COMMENTS
EPA Problem Formulations for Asbestos, HBCD and Carbon Tetrachloride
July 26, 2018

Introduction

The Environmental Protection Network (EPN) is providing the following comments on the problem formulations for asbestos, HBCD and carbon tetrachloride, which we find are setting improper precedents for future chemical risk evaluations under the new Chemical Safety Act amendment to TSCA. The final rule states that EPA is given discretion to determine the conditions of use that it will address in its evaluation of a priority chemical, "in order to ensure the agency's focus is on the conditions of use that raise the greatest potential for risk." The final rule mentions excluding de minimis conditions of use or conditions of use that have been adequately addressed by another regulatory agency. The final rule also states that while the statute is ambiguous as to whether the conditions of use should include legacy uses, "in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."

In contrast to this final rule, the Chemical Safety Act is clear that EPA must identify and evaluate risks resulting from all intended or reasonably foreseen, as well as known conditions of use of a chemical substance. EPA is required to make a determination on the chemical substance as to whether it presents an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors due to a single use or any combination of uses. If an unreasonable risk is found, TSCA provides EPA with a broad set of authorities to deploy actions that fully eliminate the unreasonable risk. The timing, frequency, location and duration of all exposures and their magnitude at a given point in time and space are key to determining unreasonable risk for susceptible subpopulations such as infants, pregnant women, the elderly, workers and disproportionately exposed communities. TSCA requires two kinds of risk assessment, one for a single or sentinel exposure to evaluate acute toxic effects and one for aggregate exposure of co-occurring sources to evaluate chronic toxic effects. Since all 10 chemicals addressed in these first problem formulations have chronic toxic effects, a comprehensive aggregate assessment of all co-occurring exposures is critical since excluding even one pathway will underestimate cancer and non-cancer effects.

In the following sections of our public comments, the Environmental Protection Network will explain: 1) why the asbestos and HBCD problem formulations should not exclude pathways of exposure to legacy uses; 2) why the asbestos problem formulation should not exclude pathways of exposure regulated under other programs; 3) why the carbon tetrachloride problem formulation should either evaluate the conditions of use now designated as "de minimis" or provide a science-based justification for their

exclusion and rationale for not seeking additional information from industry; and 4) why EPA needs to take the lead in addressing workplace risks while consulting with OSHA.

1. EPA's Proposed Approach to Risk Evaluation of Exposures Related to Legacy Use Is Flawed

The exclusion of "legacy" exposures in the problem formulation documents is particularly flawed for asbestos, and very likely problematic for the cyclic aliphatic bromide cluster chemicals (HBCD) as well.

While much of the current risks from asbestos occur among workers involved in asbestos abatement or removal during remodeling, demolition and disposal, there are also risks among maintenance workers with in-place asbestos and auto mechanics performing brake work. Reports published by CDC and IARC strongly suggest that these uses contribute to the widespread release of fibers into the general environment, even with adherence to OSHA and other regulatory limits.

It is well documented that asbestos is a carcinogenic compound. There is no safe level of exposure. The ATSDR noted that asbestos is a dangerous substance and should be avoided. Risk is dependent on frequency and duration of exposure. Breathing asbestos can cause asbestosis, lung cancer and mesothelioma. This was the finding reported in the EPA peer-reviewed report on the destruction of the World Trade Center.[1] This report stated that the continuing release of asbestos fibers posed a serious hazard to humans unknowingly exposed to residual fibers and would continue to do so for a long period of time. Exposure risks were also addressed in an EPA 2004 pamphlet describing risks from release of asbestos fibers from brake pads.[2] In the pamphlet, EPA stated that asbestos exposures during daily work on brakes and during the disposal of asbestos-containing products are a serious concern for the mechanics and other workers within the facility.

In addition, asbestos is described in the problem formulation document as primarily a respiratory disease hazard (asbestosis, lung cancer and mesothelioma), but there is strong evidence to suggest that asbestos also poses a risk of stomach, larynx, pharynx and possibly reproductive system cancers. These risks are dismissed in the problem formulation document without explanation. They should be part of the comprehensive risk assessment.

Knowing that everyone is exposed to some level of background asbestos exposure is not a reason to ignore the hazards that remain from legacy exposures such as the removal of in-place asbestos materials, and the exposure of populations who live near former mines that have produced contaminated living environments. It would be a reckless decision to ignore the long-term exposures that still occur from legacy pathways and their resultant health hazards. A recent example of asbestos exposure occurred in Manhattan when a steam pipe lined with asbestos exploded on July 19, 2018 (*New York Times*, July 19, 2018).

