

July 25, 2017

Ms. Wendy Cleland-Hamnett
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
US Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC

Re: Scoping Documents and Problem Formulations for Initial 10 Chemicals

Dear Ms. Cleland-Hamnett:

This letter is submitted by Safer Chemicals, Health Families (“SCHF”), Earthjustice, Natural Resources Defense Council (“NRDC”), Environmental Health Strategy Center, Toxic-Free Future and Asbestos Disease Awareness Organization. These organizations are committed to enhancing the safety of chemicals used in homes, workplaces and products and strongly support effective and health-protective implementation of the revised Toxic Substances Control Act (“TSCA”) enacted last year by Congress.

We write to raise concerns about two aspects of the risk evaluations currently being conducted under TSCA as amended: 1) the scoping documents for the first 10 chemicals that were released on June 22 and announced in the July 7, 2017 Federal Register,¹ and 2) EPA’s June 9, 2017 Memorandum (posted to the dockets for each of the 10 chemicals) announcing that it is commencing the problem formulation phase of its risk evaluation of these chemicals and seeking information from the public that could be useful to the Agency.

Scoping: On December 19, 2016, EPA designated 10 chemicals for initial risk evaluations under section 6(b)(4)(D) of TSCA. These 10 chemicals have widespread and substantial exposure and multiple adverse health effects. Comprehensive and health protective assessments of their safety are essential to safeguard communities and vulnerable populations and to set a precedent for strong and effective implementation of the new law. For this reason, SCHF and other members of our coalition made a significant investment in characterizing the use and exposure profiles of several of the 10 chemicals and provided extensive submissions to the Agency to help inform its scoping documents for these chemicals.

Given this background, we were dismayed to read in the July 7 Federal Register announcing the availability of the scoping documents that the Agency was unable to process all the information gathered during the scoping process and that the scoping documents were not as “refined or specific” as EPA had hoped. These deficiencies limit the utility of the scoping documents in laying the groundwork for well-informed and rigorous risk evaluations.

¹ 82 Fed. Reg. 31,592 (July 7, 2017)

Our review of these documents confirms that they fail to incorporate the important data on use and exposure that SCHF and other commenters submitted during the scoping process. For example, the EPA's scoping document on asbestos fails to consider the upstream impacts of importing, packaging and transporting asbestos in large quantities for use in chlor-alkali plants, and claims that the Agency received no public comments on its use in commercial and consumer products, although the submissions of SCHF and its partners specifically addressed the presence of asbestos in roofing materials and in some talc products.² The scoping documents also fail to address the human health and environmental risks arising from the ozone depleting potential of Methylene Chloride, Carbon Tetrachloride and 1-Bromopropane or the high global warming potential ("GWP") of these and other chemicals. Additionally the scoping documents generally note that "legacy uses" will be excluded, but that the "background exposure" from legacy uses that may be relevant to ongoing uses will be considered. However, the specifics of when and how these exposures will be taken into account are almost entirely lacking for individual chemicals. Finally, the scoping documents fail to meaningfully identify the particular "potentially exposed or susceptible populations" that the evaluations will consider, instead relying for several chemicals on nearly identical general "boilerplate" descriptions of such populations with little or no value in assessing their unique risks.

These disappointing omissions raise concern that the risk evaluations based on the scoping documents will likewise be incomplete and cursory and therefore insufficient for the informed decisions on chemical safety that the new law was intended to assure.

To allay these concerns, we believe the Agency needs to address the following questions:

1. Given EPA's recognition that it had limited ability to process the information gathered during scoping, is EPA planning to revise and expand the scoping documents? If so, will this include exposures and hazards that were not included in the scoping documents? If not, why not?
2. Can the public assume that all the conditions of use identified in the scoping documents will in fact be addressed in risk evaluations on the 10 chemicals or does EPA plan to exclude some conditions of use during problem formulation? If the latter, what criteria will be used to make these decisions and will they be subject to public comment?³

We would strongly oppose any effort by EPA to "refine" the scope of the risk evaluations during the problem formulation phase to further limit the uses,

² See EPA-HQ-OPPT-2016-0736-0064 at pages 5 & 20 for roofing and page 15 for talc, amongst others.

³ EPA's risk evaluation process rule maintains that it has discretion to limit the conditions of use addressed in risk evaluations. We believe EPA's view is inconsistent with the requirements of the amended TSCA. But even assuming EPA has the discretion it claims, it must identify the factors it will apply in choosing which uses to include in the scope of its evaluations. The final rule fails to do this.

hazards or exposures that those evaluations address. We read TSCA as requiring EPA risk evaluations to conform to the framework established in the scoping documents developed under section 6(b)(3)(D). Were EPA able to deviate from the published scope and drop uses, hazards or exposures that it encompasses, states would be preempted from assessing risk scenarios that EPA has not evaluated, undermining the preemption provisions in section 18.

3. In its comments on the scoping process, SCHF urged EPA to use its expanded information collection authorities under TSCA as amended to fill gaps in the hazard and exposure database on the 10 chemicals. Except in limited instances, however, the scoping documents do not discuss data-gaps and explain EPA's plans to fill them despite the Agency's obligation in section 26(k) to consider all "reasonably available information." Is EPA undertaking any effort to obtain more hazard and exposure data from industry on the 10 chemicals? If so, what specific steps are underway? If not, why not?

We look forward to your responses to these questions.

Problem Formulation: EPA's July 7 notice announces that it will add a new step – problem formulation – before beginning work on the 10 risk evaluations. However, the notice sheds little light on the nature and purpose of this step and thus raises more questions than it answers. EPA must more fully explain the new process it is setting in motion and provide clearer direction on how the public can participate meaningfully in it. To that end, we request that the Agency address the following questions:

1. The term "problem formulation" does not appear in TSCA or in EPA's recently issued risk evaluation process rule. How does EPA define this term and what information and analysis will problem formulation documents include? Is this step unique to the 10 chemicals or will it be a standard element of all future evaluations?
2. How does problem formulation relate to scoping? What subjects will the problem formulation documents address that the scoping documents do not?
3. The July 7 notice "invites the public to provide additional data or information that would be useful in the problem formulation to the existing public docket for each of these chemicals." Can EPA be more specific about the types of data and information that it believes will be useful in problem formulation?
4. The June 7 notice states that problem formulation documents will be released within 6 months and notes that EPA will take public comment on these documents. Can EPA clarify this process? Will a draft problem formulation document be made available for comment and when will this occur? Will final problem formulation documents be

July 25, 2017

prepared based on the comments received and when will they be made available to the public?

4. Section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either of these approaches, EPA must incorporate it in the risk evaluation design yet the scoping documents fail to do this. Will problem formulation documents address this important aspect of risk evaluation methodology? SCHF has previously maintained that aggregate exposure assessment is required for most chemicals and a clear statement of EPA's intentions in this regard is essential for each of the 10 chemicals.

We look forward to EPA's answers to these questions and believe an early meeting to discuss EPA's thinking would be a productive first step. We will be in touch to schedule such a meeting. In the meantime, do not hesitate to contact SCHF counsel Bob Sussman (bobsussman1@comcast.net) if you have any questions about this letter.

Sincerely yours,

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cc: Dr. Nancy Beck
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