In the absence of this SNUR, manufacturing, importing, or processing of asbestos for those uses could have resumed at any time and without prior notice to, and review and regulation, as appropriate to address any unreasonable risk, by EPA. Ongoing uses of existing chemicals are not impacted by SNURs because they are outside the scope of the rule.

    TSCA section 5(a)(1) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use subject to a SNUR (15 U.S.C. 2604(a)(1)(B)(i)). The SNUN obligates EPA to assess risks that may be associated with the significant new use, including risks to potentially exposed or susceptible subpopulations identified as relevant by EPA under the conditions of use; make a determination under the statute; and, if appropriate, regulate the proposed activity before it occurs. In other words, notification to EPA triggers a process that could result in regulation if unreasonable risk is identified, potentially including a ban.

    Additionally, under TSCA section 6, new uses of asbestos initiated for the first time after August 25, 1989, were banned under the final rule Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions (54 FR 29460, July 12, 1989) (FRL-3476-2).[4] Those new uses remained banned along with five other uses (corrugated, commercial and specialty papers, rollboard, and flooring felt) after that rule was partially vacated and remanded to EPA by the Fifth Circuit Court of Appeals in 1991.

[3] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0159-5897
[4] https://www.epa.gov/asbestos/asbestos-ban-and-phase-out-federal-register-notices

b. For EPA to permit its commercial production, doesn't EPA have to determine the chemical substance's use – with or without some controls -- does not present an unreasonable risk to health or the environment without regard to cost or other non-risk consideration, including to vulnerable and susceptible populations?

RESPONSE: For TSCA section 5 review of new chemical substances and significant new uses of existing chemical substances, the law sets forth five possible determinations under TSCA section 5 with related actions:[5]

- If EPA determines a new chemical substance or significant new use **presents an unreasonable risk** of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation under the conditions of use, the Agency must take action under TSCA section 5(f) to protect against the unreasonable risk.

- If EPA determines that the available information is **insufficient to allow the Agency to make a reasoned evaluation** of the health and environmental effects of the new chemical substance or significant new use, EPA must issue an order under TSCA section 5(e). A TSCA section 5(e) order prohibits or limits the manufacture, processing, distribution in commerce, use, or disposal to the extent necessary to protect against an unreasonable risk, and may include testing requirements.

- If EPA determines that, in the absence of sufficient information, the manufacture, processing, distribution in commerce, use or disposal of the chemical **may present an unreasonable risk** of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the EPA Administrator, EPA must issue an order under TSCA section 5(e). A TSCA section 5(e) order prohibits or limits the manufacture, processing, distribution in commerce, use, or disposal to the extent necessary to protect against an unreasonable risk, and may include testing requirements.

- If EPA determines that the substance is or will be **produced in substantial quantities and either enters or may enter the environment in substantial quantities or there is or may be significant or substantial exposure** to the substance, EPA must issue an order under TSCA section 5(e). A TSCA section 5(e) order prohibits or limits the manufacture, processing, distribution in commerce, use, or disposal to the extent necessary to protect against an unreasonable risk, and may include testing requirements.

- If EPA determines that a new chemical or significant new use is **not likely to present an unreasonable risk** of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation under the conditions of use, the Agency will notify the submitter and the submitter may commence manufacture of the chemical or manufacture or processing for a significant new use notwithstanding any remaining portion of the 90

[5] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#5f

day review period. EPA will notify the submitter of its decision and publish its findings in a statement in the Federal Register.

c. Does TSCA permit EPA to evaluate discontinued uses of a chemical for risk management under existing chemicals provisions in section 6?

RESPONSE: TSCA section 6 tasks EPA to prioritize, evaluate risks, and take appropriate action to address unreasonable risks from existing chemical substances. TSCA section 6(b) requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of cost or other non-risk 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. TSCA section 3(4) defines the conditions of use as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." A use which is no longer "intended, known, or reasonably foreseen" would not be considered a condition of use for the chemical substance.

d. Does TSCA section 5 permit EPA to proactively ban a new substance?

RESPONSE: In the case of a new chemical substance or a significant new use of an existing chemical substance, when someone submits a pre-manufacture notice or a significant new use notice, respectively, after finding that a chemical substance presents an unreasonable risk to health or the environment, EPA does have the authority under TSCA section 5(f) to: (1) limit the amount of the chemical substance that is manufactured/processed/distributed in commerce or impose other restrictions on the substance via an immediately effective proposed rule under section 6 of TSCA; or (2) issue an order to prohibit or limit the manufacture, processing or distribution in commerce to take effect on the expiration of the applicable review period. EPA can exercise TSCA section 5 regulatory authority, including a ban of a significant new use, but can only ban ongoing uses in commerce under TSCA section 6.