[1] EPA Report: Selecting Contaminants of Potential Concern and Setting Health-Based Benchmarks, May 2003, Prepared by the Contaminants of Potential Concern (COPC) Committee of the World Trade Center Indoor Air Task Force Working Group.
[2] EPA-747-04-004

A similar situation likely exists with regard to HBCD. While these chemicals are reportedly no longer manufactured in the U.S., they are still imported and used. There is very likely a substantial amount of legacy materials in place arising from past use in building insulation. Safer Chemicals, Healthy Families estimates that most of the 30,000 to 60,000 metric tons of HBCD used in the U.S. between 1988 and 2010 was used in building insulation and that much of it "will reach the end of its useful life in the years ahead."[3] The potential exposure resulting from the removal of the legacy insulation through demolition, remodeling and disposal, as is the case with asbestos containing materials, may pose risks, and there are no OSHA standards to protect the workers involved in such activities. Therefore, the legacy activities involving HBCD-containing materials must be evaluated if EPA is to successfully fulfill its responsibilities to comprehensively assess and eventually manage the exposures and risks of HBCD under TSCA.

2. <u>EPA's Proposed Approach to Risk Evaluation of Exposures Associated with Other EPA Regulatory Programs is Contrary to Plain Statutory Language and is Legally Unsound; is Scientifically and Methodologically Unsound and is Not Efficient.</u>

Overview

In each of the draft problem formulation documents for the first ten existing chemicals, EPA includes the following paragraphs (see, for example, page 13 of the 1-Bromopropane Problem Formulation):

> ". . . EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA) – and which EPA does not expect to include in the risk evaluation.
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> As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes. EPA does not expect to include any such excluded pathways as further explained below in the risk evaluation. The provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes."

Although these paragraphs are contained in all ten of the problem formulation documents, EPA offers no further definition of what it means by "under the jurisdiction" of regulatory programs or, "associated

[3] EPA Docket ID Number EPA-HQ-OPPT-2016-0735

analytical processes . . .under other EPA administered statutes." We have focused our comments on this issue in the asbestos problem formulation as an example case. All of our objections and concerns about this approach for asbestos would apply to the other nine chemicals, and depending on specifics, the use of this approach for those chemicals would likely raise additional concerns as well.

Comments on Exclusion of Consideration of Exposures Associated with Other EPA Regulatory Programs, with specific reference to the asbestos problem formulation:

a. EPA's planned approach to exclude exposure pathways associated with other EPA statutes is contrary to plain statutory language and legally unsound.

EPA cites only TSCA Sec (6)(b)(4)(D) as a basis for the decision to omit significant exposure pathways. The brief language of that provision, providing for publication of the key elements of a proposed risk assessment, offers no basis to alter the administrator's obligation under Section 6. Indeed, the treatment of risks that may also be subject to other EPA-administered statutes is expressly addressed in TSCA Sec 8(b), which provides:

> "(1) The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.
>
> (2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this subchapter with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the action to be taken under this subchapter and an action to be taken under such other law to protect against such risk."

Further, the specific language of Section 6 provides, in (F) that the administrator is to "integrate and assess available information on hazards and exposures," obviously inclusive of information developed under other EPA statutes.

These provisions clearly establish the role for other EPA programs: information known through other statutory programs shall be considered in the risk evaluation phase for existing chemicals under TSCA, and **after completion of the risk evaluation,** the administrator must follow a process to consider the potential

use of other programs **to address the risk under the TSCA standard.** The proposed EPA approach would reverse and fundamentally alter this process.

Further, the omission of important exposure pathways makes it impossible to make the finding required under Sec 6(b)(4)(A) which requires the administrator conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk…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." "Environment" is defined to include "air, water and land" and the relationship among and between these elements and with "all living things." The statute defines "conditions of use" to mean the circumstances under which the substance is "manufactured, processed, distributed in commerce, used or disposed."

A risk assessment that omits exposures considered under other statutes cannot be assumed to meet this standard. Indeed, other statutory schemes generally do not operate under comparable environmental standards and requirements for consideration. They often require consideration of costs, technical feasibility or other non-risk factors. They are not designed to consider the interaction among air, land and water, but are focused instead on exposure in the specified medium. Consideration of special subpopulations is rarely required and may not even be considered under other statutory schemes. In addition, even when these other regulatory programs are implemented perfectly, they only reduce exposures down to the regulatory standard, they do not eliminate exposures.

TSCA requires specific inclusion of disposal in evaluation of the subject conditions of use; omission of disposal exposures from substances subject to RCRA may have the effect of omitting disposal entirely from the required statutory scope of consideration for the subject conditions of use.

In the case of asbestos, the combination of determining that "legacy uses" are not conditions of use and of omitting disposal because of RCRA regulation has the effect of omitting entirely consideration of disposal, which is specifically enumerated in the statutory definition of conditions of use.

All of these inadequacies make it impossible for the administrator to rely on the work of other regulatory programs to meet the requirements for Section 6 risk evaluations. Indeed, the agency has made no attempt to show any comparability or even consistency between the TSCA risk assessment requirements and the approaches of the regulatory programs associated with these omissions.

Below are two examples from the asbestos problem formulation document that illustrate how legally insufficient the alternative programs can be for this purpose. Congress intended for TSCA to have a risk-based standard and to use this standard to evaluate high priority chemicals that had never been evaluated under other programs based only on risk.

Asbestos air quality regulation dates back to 1986 and is based on an older version of the Clean Air Act (CAA), which did not require consideration of residual risk or all possible exposure pathways. Even if the existing asbestos regulation had been based on the current CAA, it would not be consistent with TSCA's sole focus on health effects. The framework for regulation of hazardous air pollutants under the current CAA is generally fundamentally different from the TSCA process. Hazardous air pollutants (HAPs) are

regulated under the CAA in two stages. The first stage is based upon maximum achievable control technology (MACT) within each specific industry. Under MACT, EPA identifies the best performing technologies within an industry and sets a standard based on the performance of these technologies. The cost of achieving such emission reduction and any non-air quality health and environmental impacts and energy requirements, but not risk, are considered at this stage. The second phase of HAP control under the CAA is a "risk-based" approach in which the risk remaining after the application of MACT is assessed. Within eight years of setting the MACT standards, the CAA requires EPA to assess the remaining risks from each source category to determine whether the MACT standards protect public health with an ample margin of safety and protect against adverse environmental effects. While EPA does not have to consider the costs of any health standards imposed as a result of the risk analysis, it must consider the costs of a more stringent standard to reduce environmental risks. Furthermore, the residual risk controls only apply to major emission sources; they do not apply to small emitters considered as area sources.

EPA's own discussion of the asbestos requirements under the Resource Conservation and Recovery Act illustrates clearly the gaps between the regulatory approaches to asbestos under RCRA and those required by TSCA. Indeed, the problem formulation document itself makes clear that significant amounts of the considerable quantities of disposal (>25 million pounds) from the on-going asbestos uses are subject only to certain state-level requirements.[4]

The amended TSCA contains new standards for assessment of chemicals, but also a host of new provisions to ensure open processes, fairness and other vital good government goals. The approaches to regulation of asbestos under other statutes generally not only have different substantive standards of review, but also different processes and procedures, especially for the risk assessment aspects of the regulatory process. EPA offers no analysis of the way in which evaluations under other statutes have met the procedural requirements of TSCA.

b. EPA's planned approach to exclude important exposures associated with other EPA-statutes is also scientifically and methodologically unsound.

Risk assessments that are currently available (for appropriate consideration under TSCA Sec 6(F)) are identified in the problem formulation document. Notably, the identified risk assessments under the SDWA and the CAA are from 1985 and 1986 respectively. Nothing under RCRA is identified. Obviously, these programs have not completed risk assessments reflecting changes in the science for more than 30 years. Conclusions based on any such assessments would, at a minimum, require a serious updating of most aspects of the science involved. There is no indication that EPA intends to devote the resources that would be required to update program-specific risk assessments for asbestos even for the narrow purposes of determining whether further action is warranted under such statute. EPA's other regulatory programs have limited resources and many competing priorities, including those required by specific statutory provisions and/or court orders. Congress has provided additional resources specifically for implementation of TSCA, which can compensate for the lack of resources in these other programs. In addition to the advantage TSCA affords EPA to conduct risk assessments and issue regulations covering all sources of

[4] Asbestos Document, page 44

exposure, EPA should use the potent information gathering provisions of TSCA 8(a) and 8(d) to update or supplement the risk evaluations conducted under other statutes which are so out of date today. Staff from other program offices should be involved in the assessments conducted under TSCA so they can assist the TSCA program while also updating their media-specific risk evaluations.

c. EPA's planned approach to justify the exclusion of pathways regulated by other programs based on efficiency is flawed.

EPA invokes efficiency as a rationale for its approach to excluding exposures under other statutes. But it is clear that nothing is preventing the agency from making use of prior work conducted under other statutes and the expertise developed throughout the agency. Further, as noted above, TSCA provides a clear path by which the administrator may, after conducting the risk assessment and making the risk findings required by TSCA, turn to all the other statutes he administers as part of crafting a risk management approach for existing chemicals under TSCA.

This extreme, legally and scientifically unsound refusal to consider significant exposures clearly resulting from current conditions of use is not warranted on efficiency grounds.

3. EPA's Proposed Approach to Risk Evaluation of Pathways Deemed De minimis Is Flawed.

In the carbon tetrachloride problem formulation, EPA asserts without justification that it will exclude multiple uses of the chemical (cleaning and degreasing solvents, adhesives and sealants, paints and coatings) because they pose only de minimis risks. This was the only problem formulation that excluded uses because they were deemed de minimis. While the final chemical risk evaluation rule mentions that de minimis uses could be excluded from consideration, no criteria were provided for determining a use that poses de minimis risks for a chronic toxicant. Since carbon tetrachloride is a carcinogen, EPA must document in the problem formulation the carcinogenic risk level used to designate a pathway as posing de minimis risk. In addition, combined low level exposures resulting from multiple uses and sources of a chemical can result in unreasonable risks to particular subpopulations, so EPA must document that co-occurring de minimis pathways were appropriately evaluated in combination and still found to be below the carcinogenic level of concern if people can experience more than one of these pathways at any given time. Further, the carbon tetrachloride problem formulation should justify why EPA is not using its authority to request new testing by industry to better evaluate these de minimis pathways. The new testing provision of the Chemical Safety Act is clear that the administrator must not interpret the lack of exposure information as a lack of exposure or exposure potential and must seek new information to resolve this issue.

4. EPA's Potential Approach to Rely on OSHA to Regulate Worker Exposure is Flawed.

In addition to the inadequacy of EPA's proposed exclusion of exposures that are "already regulated" by EPA (by statutes other than TSCA, such as the CAA), as discussed above in these comments, this exclusion

also reveals a potentially very serious flaw in EPA's methods if the agency intends to apply the same approach to workplace exposures. The Chemical Safety Act requires EPA to consult with OSHA "prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination to address workplace exposures." So far, the agency has been silent regarding how it intends to address workplace risks, but the strategy of having EPA "punt" its responsibilities regarding workers by transferring them to OSHA is being heavily advocated by industry groups, and it must not remain unchallenged.[5] Any wholesale "referral" to OSHA for potential regulation would in effect leave the workers unprotected, because it is well known that OSHA is unable to promulgate occupational health standards in a timely fashion, if at all.[6]

To better understand this concern, it is important to note that all ten chemicals slated for analysis at this stage of the TSCA mandates, and eventually slated for potential regulation, have their highest exposures and pose their most serious risks to workers who manufacture, process, transport, dispose of or otherwise handle these chemicals. This is no surprise: workers are nearly always the first and most seriously exposed populations, experiencing the highest risks. In addition, four of the chemicals are not regulated at all by OSHA, and the remaining six are currently regulated by OSHA standards that are scientifically obsolete, based on studies more than a half century old. Because of OSHA's inability to regulate in a timely manner, referral of the responsibility to regulate these chemicals would condemn workers to significant risks for a long time, or even indefinitely. Table 1 shows the contrast between current OSHA standards for the ten chemicals with more modern standards (Cal-OSHA) or recommendations (NIOSH and ACGIH). It is evident that current OSHA protections are highly inadequate and TSCA regulation will be necessary.

TABLE 1. OSHA PERMISSIBLE EXPOSURE LEVELS COMPARED WITH OTHER STANDARDS/GUIDELINES

CHEMICAL	OSHA Permissible Exposure Level (PEL)	California OSHA Permissible Exposure Level (PEL)	NIOSH Recommended Exposure Level (REL)	ACGIH Threshold Limit Value (TLV)
Asbestos	0.1 fibers/cm^3	0.1 fibers/cm3	0.1 fibers/cm3	0.1 fibers/cm3
1-Bromopropane	None	5 ppm	0.3 ppm	0.1 ppm
Carbon Tetrachloride	10 ppm	2 ppm	Carcinogen*	5 ppm
1,4 Dioxane	100 ppm	0.28 ppm	Carcinogen*	20 ppm
HBCD	None	None	None	None
NMP	None	1 ppm	None	None

[5] Submissions to the dicket, TSCA New Chemicals Coalition

[6] GAO report, https://www.gao.gov/products/GAO-12-330 and testimony by Dr. David Michaels, http://democrats-dworkforce.house.gov/imo/media/doc/DMichaels%20Testimony_w.attachments2%2027%202018.pdf

Methylene Chloride	25 ppm	25 ppm	Carcinogen*	50 ppm
Perchloroethylene	100 ppm	25 ppm	Carcinogen*	25 ppm
Pigment Violet	None	None	None	None
Trichloroethylene	100 ppm	25 ppm	Carcinogen*	10 ppm

*Lowest Feasible Exposure

While it is commendable that the agency recognizes the workplace hazards posed by these chemicals and intends to evaluate the risks at this stage, it is crucial that EPA state explicitly that it will take steps to make sure that workplace risks are regulated in a timely fashion under TSCA, even as OSHA, NIOSH and other agencies are consulted in the process of doing so, as TSCA allows.

Respectfully submitted,

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